

MINNESOTA DEPARTMENT OF HEALTH



AGREEMENT STATE APPLICATION Volume I

 <p>Radioactive Materials Group Minnesota Department of Health</p>	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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STATE OF MINNESOTA

Office of Governor Tim Pawlenty

130 State Capitol ♦ 75 Rev. Dr. Martin Luther King Jr. Boulevard ♦ Saint Paul, MN 55155

July 6, 2004

Nils J. Diaz, Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Diaz:

I am writing to formally request that an agreement be established between the United States Nuclear Regulatory Commission and the State of Minnesota as authorized under Section 274b of the Atomic Energy Act of 1954, as amended, and the Minnesota Statutes Section 144.1202. Under this agreement the US Nuclear Regulatory Commission will discontinue certain regulatory authority for radioactive materials now under federal jurisdiction and that authority will be assumed by the State of Minnesota. As provided by Minnesota Statutes Section 144.1202, subd. 2, the Department of Health is the agency responsible for the implementation of the agreement. The specific authority requested is for the following:

- A. Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material (i.e., byproduct materials as defined in Section 11e(1) of the Atomic Energy Act of 1954, as amended)
- B. Source materials
- C. Special nuclear materials in quantities not sufficient to form a critical mass

I certify that the State of Minnesota wants to assume regulatory authority and oversight responsibility for such materials, and that the State of Minnesota has an adequate program for the control of radiation hazards covered by this proposed agreement. Enclosed are volumes 1 through 4 of the formal application, which contain a copy of the radioactive materials rules and describe Minnesota's radiation control program as well as its regulatory capabilities.

Your expeditious consideration of this proposed agreement is most appreciated.

Sincerely,

A handwritten signature in black ink, appearing to read "Tim Pawlenty".

Tim Pawlenty
Governor

cc: Dianne Mandernach, Commissioner, Minnesota Department of Health
Michael Campion, Commissioner, Department of Public Safety
Patricia Bloomgren, Director, Environmental Health Division

Introduction to the Application

The following application includes all information necessary to assess Minnesota's qualifications for Agreement State status. The Nuclear Regulatory Commission (NRC), in its instructions for processing an agreement, has identified and numbered each element needed to process the application. This application is divided into sections (4.1.1, 4.1.2, etc.), with each section containing the necessary information for Minnesota to fulfill the NRC requirements. Below is an outline of the documents that fulfill each section. Detailed descriptions of the ways in which Minnesota meets the requirements can be found in the individually tabbed sections. Whenever possible, documents have been included in these individually tabbed sections. However, if a document is required in more than one section, the document has been placed in a separate volume to provide easier access.

4.1.1 Statutory Authority

- Select Minnesota Statutes
- The Act
- Minnesota Rules Chapter 4731
- Statute Compliance Letter

4.1.2 Program Organization

- Background of the Minnesota Department of Health
- History of Radiation Control in Minnesota
- Radiation Control Organizational Description
- Organizational Charts
- Introduction to the Application
- Intra-agency Lab Agreement
- University of Minnesota Interagency Disposal Agreement

4.1.3 Content of Agreement

- Proposed Agreement

4.2.1 Radiation Protection Standards

- Minnesota Rules Chapter 4731

4.2.2 Transboundary Requirements

- Minnesota Rules Chapter 4731
- Compatibility Chart

4.2.3 Orderly Pattern of Regulation or Health and Safety Significance

- Minnesota Rules Chapter 4731
- Compatibility Chart

4.3.1 Materials Licensing

- Licensing Procedures Manual
- Regulatory Guides

- Licensing Checklists
- Inspection Procedures Manual
- Licensing and Inspections Qualification Journal
- Minnesota Rules Chapter 4731

4.3.2 SS&D Safety Evaluations

- Not Applicable

4.3.3 Low-Level Waste Site Licensing

- Not Applicable

4.3.4 Uranium or Thorium Mill Licensing

- Not Applicable

4.3.5 Licensing Quality Assurance

- Licensing Procedures Manual
- Inspection Procedures Manual

4.3.6 Licensing Administrative Procedures

- Licensing Procedures Manual

4.4.1 Inspection Procedures

- Inspection Procedures Manual
- Inspection Report Forms
- MDH Instrument Inventory
- MDH Laboratory Facility Description

4.4.2 Inspections Quality Assurance

- Inspection Procedures Manual
- Licensing Procedures Manual
- Response Manual for Incidents Involving Radioactive Material
- Licensing and Inspections Qualification Journal

4.4.3 Inspection Administrative Procedures

- Inspection Procedures Manual

4.5.1 Routine Enforcement Procedures

- Enforcement Applications Manual
- Sample Cover Letter
- Sample Notice of Violation

4.5.2 Escalated Enforcement Procedures

- Plan for Use of Administrative Penalty and Cease and Desist Authority
- Sample APO
- Sample Notice of Violation

4.6.1 Technical Staff Organization

- Organizational Charts
- Staff Needs Analysis
- Staff Balance Sheet
- Staff Resource Analysis
- Professional Staff Assignments

4.6.2 Formal Qualification Plan

- Licensing and Inspections Qualification Journal
- Position Descriptions

4.6.3 Current Technical Staff Qualifications

- Curriculum Vitae
- Staff Training Schedule

4.7.1 Event and Allegation Response Procedures

- Response Manual for Incidents Involving Radioactive Material
- Data Privacy Puzzle

4.7.2 Event Reporting Procedures

- Response Manual for Incidents Involving Radioactive Material

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4.1.1

Statutory Authority

**4.1.1
STATUTORY AUTHORITY**

Authority for Minnesota's radiation control unit and proposed Agreement State activities is primarily found in *Minnesota Statutes*, Sections 144.12-144.121, and in the *Minnesota Rules Chapter 4731*. Below is a brief description of all statutes included in this section. Minnesota's statutes and rules are also accessible on the Internet at <http://www.revisor.leg.state.mn.us/stats/>. The NRC's *Statute Compliance Letter* is also included in this section. Finally, the initial version of Minnesota Statute 144.1205 and *The Act*, which was approved by the 2004 Legislature, are found here also. *The Act* will become Minnesota Statute 144.1205 as amended.

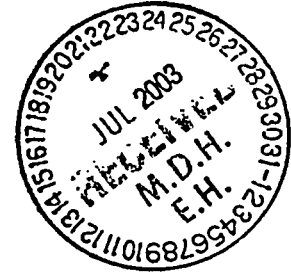
Statute	Subject
13.02	Collection, security and dissemination of records; definitions.
13.39	Civil investigation. Covers the requirements the Commissioner follows in a pending civil legal action.
13.41	Licensing data. Covers the requirements that the Commissioner must follow to ensure that data collected for licenses is kept within the statutory guidelines of data privacy.
144.05	General duties of Commissioner; reports.
144.12	Regulations, enforcement, licenses, fees. Overall commissioner authority to regulate, adopt rules, enforce, license and collect fees.
144.99	Enforcement. Outlines the authority that the Commissioner has to access information and issue correction orders, administrative penalty orders, injunctive relief, cease and desist orders, suspension or revocation of permits, licenses, registration or certificates. Allows for hearing, misdemeanor penalties, and the authority to impound radioactive materials and associate shielding.
144.121	X-ray machine and facilities using other sources of ionizing radiation. Indicates that machines and materials must be registered and that the Commissioner can collect fees and perform inspections.
144.989	Title; citation. This legislation is the title for the enforcement. Parts 144.989 to 144.993 are referred to as the Health Enforcement Consolidation Act of 1993.
144.991	Administrative penalty order procedure. Outlines the administrative penalty order procedure that must be followed.

- 144.992 False information. Asserts that a person cannot make false material statements, representation or certification in any of the commissioner's areas or they are subject to actions listed in section 144.99, subdivision 1.
- 144.993 Recovery of litigation costs and expenses. Allows the Commissioner to recover any costs brought on my any litigation.
- 144.1201 Definitions. For agreement state program. Provides clarification for 144.1202.
- 144.1202 U.S. NRC agreement. Gives the responsibility and authority for an agreement state program to the Department of Health.
- 144.1203 Training; rulemaking. Authority given to the Commissioner to adopt rules to ensure that individuals handling or utilizing radioactive materials are properly trained and have the qualifications to do so.
- 144.1204 Surety requirement. Gives the Commissioner authority to require financial assurance for radioactive materials licensees.
- 144.1205 Radioactive material; source and special nuclear material; fees; inspection. Gives the Commissioner authority to collect fees and penalties, and to conduct inspections.
- 181.931 Definitions. Definitions used in the sections 181.931 to 181.935. This section covers employee rights.
- 181.932 Disclosure of information by employees. Actions prohibited by an employer whose employee files a complaint against the employer.
- 181.933 Notice of termination. Addresses employee who has been involuntarily terminated, and that any defamation action is prohibited.
- 181.934 Employee notice. The Department of Labor and Industry will have rules for the notification of employees by employers of an employee's rights.
- 181.935 Individual remedies; penalty. Refers to the ability of the employee to bring civil action to recover costs and damages caused by violation of 181.932.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 16, 2003



Ms. Patricia A. Bloomgren, Director
Environmental Health Division
P. O. Box 64975
St. Paul, Minnesota 55164-0975

Dear Ms. Bloomgren:

This letter is in response to a letter dated May 8, 2003 to me from Ms. Jennifer Beens Harper, Assistant Attorney General. Ms. Harper's letter responded to the seven comments identified during the Nuclear Regulatory Commission's (NRC) completeness review of Section 4.1, Legal Elements, of the Draft Minnesota application. In addition, this letter is to follow-up on items discussed in my November 18, 2002 letter to you.

The results of our review of the State's response to our seven comments are enclosed in Enclosure 1. We have determined that based upon the State's response, two of the seven comments have been resolved. For the remaining five comments, the State's response referenced proposed regulations as the legal mechanism for addressing these comments. If your proposed regulations are adopted as indicated in these responses, without significant change, our remaining five comments would be addressed.

In my November 18, 2002 letter, I indicated that it is important to the NRC budget planning process that the best projections are made regarding your schedule for becoming an Agreement State. NRC's resources are allocated and committed based upon your projected schedule. We would really appreciate the State's assistance in this area by providing us with a schedule for completion of the proposed Minnesota Agreement.

We have enclosed an outline of a draft schedule for completion of an Agreement application. The enclosed draft schedule incorporates guidance in Appendix C-1 of the State and Tribal Program (STP) Procedure SA-700, *Processing an Agreement*, which can be viewed at STP's Website: <http://www.hsrdo.ml.gov/nrc/procedures/sa700.pdf>.

We would appreciate your providing us with a completed draft schedule within 30 days of the date of this letter. If you have any questions, please contact me or Ms. Cardelia Maupin of my staff at 301-415-2312 or E-mail: chm1@nrc.gov on this matter.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Paul Lohaus".

Paul Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

AN ACT

1

2 relating to health; modifying fees for radioactive and
3 nuclear material; approving state agreement with the
4 Nuclear Regulatory Commission; providing a certain
5 effective date; amending Minnesota Statutes 2002,
6 section 144.1205, subdivisions 2, 4, 8, 9; repealing
7 Minnesota Statutes 2003 Supplement, section 144.1202,
8 subdivision 4.

9 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

10 Section 1. Minnesota Statutes 2002, section 144.1205,
11 subdivision 2, is amended to read:

12 Subd. 2. [ANNUAL FEE.] A licensee must pay an annual fee
13 at least 60 days before the anniversary date of the issuance of
14 the license. The annual fee is ~~an amount equal to 80 percent of~~
15 ~~the application fee under subdivision 4, rounded to the nearest~~
16 ~~whole dollar~~ as follows:

17	<u>TYPE</u>	<u>ANNUAL FEE</u>
18	<u>Academic broad scope - type A</u>	<u>\$19,920</u>
19	<u>Academic broad scope - type B</u>	<u>19,920</u>
20	<u>Academic broad scope - type C</u>	<u>19,920</u>
21	<u>Medical broad scope - type A</u>	<u>19,920</u>
22	<u>Medical institution - diagnostic and therapeutic</u>	<u>3,680</u>
23	<u>Medical institution - diagnostic</u>	
24	<u>(no written directives)</u>	<u>3,680</u>
25	<u>Medical private practice - diagnostic and therapeutic</u>	<u>3,680</u>
26	<u>Medical private practice - diagnostic (no written</u>	<u>3,680</u>
27	<u>directives)</u>	

1	<u>Eye applicators</u>	<u>3,680</u>
2	<u>Nuclear medical vans</u>	<u>3,680</u>
3	<u>High dose rate afterloader</u>	<u>3,680</u>
4	<u>Mobile high dose rate afterloader</u>	<u>3,680</u>
5	<u>Medical therapy - other emerging technology</u>	<u>3,680</u>
6	<u>Teletherapy</u>	<u>8,960</u>
7	<u>Gamma knife</u>	<u>8,960</u>
8	<u>Veterinary medicine</u>	<u>2,000</u>
9	<u>In vitro testing lab</u>	<u>2,000</u>
10	<u>Nuclear pharmacy</u>	<u>8,800</u>
11	<u>Radiopharmaceutical distribution (10 CFR 32.72)</u>	<u>3,840</u>
12	<u>Radiopharmaceutical processing and</u>	
13	<u>distribution (10 CFR 32.72)</u>	<u>8,800</u>
14	<u>Medical sealed sources - distribution (10 CFR 32.74)</u>	<u>3,840</u>
15	<u>Medical sealed sources - processing and</u>	
16	<u>distribution (10 CFR 32.74)</u>	<u>8,800</u>
17	<u>Well logging - sealed sources</u>	<u>3,760</u>
18	<u>Measuring systems - fixed gauge</u>	<u>2,000</u>
19	<u>Measuring systems - portable gauge</u>	<u>2,000</u>
20	<u>X-ray fluorescent analyzer</u>	<u>1,520</u>
21	<u>Measuring systems - gas chromatograph</u>	<u>2,000</u>
22	<u>Measuring systems - other</u>	<u>2,000</u>
23	<u>Broad scope manufacturing and distribution - type A</u>	<u>19,920</u>
24	<u>Broad scope manufacturing and distribution - type B</u>	<u>17,600</u>
25	<u>Broad scope manufacturing and distribution - type C</u>	<u>17,600</u>
26	<u>Manufacturing and distribution - other</u>	<u>5,280</u>
27	<u>Nuclear laundry</u>	<u>18,640</u>
28	<u>Decontamination services</u>	<u>4,960</u>
29	<u>Leak test services only</u>	<u>2,000</u>
30	<u>Instrument calibration service only,</u>	
31	<u>less than 100 curies</u>	<u>2,000</u>
32	<u>Instrument calibration service only,</u>	
33	<u>100 curies or more</u>	<u>2,000</u>
34	<u>Service, maintenance, installation,</u>	
35	<u>source changes, etc.</u>	<u>4,960</u>
36	<u>Waste disposal service, prepackaged only</u>	<u>6,000</u>

1	<u>Waste disposal</u>	8,320
2	<u>Distribution - general licensed</u>	
3	<u>devices (sealed sources)</u>	1,760
4	<u>Distribution - general licensed</u>	
5	<u>material (unsealed sources)</u>	1,120
6	<u>Industrial radiography - fixed location</u>	9,840
7	<u>Industrial radiography - temporary job sites</u>	9,840
8	<u>Irradiators, self-shielding, less than 10,000 curies</u>	2,880
9	<u>Irradiators, other, less than 10,000 curies</u>	5,360
10	<u>Irradiators, self-shielding, 10,000 curies or more</u>	2,880
11	<u>Research and development - type A broad scope</u>	9,520
12	<u>Research and development - type B broad scope</u>	9,520
13	<u>Research and development - type C broad scope</u>	9,520
14	<u>Research and development - other</u>	4,480
15	<u>Storage - no operations</u>	2,000
16	<u>Source material - shielding</u>	584
17	<u>Special nuclear material plutonium -</u>	
18	<u>neutron source in device</u>	3,680
19	<u>Pacemaker by-product and/or special nuclear</u>	
20	<u>material - medical (institution)</u>	3,680
21	<u>Pacemaker by-product and/or special nuclear</u>	
22	<u>material - manufacturing and distribution</u>	5,280
23	<u>Accelerator-produced radioactive material</u>	3,840
24	<u>Nonprofit educational institutions</u>	300
25	<u>General license registration</u>	150

26 Sec. 2. Minnesota Statutes 2002, section 144.1205,
27 subdivision 4, is amended to read:

28 Subd. 4. [APPLICATION FEE.] A licensee must pay an
29 application fee as follows:

30	Radioactive-material,	Application	U-S--Nuclear-Regulatory
31	source-and	fee	Commission-licensing
32	special-material		category-as-reference

33

34	Type-A-broadscope	\$20,000	Medical-institution-type-A
35	Type-B-broadscope	\$15,000	Research-and-development
36			type-B

1	Type-C-broadscope	\$107000	Academic-type-C
2	Medical-use	\$47000	Medical
3			Medical-institution
4			Medical-private-practice
5	Mobile-nuclear		
6	medical-laboratory	\$47000	Mobile-medical-laboratory
7	Medical-special-use		
8	sealed-sources	\$67000	Teletherapy
9			High-dose-rate-remote
10			afterloaders
11			Stereotactic
12			radiosurgery-devices
13	In-vitro-testing	\$27300	In-vitro-testing
14			laboratories
15	Measuring-gauge		
16	sealed-sources	\$27000	Fixed-gauges
17			Portable-gauges
18			Analytical-instruments
19			Measuring-systems---other
20	Gas-chromatographs	\$17200	Gas-chromatographs
21	Manufacturing-and		
22	distribution	\$147700	Manufacturing-and
23			distribution---other
24	Distribution-only	\$87800	Distribution-of
25			radioactive-material
26			for-commercial-use-only
27	Other-services	\$17500	Other-services
28	Nuclear-medicine		
29	pharmacy	\$47100	Nuclear-pharmacy
30	Waste-disposal	\$97400	Waste-disposal-service
31			prepackage
32			Waste-disposal-service
33			processing/repackage
34	Waste-storage-only	\$77000	To-receive-and-store
35			radioactive-material-waste
36	Industrial		

1	radiography	\$87400	Industrial-radiography
2			fixed-location
3			Industrial-radiography
4			portable/temporary-sites
5	Irradiator--		
6	self-shielded	\$47100	Irradiators-self-shielded
7			less-than-107000-curies
8	Irradiator--		
9	less-than-107000-Ci	\$77500	Irradiators-less-than
10			107000-curies
11	Irradiator--		
12	more-than-107000-Ci	\$117500	Irradiators-greater-than
13			107000-curies
14	Research-and		
15	development,		
16	no-distribution	\$47100	Research-and-development
17	Radioactive-material		
18	possession-only	\$17000	Byproduct-possession-only
19	Source-material	\$17000	Source-material-shielding
20	Special-nuclear		
21	material--less-than		
22	200-grams	\$17000	Special-nuclear-material
23			plutonium-neutron-sources
24			less-than-200-grams
25	Pacemaker		
26	manufacturing	\$17000	Pacemaker-byproduct
27			and/or-special-nuclear
28			material--medical
29			institution
30	General-license		
31	distribution	\$27100	General-license
32			distribution
33	General-license		
34	distribution--exempt	\$17500	General-license
35			distribution--
36			certain-exempt-items

1	Academic, small	\$17,000	Possession-limit-of-ten
2			radionuclides, not-to
3			exceed-a-total-of-one-curie
4			of-activity
5	Veterinary	\$27,000	Veterinary-use
6	Well-logging	\$57,000	Well-logging
7	<u>TYPE</u>		<u>APPLICATION FEE</u>
8	<u>Academic broad scope - type A</u>		<u>\$ 5,920</u>
9	<u>Academic broad scope - type B</u>		<u>5,920</u>
10	<u>Academic broad scope - type C</u>		<u>5,920</u>
11	<u>Medical broad scope - type A</u>		<u>3,920</u>
12	<u>Medical institution - diagnostic and therapeutic</u>		<u>1,520</u>
13	<u>Medical institution - diagnostic</u>		
14	<u>(no written directives)</u>		<u>1,520</u>
15	<u>Medical private practice - diagnostic and therapeutic</u>		<u>1,520</u>
16	<u>Medical private practice - diagnostic (no written</u>		<u>1,520</u>
17	<u>directives)</u>		
18	<u>Eye applicators</u>		<u>1,520</u>
19	<u>Nuclear medical vans</u>		<u>1,520</u>
20	<u>High dose rate afterloader</u>		<u>1,520</u>
21	<u>Mobile high dose rate afterloader</u>		<u>1,520</u>
22	<u>Medical therapy - other emerging technology</u>		<u>1,520</u>
23	<u>Teletherapy</u>		<u>5,520</u>
24	<u>Gamma knife</u>		<u>5,520</u>
25	<u>Veterinary medicine</u>		<u>960</u>
26	<u>In vitro testing lab</u>		<u>960</u>
27	<u>Nuclear pharmacy</u>		<u>4,880</u>
28	<u>Radiopharmaceutical distribution (10 CFR 32.72)</u>		<u>2,160</u>
29	<u>Radiopharmaceutical processing and</u>		
30	<u>distribution (10 CFR 32.72)</u>		<u>4,880</u>
31	<u>Medical sealed sources - distribution (10 CFR 32.74)</u>		<u>2,160</u>
32	<u>Medical sealed sources - processing and</u>		
33	<u>distribution (10 CFR 32.74)</u>		<u>4,880</u>
34	<u>Well logging - sealed sources</u>		<u>1,600</u>
35	<u>Measuring systems - fixed gauge</u>		<u>960</u>
36	<u>Measuring systems - portable gauge</u>		<u>960</u>

1	<u>X-ray fluorescent analyzer</u>	584
2	<u>Measuring systems - gas chromatograph</u>	960
3	<u>Measuring systems - other</u>	960
4	<u>Broad scope manufacturing and distribution - type A</u>	5,920
5	<u>Broad scope manufacturing and distribution - type B</u>	5,920
6	<u>Broad scope manufacturing and distribution - type C</u>	5,920
7	<u>Manufacturing and distribution - other</u>	2,320
8	<u>Nuclear laundry</u>	10,080
9	<u>Decontamination services</u>	2,640
10	<u>Leak test services only</u>	960
11	<u>Instrument calibration service only,</u>	
12	<u>less than 100 curies</u>	960
13	<u>Instrument calibration service only,</u>	
14	<u>100 curies or more</u>	960
15	<u>Service, maintenance, installation,</u>	
16	<u>source changes, etc.</u>	2,640
17	<u>Waste disposal service, prepackaged only</u>	2,240
18	<u>Waste disposal</u>	1,520
19	<u>Distribution - general licensed</u>	
20	<u>devices (sealed sources)</u>	880
21	<u>Distribution - general licensed</u>	
22	<u>material (unsealed sources)</u>	520
23	<u>Industrial radiography - fixed location</u>	2,640
24	<u>Industrial radiography - temporary job sites</u>	2,640
25	<u>Irradiators, self-shielding, less than 10,000 curies</u>	1,440
26	<u>Irradiators, other, less than 10,000 curies</u>	2,960
27	<u>Irradiators, self-shielding, 10,000 curies or more</u>	1,440
28	<u>Research and development - type A broad scope</u>	4,960
29	<u>Research and development - type B broad scope</u>	4,960
30	<u>Research and development - type C broad scope</u>	4,960
31	<u>Research and development - other</u>	2,400
32	<u>Storage - no operations</u>	960
33	<u>Source material - shielding</u>	136
34	<u>Special nuclear material plutonium -</u>	
35	<u>neutron source in device</u>	1,200
36	<u>Pacemaker by-product and/or special nuclear</u>	

1	<u>material - medical (institution)</u>	<u>1,200</u>
2	<u>Pacemaker by-product and/or special nuclear</u>	
3	<u>material - manufacturing and distribution</u>	<u>2,320</u>
4	<u>Accelerator-produced radioactive material</u>	<u>4,100</u>
5	<u>Nonprofit educational institutions</u>	<u>300</u>
6	<u>General license registration</u>	<u>0</u>
7	<u>Industrial radiographer certification</u>	<u>150</u>

8 Sec. 3. Minnesota Statutes 2002, section 144.1205,
9 subdivision 8, is amended to read:

10 Subd. 8. [RECIPROCITY FEE.] A licensee submitting an
11 application for reciprocal recognition of a materials license
12 issued by another agreement state or the United States Nuclear
13 Regulatory Commission for a period of 180 days or less during a
14 calendar year must pay ~~one-half-of-the-application-fee-specified~~
15 ~~under-subdivision-4~~ \$1,200. For a period of 181 days or more,
16 the licensee must ~~pay-the-entire-application-fee~~ obtain a
17 license under subdivision 4.

18 Sec. 4. Minnesota Statutes 2002, section 144.1205,
19 subdivision 9, is amended to read:

20 Subd. 9. [FEES FOR LICENSE AMENDMENTS.] A licensee must
21 pay a fee of \$300 to amend a license as follows:

22 ~~(1) to amend a license requiring no license review~~
23 ~~including, but not limited to, facility name change or removal~~
24 ~~of a previously authorized user, no fee,~~

25 ~~(2) to amend a license requiring review including, but not~~
26 ~~limited to, addition of isotopes, procedure changes, new~~
27 ~~authorized users, or a new radiation safety officer, \$200; and~~

28 ~~(3) (2) to amend a license requiring review and a site~~
29 ~~visit including, but not limited to, facility move or addition~~
30 ~~of processes, \$400.~~

31 Sec. 5. [APPROVAL; AGREEMENT STATE APPLICATION AND RULES.]

32 The application for the agreement under Minnesota Statutes,
33 section 144.1202, subdivision 1, between the state of Minnesota
34 and the United States Nuclear Regulatory Commission is approved
35 as required under Minnesota Statutes, section 144.1202,
36 subdivision 4, paragraph (b), and the agreement may be

1 implemented.

2 Sec. 6. [HOSPITAL CONSTRUCTION MORATORIUM EXEMPTION;
3 EFFECTIVE DATE.]

4 Laws 2004, chapter 187, is effective July 1, 2004.

5 Sec. 7. [REPEALER.]

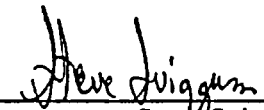
6 Minnesota Statutes 2003 Supplement, section 144.1202,
7 subdivision 4, is repealed.

8 Sec. 8. [EFFECTIVE DATE.]


9 Sections 1 to 7 are effective the day following final
10 enactment.

This bill was passed in conformity to the rules of each house and the joint rules of the two houses as required by the Constitution of the State of Minnesota.

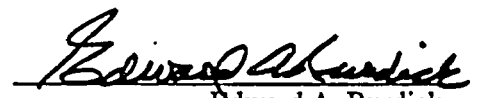

James Metzen
President of the Senate


Steve Sviggum
Speaker of the House of Representatives

Passed the Senate on May 14, 2004.


Patrick E. Flahaven
Secretary of the Senate

Passed the House of Representatives on May 13, 2004.


Edward A. Burdick
Chief Clerk, House of Representatives

This bill is properly enrolled and was presented to the Governor on May 18, 2004.


Michele L. Timmons
Revisor of Statutes

Approved on May 29, 2004, at 8:10 A.M.


Tim Pawlenty
Governor

Filed on May 29, 2004.


Mary Kinnear
Secretary of State

Minnesota Statutes 2003, Chapter 13

13.02 Collection, security, and dissemination of records; definitions.

Subdivision 1. Applicability. As used in this chapter, the terms defined in this section have the meanings given them.

Subd. 2. Commissioner. "Commissioner" means the commissioner of the Department of Administration.

Subd. 3. Confidential data on individuals. "Confidential data on individuals" means data which is made not public by statute or federal law applicable to the data and is inaccessible to the individual subject of that data.

Subd. 3a. Criminal justice agencies. "Criminal justice agencies" means all state and local prosecution authorities, all state and local law enforcement agencies, the Sentencing Guidelines Commission, the Bureau of Criminal Apprehension, the Department of Corrections, and all probation officers who are not part of the judiciary.

Subd. 4. Data not on individuals. "Data not on individuals" means all government data which is not data on individuals.

Subd. 5. Data on individuals. "Data on individuals" means all government data in which any individual is or can be identified as the subject of that data, unless the appearance of the name or other identifying data can be clearly demonstrated to be only incidental to the data and the data are not accessed by the name or other identifying data of any individual.

Subd. 6. Designee. "Designee" means any person designated by a responsible authority to be in charge of individual files or systems containing government data and to receive and comply with requests for government data.

Subd. 7. Government data. "Government data" means all data collected, created, received, maintained or disseminated by any state agency, political subdivision, or statewide system regardless of its physical form, storage media or conditions of use.

Subd. 7a. Government entity. "Government entity" means a state agency, statewide system, or political subdivision.

Subd. 8. Individual. "Individual" means a natural person. In the case of a minor or an individual adjudged mentally incompetent, "individual" includes a parent or guardian or an individual acting as a parent or guardian in the absence of a parent or guardian, except that the responsible authority shall withhold data from parents or guardians, or individuals acting as parents or guardians in the absence of parents or guardians, upon request by the minor if the responsible authority determines that withholding the data would be in the best interest of the minor.

Subd. 8a. **Not public data.** "Not public data" means any government data which is classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic.

Subd. 9. **Nonpublic data.** "Nonpublic data" means data not on individuals that is made by statute or federal law applicable to the data: (a) not accessible to the public; and (b) accessible to the subject, if any, of the data.

Subd. 10. **Person.** "Person" means any individual, partnership, corporation, association, business trust, or a legal representative of an organization.

Subd. 11. **Political subdivision.** "Political subdivision" means any county, statutory or home rule charter city, school district, special district, any town exercising powers under chapter 368 and located in the metropolitan area, as defined in section 473.121, subdivision 2, and any board, commission, district or authority created pursuant to law, local ordinance or charter provision. It includes any nonprofit corporation which is a community action agency organized pursuant to the Economic Opportunity Act of 1964 (Public Law 88-452) as amended, to qualify for public funds, or any nonprofit social service agency which performs services under contract to any political subdivision, statewide system or state agency, to the extent that the nonprofit social service agency or nonprofit corporation collects, stores, disseminates, and uses data on individuals because of a contractual relationship with state agencies, political subdivisions or statewide systems.

Subd. 12. **Private data on individuals.** "Private data on individuals" means data which is made by statute or federal law applicable to the data: (a) not public; and (b) accessible to the individual subject of that data.

Subd. 13. **Protected nonpublic data.** "Protected nonpublic data" means data not on individuals which is made by statute or federal law applicable to the data (a) not public and (b) not accessible to the subject of the data.

Subd. 14. **Public data not on individuals.** "Public data not on individuals" means data which is accessible to the public pursuant to section 13.03.

Subd. 15. **Public data on individuals.** "Public data on individuals" means data which is accessible to the public in accordance with the provisions of section 13.03.

Subd. 16. **Responsible authority.** "Responsible authority" in a state agency or statewide system means the state official designated by law or by the commissioner as the individual responsible for the collection, use and dissemination of any set of data on individuals, government data, or summary data. "Responsible authority" in any political subdivision means the individual designated by the governing body of that political subdivision as the individual responsible for the collection, use, and dissemination of any set of data on individuals, government data, or summary data, unless otherwise provided by state law.

Subd. 17. **State agency.** "State agency" means the state, the University of Minnesota, and any office, officer, department, division, bureau, board, commission, authority, district or agency of the state.

Subd. 18. **Statewide system.** "Statewide system" includes any record-keeping system in which government data is collected, stored, disseminated and used by means of a system common to one or more state agencies or more than one of its political subdivisions or any combination of state agencies and political subdivisions.

Subd. 19. **Summary data.** "Summary data" means statistical records and reports derived from data on individuals but in which individuals are not identified and from which neither their identities nor any other characteristic that could uniquely identify an individual is ascertainable.

HIST: 1974 c 479 s 1; 1975 c 401 s 1; 1976 c 239 s 2; 1976 c 283 s 1-5; 1977 c 375 s 1-5; 1978 c 790 s 1; 1979 c 328 s 2-6; 1980 c 603 s 1-6; 1980 c 618 s 25; 1981 c 311 s 2-6,39; 1982 c 545 s 1,24; 1984 c 436 s 1; 1989 c 351 s 2; 1996 c 440 art 1 s 1; 1999 c 227 s 22; 2000 c 468 s 3; 2001 c 202 s 1

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Minnesota Statutes 2003, Chapter 13

13.39 Civil investigation.

Subdivision 1. Definitions. A "pending civil legal action" includes but is not limited to judicial, administrative or arbitration proceedings. Whether a civil legal action is pending shall be determined by the chief attorney acting for the state agency, political subdivision or statewide system.

Subd. 2. Civil actions. (a) Except as provided in paragraph (b), data collected by state agencies, political subdivisions, or statewide systems as part of an active investigation undertaken for the purpose of the commencement or defense of a pending civil legal action, or which are retained in anticipation of a pending civil legal action, are classified as protected nonpublic data pursuant to section 13.02, subdivision 13, in the case of data not on individuals and confidential pursuant to section 13.02, subdivision 3, in the case of data on individuals. Any agency, political subdivision, or statewide system may make any data classified as confidential or protected nonpublic pursuant to this subdivision accessible to any person, agency or the public if the agency, political subdivision, or statewide system determines that the access will aid the law enforcement process, promote public health or safety or dispel widespread rumor or unrest.

(b) A complainant has access to a statement provided by the complainant to a state agency, statewide system, or political subdivision under paragraph (a).

Subd. 2a. Disclosure of data. During the time when a civil legal action is determined to be pending under subdivision 1, any person may bring an action in the district court in the county where the data is maintained to obtain disclosure of data classified as confidential or protected nonpublic under subdivision 2. The court may order that all or part of the data be released to the public or to the person bringing the action. In making the determination whether data shall be disclosed, the court shall consider whether the benefit to the person bringing the action or to the public outweighs any harm to the public, the agency, or any person identified in the data. The data in dispute shall be examined by the court in camera.

Subd. 3. Inactive investigative data. Inactive civil investigative data are public, unless the release of the data would jeopardize another pending civil legal action, and except for those portions of a civil investigative file that are classified as not public data by this chapter or other law. Any civil investigative data presented as evidence in court or made part of a court record shall be public. Civil investigative data become inactive upon the occurrence of any of the following events:

- (1) a decision by the state agency, political subdivision, or statewide system or by the chief attorney acting for the state agency, political subdivision, or statewide system not to pursue the civil action;
- (2) expiration of the time to file a complaint under the statute of limitations or agreement applicable to the civil action; or

(3) exhaustion of or expiration of rights of appeal by either party to the civil action.

Data determined to be inactive under clause (1) may become active if the state agency, political subdivision, statewide system, or its attorney decides to renew the civil action.

HIST: 1981 c 311 s 22,39; 1982 c 545 s 11,24; 1985 c 298 s 11; 1987 c 351 s 5; 1994 c 618 art 1 s 6,7

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Minnesota Statutes 2003, Chapter 13

13.41 Licensing data.

Subdivision 1. Definition. As used in this section "licensing agency" means any board, department or agency of this state which is given the statutory authority to issue professional or other types of licenses, except the various agencies primarily administered by the commissioner of human services. Data pertaining to persons or agencies licensed or registered under authority of the commissioner of human services shall be administered pursuant to section 13.46.

Subd. 2. Private data; designated addresses and telephone numbers. (a) The following data collected, created or maintained by any licensing agency are classified as private, pursuant to section 13.02, subdivision 12: data, other than their names and designated addresses, submitted by applicants for licenses; the identity of complainants who have made reports concerning licensees or applicants which appear in inactive complaint data unless the complainant consents to the disclosure; the nature or content of unsubstantiated complaints when the information is not maintained in anticipation of legal action; the identity of patients whose medical records are received by any health licensing agency for purposes of review or in anticipation of a contested matter; inactive investigative data relating to violations of statutes or rules; and the record of any disciplinary proceeding except as limited by subdivision 5.

(b) An applicant for a license shall designate on the application a residence or business address and telephone number at which the applicant can be contacted in connection with the license application. A licensee shall designate a residence or business address and telephone number at which the licensee can be contacted in connection with the license. By designating an address under this paragraph other than a residence address, the applicant or licensee consents to accept personal service of process by service on the licensing agency for legal or administrative proceedings. The licensing agency shall mail a copy of the documents to the applicant or licensee at the last known residence address.

Subd. 3. Board of Peace Officer Standards and Training. The following government data of the Board of Peace Officer Standards and Training are private data:

- (1) home addresses of licensees and applicants for licenses; and
- (2) data that identify the state agency, statewide system, or political subdivision that employs a licensed peace officer.

The board may disseminate private data on applicants and licensees as is necessary to administer law enforcement licensure or to provide data under section 626.845, subdivision 1, to law enforcement agencies who are conducting employment background investigations.

Subd. 4. Confidential data. The following data collected, created or maintained by any licensing agency are classified as confidential, pursuant to section 13.02, subdivision 3: active investigative data relating to the investigation of complaints against any licensee.

Subd. 5. **Public data.** Licensing agency minutes, application data on licensees except nondesignated addresses, orders for hearing, findings of fact, conclusions of law and specification of the final disciplinary action contained in the record of the disciplinary action are classified as public, pursuant to section 13.02, subdivision 15. The entire record concerning the disciplinary proceeding is public data pursuant to section 13.02, subdivision 15, in those instances where there is a public hearing concerning the disciplinary action. If the licensee and the licensing agency agree to resolve a complaint without a hearing, the agreement and the specific reasons for the agreement are public data. The license numbers, the license status, and continuing education records issued or maintained by the Board of Peace Officer Standards and Training are classified as public data, pursuant to section 13.02, subdivision 15.

Subd. 6. **Releasing data.** Any licensing agency may make any data classified as private or confidential pursuant to this section accessible to an appropriate person or agency if the licensing agency determines that failure to make the data accessible is likely to create a clear and present danger to public health or safety.

HIST: 1981 c 311 s 27,39; 1982 c 545 s 12-14,24; 1984 c 436 s 16; 1984 c 654 art 5 s 58; 1987 c 351 s 6; 1990 c 573 s 5; 1993 c 351 s 5; 1994 c 618 art 1 s 8; 1997 c 214 s 1; 1Sp1997 c 3 s 4; 1999 c 227 s 22; 2000 c 468 s 11; 2002 c 375 art 1 s 1; 2002 c 389 s 1

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144.05 General duties of commissioner; reports.

Subdivision 1. General duties. The state commissioner of health shall have general authority as the state's official health agency and shall be responsible for the development and maintenance of an organized system of programs and services for protecting, maintaining, and improving the health of the citizens. This authority shall include but not be limited to the following:

- (a) Conduct studies and investigations, collect and analyze health and vital data, and identify and describe health problems;
- (b) Plan, facilitate, coordinate, provide, and support the organization of services for the prevention and control of illness and disease and the limitation of disabilities resulting therefrom;
- (c) Establish and enforce health standards for the protection and the promotion of the public's health such as quality of health services, reporting of disease, regulation of health facilities, environmental health hazards and personnel;
- (d) Affect the quality of public health and general health care services by providing consultation and technical training for health professionals and paraprofessionals;
- (e) Promote personal health by conducting general health education programs and disseminating health information;
- (f) Coordinate and integrate local, state and federal programs and services affecting the public's health;
- (g) Continually assess and evaluate the effectiveness and efficiency of health service systems and public health programming efforts in the state; and
- (h) Advise the governor and legislature on matters relating to the public's health.

Subd. 2. Mission; efficiency. It is part of the department's mission that within the department's resources the commissioner shall endeavor to:

- (1) prevent the waste or unnecessary spending of public money;
- (2) use innovative fiscal and human resource practices to manage the state's resources and operate the department as efficiently as possible;
- (3) coordinate the department's activities wherever appropriate with the activities of other governmental agencies;

(4) use technology where appropriate to increase agency productivity, improve customer service, increase public access to information about government, and increase public participation in the business of government;

(5) utilize constructive and cooperative labor-management practices to the extent otherwise required by chapters 43A and 179A;

(6) report to the legislature on the performance of agency operations and the accomplishment of agency goals in the agency's biennial budget according to section 16A.10, subdivision 1; and

(7) recommend to the legislature appropriate changes in law necessary to carry out the mission and improve the performance of the department.

Subd. 3. Appropriation transfers to be reported. When the commissioner transfers operational money between programs under section 16A.285, in addition to the requirements of that section the commissioner must provide the chairs of the legislative committees that have jurisdiction over the agency's budget with sufficient detail to identify the account to which the money was originally appropriated, and the account to which the money is being transferred.

Subd. 4. Identification of deceased individuals. Upon receiving notice under section 149A.90, subdivision 1, of the death of an individual who cannot be identified, the commissioner must post on the department's Web site information regarding the individual for purposes of obtaining information that may aid in identifying the individual and for purposes of notifying relatives who may be seeking the individual. The information must remain on the Web site continuously until the person's identity is determined.

HIST: (5339) RL s 2130; 1973 c 356 s 2; 1977 c 305 s 45; 1986 c 444; 1995 c 248 art 11 s 11; 1998 c 366 s 57; 1999 c 245 art 1 s 14; 2002 c 375 art 3 s 4

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Minnesota Statutes 2003, Chapter 144

144.12 Regulation, enforcement, licenses, fees.

Subdivision 1. Rules. The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health. The rules shall not conflict with the charter or ordinance of a city of the first class upon the same subject. The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means, any of the following matters:

- (1) The manufacture into articles of commerce, other than food, of diseased, tainted, or decayed animal or vegetable matter;
- (2) The business of scavenging and the disposal of sewage;
- (3) The location of mortuaries and cemeteries and the removal and burial of the dead;
- (4) The management of boarding places for infants and the treatment of infants in them;
- (5) The pollution of streams and other waters and the distribution of water by persons for drinking or domestic use;
- (6) The construction and equipment, in respect to sanitary conditions, of schools, hospitals, almshouses, prisons, and other public institutions, and of lodging houses and other public sleeping places kept for gain;
- (7) The treatment, in hospitals and elsewhere, of persons suffering from communicable diseases, including all manner of venereal disease and infection, the disinfection and quarantine of persons and places in case of those diseases, and the reporting of sicknesses and deaths from them;

Neither the commissioner nor any board of health as defined in section 145A.02, subdivision 2, nor director of public health may adopt any rule or regulation for the treatment in any penal or correctional institution of any person suffering from any communicable disease or venereal disease or infection, which requires the involuntary detention of any person after the expiration of the period of sentence to the penal or correctional institution, or after the expiration of the period to which the sentence may be reduced by good time allowance or by the lawful order of any judge or the Department of Corrections;

- (8) The prevention of infant blindness and infection of the eyes of the newly born by the designation, from time to time, of one or more prophylactics to be used in those cases and in the manner that the commissioner directs, unless specifically objected to by a parent of the infant;
- (9) The furnishing of vaccine matter; the assembling, during epidemics of smallpox, with other persons not vaccinated, but no rule of the board or of any public board or officer

shall at any time compel the vaccination of a child, or exclude, except during epidemics of smallpox and when approved by the local board of education, a child from the public schools for the reason that the child has not been vaccinated; any person required to be vaccinated may select for that purpose any licensed physician and no rule shall require the vaccination of any child whose physician certifies that by reason of the child's physical condition vaccination would be dangerous;

(10) The accumulation of filthy and unwholesome matter to the injury of the public health and its removal;

(11) The collection, recording, and reporting of vital statistics by public officers and the furnishing of information to them by physicians, undertakers, and others of births, deaths, causes of death, and other pertinent facts;

(12) The construction, equipment, and maintenance, in respect to sanitary conditions, of lumber camps, migratory or migrant labor camps, and other industrial camps;

(13) The general sanitation of tourist camps, summer hotels, and resorts in respect to water supplies, disposal of sewage, garbage, and other wastes and the prevention and control of communicable diseases; and, to that end, may prescribe the respective duties of agents of a board of health as authorized under section 145A.04; and all boards of health shall make such investigations and reports and obey such directions as the commissioner may require or give and, under the supervision of the commissioner, enforce the rules;

(14) Atmospheric pollution which may be injurious or detrimental to public health;

(15) Sources of radiation, and the handling, storage, transportation, use and disposal of radioactive isotopes and fissionable materials; and

(16) The establishment, operation and maintenance of all clinical laboratories not owned, or functioning as a component of a licensed hospital. These laboratories shall not include laboratories owned or operated by five or less licensed practitioners of the healing arts, unless otherwise provided by federal law or regulation, and in which these practitioners perform tests or procedures solely in connection with the treatment of their patients. Rules promulgated under the authority of this clause, which shall not take effect until federal legislation relating to the regulation and improvement of clinical laboratories has been enacted, may relate at least to minimum requirements for external and internal quality control, equipment, facility environment, personnel, administration and records. These rules may include the establishment of a fee schedule for clinical laboratory inspections. The provisions of this clause shall expire 30 days after the conclusion of any fiscal year in which the federal government pays for less than 45 percent of the cost of regulating clinical laboratories.

Subd. 2. Mass gatherings. The commissioner may regulate the general sanitation of mass gatherings by promulgation of rules in respect to, but not limited to, the following areas: water supply, disposal of sewage, garbage and other wastes, the prevention and control of

communicable diseases, the furnishing of suitable and adequate sanitary accommodations, and all other reasonable and necessary precautions to protect and insure the health, comfort and safety of those in attendance. No permit, license, or other prior approval shall be required of the commissioner for a mass gathering. A "mass gathering" shall mean an actual or reasonably anticipated assembly of more than 1,500 persons which will continue, or may reasonably be expected to continue, for a period of more than ten consecutive hours and which is held in an open space or temporary structure especially constructed, erected or assembled for the gathering. For purposes of this subdivision, "mass gatherings" shall not include public gatherings sponsored by a political subdivision or a nonprofit organization.

Subd. 3. Licenses; permits. Applications for licenses or permits issued pursuant to this section shall be submitted with a fee prescribed by the commissioner pursuant to section 144.122. Licenses or permits shall expire and be renewed as prescribed by the commissioner pursuant to section 144.122.

HIST: (5345) RL s 2131; 1917 c 345 s 1; 1923 c 227 s 1; 1951 c 537 s 1; 1953 c 134 s 1; 1957 c 361 s 1; 1975 c 310 s 4; 1975 c 351 s 1; 1977 c 66 s 10; 1977 c 305 s 45; 1977 c 406 s 1; 1983 c 359 s 9; 1985 c 248 s 70; 1986 c 444; 1987 c 309 s 24

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Minnesota Statutes 2003, Chapter 144

144.99 Enforcement.

Subdivision 1. Remedies available. The provisions of chapters 103I and 157 and sections 115.71 to 115.77; 144.12, subdivision 1, paragraphs (1), (2), (5), (6), (10), (12), (13), (14), and (15); 144.1201 to 144.1204; 144.121; 144.1222; 144.35; 144.381 to 144.385; 144.411 to 144.417; 144.495; 144.71 to 144.74; 144.9501 to 144.9509; 144.992; 326.37 to 326.45; 326.57 to 326.785; 327.10 to 327.131; and 327.14 to 327.28 and all rules, orders, stipulation agreements, settlements, compliance agreements, licenses, registrations, certificates, and permits adopted or issued by the department or under any other law now in force or later enacted for the preservation of public health may, in addition to provisions in other statutes, be enforced under this section.

Subd. 2. Access to information and property. The commissioner or an employee or agent authorized by the commissioner, upon presentation of credentials, may:

- (1) examine and copy any books, papers, records, memoranda, or data of any person subject to regulation under the statutes listed in subdivision 1; and
- (2) enter upon any property, public or private, for the purpose of taking any action authorized under statutes, rules, or other actions listed in subdivision 1 including obtaining information from a person who has a duty to provide information under the statutes listed in subdivision 1, taking steps to remedy violations, or conducting surveys or investigations.

Subd. 3. Correction orders. (a) The commissioner may issue correction orders that require a person to correct a violation of the statutes, rules, and other actions listed in subdivision 1. The correction order must state the deficiencies that constitute the violation; the specific statute, rule, or other action; and the time by which the violation must be corrected.

(b) If the person believes that the information contained in the commissioner's correction order is in error, the person may ask the commissioner to reconsider the parts of the order that are alleged to be in error. The request must be in writing, delivered to the commissioner by certified mail within seven calendar days after receipt of the order, and:

- (1) specify which parts of the order for corrective action are alleged to be in error;
- (2) explain why they are in error; and
- (3) provide documentation to support the allegation of error.

The commissioner must respond to requests made under this paragraph within 15 calendar days after receiving a request. A request for reconsideration does not stay the correction order; however, after reviewing the request for reconsideration, the commissioner may provide

additional time to comply with the order if necessary. The commissioner's disposition of a request for reconsideration is final.

Subd. 4. Administrative penalty orders. (a) The commissioner may issue an order requiring violations to be corrected and administratively assessing monetary penalties for violations of the statutes, rules, and other actions listed in subdivision 1. The procedures in section 144.991 must be followed when issuing administrative penalty orders. Except in the case of repeated or serious violations, the penalty assessed in the order must be forgiven if the person who is subject to the order demonstrates in writing to the commissioner before the 31st day after receiving the order that the person has corrected the violation or has developed a corrective plan acceptable to the commissioner. The maximum amount of an administrative penalty order is \$10,000 for each violator for all violations by that violator identified in an inspection or review of compliance.

(b) Notwithstanding paragraph (a), the commissioner may issue to a large public water supply, serving a population of more than 10,000 persons, an administrative penalty order imposing a penalty of at least \$1,000 per day per violation, not to exceed \$10,000 for each violation of sections 144.381 to 144.385 and rules adopted thereunder.

Subd. 5. Injunctive relief. In addition to any other remedy provided by law, the commissioner may bring an action for injunctive relief in the district court in Ramsey County or, at the commissioner's discretion, in the district court in the county in which a violation of the statutes, rules, or other actions listed in subdivision 1 has occurred to enjoin the violation.

Subd. 6. Cease and desist. The commissioner, or an employee of the department designated by the commissioner, may issue an order to cease an activity covered by subdivision 1 if continuation of the activity would result in an immediate risk to public health. An order issued under this paragraph is effective for a maximum of 72 hours. In conjunction with the issuance of the cease and desist order, the commissioner may post a sign to cease an activity until the cease and desist order is lifted and the sign is removed by the commissioner. The commissioner must seek an injunction or take other administrative action authorized by law to restrain activities for a period beyond 72 hours. The issuance of a cease and desist order does not preclude the commissioner from pursuing any other enforcement action available to the commissioner.

Subd. 7. Plan for use of administrative penalties and cease and desist authority. The commissioner of health shall prepare a plan for using the administrative penalty and cease and desist authority in this section. The commissioner shall provide a 30-day period for public comment on the plan. The plan must be finalized by December 1, 1993.

Subd. 8. Denial or refusal to reissue permits, licenses, registrations, or certificates. (a) The commissioner may deny or refuse to renew an application for a permit, license, registration, or certificate required under the statutes or rules cited in subdivision 1, if the applicant does not meet or fails to maintain the minimum qualifications for holding a permit, license, registration, or certificate or has any unresolved violations related to the activity for which the permit, license, registration, or certificate was issued.

(b) The commissioner may also deny or refuse to renew a permit, license, registration, or certificate required under the statutes or rules cited in subdivision 1 if the applicant has a persistent pattern of violations related to the permit, license, registration, or certificate, or if the applicant submitted false material information to the department in connection with the application.

(c) The commissioner may condition the grant or renewal of a permit, license, registration, or certificate on a demonstration by the applicant that actions needed to ensure compliance with the requirements of the statutes listed in subdivision 1 have been taken, or may place conditions on or issue a limited permit, license, registration, or certificate as a result of previous violations by the applicant.

Subd. 9. Suspension or revocation of permits, licenses, registrations, or certificates. The commissioner may suspend, place conditions on, or revoke a permit, license, registration, or certificate issued under the statutes or rules cited in subdivision 1 for:

- (1) serious or repeated violations of the requirements in the statutes, rules, or other actions listed in subdivision 1 that apply to the permit, license, registration, or certificate;
- (2) submitting false material information to the department in connection with activities for which the permit, license, registration, or certificate is issued;
- (3) allowing the alteration or use of one's own permit, license, registration, or certificate by another; or
- (4) within the previous five years, conviction of a crime in connection with activities for which the permit, license, registration, or certificate was issued.

Subd. 10. Hearings related to denial, refusal to renew, suspension, or revocation of a permit, license, registration, or certificate. If the commissioner proposes to deny, refuses to renew, suspends, or revokes a permit, license, registration, or certificate under subdivision 8 or 9, the commissioner must first notify, in writing, the person against whom the action is proposed to be taken and provide the person an opportunity to request a hearing under the contested case provisions of chapter 14. If the person does not request a hearing by notifying the commissioner within 20 days after receipt of the notice of proposed action, the commissioner may proceed with the action without a hearing. This subdivision does not apply to:

- (1) the denial of or refusal to renew a permit, license, registration, or certificate based on the applicant's failure to meet or maintain the minimum qualifications for holding the permit, license, registration, or certificate; or
- (2) the denial of, refusal to renew, suspension of, or revocation of a permit, license, registration, or certificate if the person against whom the action is proposed to be taken has been granted a hearing under this subdivision within the previous 12 months.

Subd. 11. **Misdemeanor penalties.** A person convicted of violating a statute or rule listed in subdivision 1 is guilty of a misdemeanor.

Subd. 12. **Securing radioactive materials.** (a) In the event of an emergency that poses a danger to the public health, the commissioner shall have the authority to impound radioactive materials and the associated shielding in the possession of a person who fails to abide by the provisions of the statutes, rules, and any other item listed in subdivision 1. If impounding the source of these materials is impractical, the commissioner shall have the authority to lock or otherwise secure a facility that contains the source of such materials, but only the portions of the facility as is necessary to protect the public health. An action taken under this paragraph is effective for up to 72 hours. The commissioner must seek an injunction or take other administrative action to secure radioactive materials beyond the initial 72-hour period.

(b) The commissioner may release impounded radioactive materials and the associated shielding to the owner of the radioactive materials and associated shielding, upon terms and conditions that are in accordance with the provisions of statutes, rules, and other items listed in subdivision 1. In the alternative, the commissioner may bring an action in a court of competent jurisdiction for an order directing the disposal of impounded radioactive materials and associated shielding or directing other disposition as necessary to protect the public health and safety and the environment. The costs of decontamination, transportation, burial, disposal, or other disposition shall be borne by the owner or licensee of the radioactive materials and shielding or by any other person who has used the radioactive materials and shielding for business purposes.

HIST: 1993 c 206 s 8; 1Sp1993 c 6 s 33; 1994 c 465 art 2 s 1; 1995 c 165 s 5-9; 1995 c 180 s 13; 1995 c 213 art 1 s 12; 1997 c 205 s 29,30; 1998 c 261 s 2; 1998 c 407 art 2 s 80; 1999 c 245 art 2 s 28,29

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144.121 X-ray machines and facilities using other sources of ionizing radiation.

Subdivision 1. Registration; fees. The fee for the registration for x-ray machines and other sources of ionizing radiation required to be registered under rules adopted by the state commissioner of health pursuant to section 144.12, shall be in an amount as described in subdivision 1a pursuant to section 144.122. The registration shall expire and be renewed as prescribed by the commissioner pursuant to section 144.122.

Subd. 1a. Fees for x-ray machines and other sources of ionizing radiation. A facility with x-ray machines or other sources of ionizing radiation must biennially pay an initial or biennial renewal registration fee consisting of a base facility fee of \$132 and an additional fee for each x-ray machine or other source of ionizing radiation as follows:

(1) medical or veterinary equipment	\$106
(2) dental x-ray equipment	\$66
(3) accelerator	\$132
(4) radiation therapy equipment	\$132
(5) x-ray equipment not used on humans or animals	\$106
(6) devices with sources of ionizing radiation not used on humans or animals	\$106
(7) sources of radium	\$198

Subd. 1b. Penalty fee for late registration. Applications for initial or renewal registrations submitted to the commissioner after the time specified by the commissioner shall be accompanied by a penalty fee of \$20 in addition to the fees prescribed in subdivision 1a.

Subd. 1c. Fee for x-ray machines and other sources of ionizing radiation registered during last 12 months of a biennial registration period. The initial registration fee of x-ray machines or other sources of radiation required to be registered during the last 12 months of a biennial registration period will be 50 percent of the applicable registration fee prescribed in subdivision 1a.

Subd. 2. Inspections. Periodic radiation safety inspections of the sources of ionizing radiation shall be made by the state commissioner of health. The frequency of safety inspections shall be prescribed by the commissioner on the basis of the frequency of use of the source of ionizing radiation; provided that each source shall be inspected at least once every four years.

Subd. 3. Exemption. Notwithstanding rules adopted by the commissioner under section 144.12, subdivision 1, clause (15), practitioners of veterinary medicine are not required to conduct densitometry and sensitometry tests as part of any ionizing radiation quality assurance program.

Subd. 4. Radiation monitoring. Whenever involved in radiation procedures, practitioners of veterinary medicine and staff shall wear film-based radiation monitoring badges to monitor individual exposure. The badges must be submitted periodically to a dosimetry service for individual exposure determination.

Subd. 5. Examination for individual operating x-ray equipment. After January 1, 1997, an individual in a facility with x-ray equipment for use on humans that is registered under subdivision 1 may not operate, nor may the facility allow the individual to operate, x-ray equipment unless the individual has passed an examination approved by the commissioner of health, or an examination determined to the satisfaction of the commissioner of health to be an equivalent national, state, or regional examination, that demonstrates the individual's knowledge of basic radiation safety, proper use of x-ray equipment, darkroom and film processing, and quality assurance procedures. The commissioner shall establish by rule criteria for the approval of examinations required for an individual operating an x-ray machine in Minnesota.

Subd. 6. Inspection. At the time a facility with x-ray equipment is inspected by the commissioner of health in accordance with subdivision 2, an individual operating x-ray equipment in the facility must be able to show compliance with the requirements of subdivision 5.

Subd. 7. Repealed, 1999 c 86 art 2 s 6

Subd. 8. Exemption from examination requirements; operators of certain bone densitometers. (a) This subdivision applies to a bone densitometer that is used on humans to estimate bone mineral content and bone mineral density in a region of a finger on a person's nondominant hand, gives an x-ray dose equivalent of less than 0.001 microsieverts per scan, and has an x-ray leakage exposure rate of less than two milliroentgens per hour at a distance of one meter, provided that the bone densitometer is operating in accordance with manufacturer specifications.

(b) An individual who operates a bone densitometer that satisfies the definition in paragraph (a) and the facility in which an individual operates such a bone densitometer are exempt from the requirements of subdivisions 5 and 6.

HIST: 1974 c 81 s 1; 1975 c 310 s 35; 1977 c 305 s 45; 1985 c 248 s 70; 1993 c 188 s 1,2; 1995 c 146 s 1-3; 1997 c 203 art 2 s 7-10; 1999 c 245 art 2 s 20

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144.989 Title; citation.

Sections 144.989 to 144.993 may be cited as the "Health Enforcement Consolidation Act of 1993."

HIST: 1993 c 206 s 7

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Minnesota Statutes 2003, Chapter 144

144.991 Administrative penalty order procedure.

Subdivision 1. Amount of penalty; considerations. (a) In determining the amount of a penalty under section 144.99, subdivision 4, the commissioner may consider:

- (1) the willfulness of the violation;
- (2) the gravity of the violation, including damage to humans, animals, air, water, land, or other natural resources of the state;
- (3) the history of past violations;
- (4) the number of violations;
- (5) the economic benefit gained by the person by allowing or committing the violation; and
- (6) other factors as justice may require, if the commissioner specifically identifies the additional factors in the commissioner's order.

(b) For a violation after an initial violation, the commissioner shall, in determining the amount of a penalty, consider the factors in paragraph (a) and the:

- (1) similarity of the most recent previous violation and the violation to be penalized;
- (2) time elapsed since the last violation;
- (3) number of previous violations; and
- (4) response of the person to the most recent previous violation identified.

Subd. 2. Contents of order. An order assessing an administrative penalty under section 144.99, subdivision 4, must include:

- (1) a concise statement of the facts alleged to constitute a violation;
- (2) a reference to the section of the statute, rule, variance, order, stipulation agreement, or term or condition of a permit that has been violated;
- (3) a statement of the amount of the administrative penalty to be imposed and the factors upon which the penalty is based; and
- (4) a statement of the person's right to review of the order.

Subd. 3. **Corrective order.** (a) The commissioner may issue an order assessing a penalty and requiring the violations cited in the order to be corrected within 30 calendar days from the date the order is received.

(b) The person to whom the order was issued shall provide information to the commissioner before the 31st day after the order was received demonstrating that the violation has been corrected or that the person has developed a corrective plan acceptable to the commissioner. The commissioner shall determine whether the violation has been corrected and notify the person subject to the order of the commissioner's determination.

Subd. 4. **Penalty.** (a) Except as provided in paragraph (b), if the commissioner determines that the violation has been corrected or the person to whom the order was issued has developed a corrective plan acceptable to the commissioner, the penalty must be forgiven. Unless the person requests review of the order under subdivision 5 before the penalty is due, the penalty in the order is due and payable:

(1) on the 31st day after the order was received, if the person subject to the order fails to provide information to the commissioner showing that the violation has been corrected or that appropriate steps have been taken toward correcting the violation; or

(2) on the 20th day after the person receives the commissioner's determination under paragraph (b), if the person subject to the order has provided information to the commissioner that the commissioner determines is not sufficient to show the violation has been corrected or that appropriate steps have been taken toward correcting the violation.

(b) For repeated or serious violations, the commissioner may issue an order with a penalty that will not be forgiven after the corrective action is taken. The penalty is due by 31 days after the order was received unless review of the order under subdivision 5 has been sought.

(c) Interest at the rate established in section 549.09 begins to accrue on penalties under this subdivision on the 31st day after the order with the penalty was received.

Subd. 5. **Expedited administrative hearing.** (a) Within 30 days after receiving an order or within 20 days after receiving notice that the commissioner has determined that a violation has not been corrected or appropriate steps have not been taken, the person subject to an order under this section may request an expedited hearing, using the procedures of Minnesota Rules, parts 1400.8510 to 1400.8612, to review the commissioner's action. The hearing request must specifically state the reasons for seeking review of the order. The person to whom the order is directed and the commissioner are the parties to the expedited hearing. The commissioner must notify the person to whom the order is directed of the time and place of the hearing at least 15 days before the hearing. The expedited hearing must be held within 30 days after a request for hearing has been filed with the commissioner unless the parties agree to a later date.

(b) All written arguments must be submitted within ten days following the close of the hearing. The hearing shall be conducted under Minnesota Rules, parts 1400.8510 to 1400.8612, as

modified by this subdivision. The Office of Administrative Hearings may, in consultation with the agency, adopt rules specifically applicable to cases under this section.

(c) The administrative law judge shall issue a report making recommendations about the commissioner's action to the commissioner within 30 days following the close of the record. The administrative law judge may not recommend a change in the amount of the proposed penalty unless the administrative law judge determines that, based on the factors in subdivision 1, the amount of the penalty is unreasonable.

(d) If the administrative law judge makes a finding that the hearing was requested solely for purposes of delay or that the hearing request was frivolous, the commissioner may add to the amount of the penalty the costs charged to the agency by the Office of Administrative Hearings for the hearing.

(e) If a hearing has been held, the commissioner may not issue a final order until at least five days after receipt of the report of the administrative law judge. The person to whom an order is issued may, within those five days, comment to the commissioner on the recommendations and the commissioner will consider the comments. The final order may be appealed in the manner provided in sections 14.63 to 14.69.

(f) If a hearing has been held and a final order issued by the commissioner, the penalty shall be paid by 30 days after the date the final order is received unless review of the final order is requested under sections 14.63 to 14.69. If review is not requested or the order is reviewed and upheld, the amount due is the penalty, together with interest accruing from 31 days after the original order was received at the rate established in section 549.09.

Subd. 6. Mediation. In addition to review under subdivision 5, the commissioner is authorized to enter into mediation concerning an order issued under this section if the commissioner and the person to whom the order is issued both agree to mediation.

Subd. 7. Enforcement. (a) The attorney general may proceed on behalf of the state to enforce penalties that are due and payable under this section in any manner provided by law for the collection of debts.

(b) The attorney general may petition the district court to file the administrative order as an order of the court. At any court hearing, the only issues parties may contest are procedural and notice issues. Once entered, the administrative order may be enforced in the same manner as a final judgment of the district court.

(c) If a person fails to pay the penalty, the attorney general may bring a civil action in district court seeking payment of the penalties, injunctive, or other appropriate relief including monetary damages, attorney fees, costs, and interest.

Subd. 8. **Revocation and suspension of permit, license, registration, or certificate.** If a person fails to pay a penalty owed under this section, the agency has grounds to revoke or refuse to reissue or renew a permit, license, registration, or certificate issued by the department.

Subd. 9. **Cumulative remedy.** The authority of the agency to issue a corrective order assessing penalties is in addition to other remedies available under statutory or common law, except that the state may not seek civil penalties under any other provision of law for the violations covered by the administrative penalty order. The payment of a penalty does not preclude the use of other enforcement provisions, under which penalties are not assessed, in connection with the violation for which the penalty was assessed.

HIST: 1993 c 206 s 9; 1994 c 465 art 1 s 18,19; 1995 c 165 s 10

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Minnesota Statutes 2003, Chapter 144

144.992 False information.

A person subject to any of the requirements listed in section 144.99, subdivision 1, may not make a false material statement, representation, or certification in; omit material information from; or alter, conceal, or fail to file or maintain a notice, application, record, report, plan, or other document required under the statutes, rules, or other actions listed in section 144.99, subdivision 1.

HIST: 1993 c 206 s 10

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Minnesota Statutes 2003, Chapter 144

144.993 Recovery of litigation costs and expenses.

In any judicial action brought by the attorney general for civil penalties, injunctive relief, or an action to compel performance pursuant to the authority cited in section 144.99, subdivision 1, if the state finally prevails, and if the proven violation was willful, the state, in addition to other penalties provided by law, may be allowed an amount determined by the court to be the reasonable value of all or part of the litigation expenses incurred by the state. In determining the amount of the litigation expenses to be allowed, the court shall give consideration to the economic circumstances of the defendant.

HIST: 1993 c 206 s 11

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Minnesota Statutes 2003, Chapter 144

144.1201 Definitions.

Subdivision 1. Applicability. For purposes of sections 144.1201 to 144.1204, the terms defined in this section have the meanings given to them.

Subd. 2. By-product nuclear material. "By-product nuclear material" means a radioactive material, other than special nuclear material, yielded in or made radioactive by exposure to radiation created incident to the process of producing or utilizing special nuclear material.

Subd. 3. Radiation. "Radiation" means ionizing radiation and includes alpha rays; beta rays; gamma rays; x-rays; high energy neutrons, protons, or electrons; and other atomic particles.

Subd. 4. Radioactive material. "Radioactive material" means a matter that emits radiation. Radioactive material includes special nuclear material, source nuclear material, and by-product nuclear material.

Subd. 5. Source nuclear material. "Source nuclear material" means uranium or thorium, or a combination thereof, in any physical or chemical form; or ores that contain by weight 1/20 of one percent (0.05 percent) or more of uranium, thorium, or a combination thereof. Source nuclear material does not include special nuclear material.

Subd. 6. Special nuclear material. "Special nuclear material" means:

(1) plutonium, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Nuclear Regulatory Commission determines to be special nuclear material according to United States Code, title 42, section 2071, except that source nuclear material is not included; and

(2) a material artificially enriched by any of the materials listed in clause (1), except that source nuclear material is not included.

HIST: 1999 c 245 art 2 s 16

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Minnesota Statutes 2003, Chapter 144

144.1202 United States Nuclear Regulatory Commission agreement.

Subdivision 1. Agreement authorized. In order to have a comprehensive program to protect the public from radiation hazards, the governor, on behalf of the state, is authorized to enter into agreements with the United States Nuclear Regulatory Commission under the Atomic Energy Act of 1954, section 274b, as amended. The agreement shall provide for the discontinuance of portions of the Nuclear Regulatory Commission's licensing and related regulatory authority over by-product, source, and special nuclear materials, and the assumption of regulatory authority over these materials by the state.

Subd. 2. Health Department designated lead. The Department of Health is designated as the lead agency to pursue an agreement on behalf of the governor and for any assumption of specified licensing and regulatory authority from the Nuclear Regulatory Commission under an agreement with the commission. The commissioner of health shall establish an advisory group to assist in preparing the state to meet the requirements for reaching an agreement. The commissioner may adopt rules to allow the state to assume regulatory authority under an agreement under this section, including the licensing and regulation of radioactive materials. Any regulatory authority assumed by the state includes the ability to set and collect fees.

Subd. 3. Transition. A person who, on the effective date of an agreement under this section, possesses a Nuclear Regulatory Commission license that is subject to the agreement is deemed to possess a similar license issued by the Department of Health. A Department of Health license obtained under this subdivision expires on the expiration date specified in the federal license.

Subd. 4. Agreement; conditions of implementation. (a) An agreement entered into before August 2, 2006, must remain in effect until terminated under the Atomic Energy Act of 1954, United States Code, title 42, section 2021, paragraph (j). The governor may not enter into an initial agreement with the Nuclear Regulatory Commission after August 1, 2006. If an agreement is not entered into by August 1, 2006, any rules adopted under this section are repealed effective August 1, 2006.

(b) An agreement authorized under subdivision 1 must be approved by law before it may be implemented.

HIST: 1999 c 245 art 2 s 17; 1Sp2001 c 9 art 1 s 28; 2002 c 379 art 1 s 113; 2003 c 111 s 1

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Minnesota Statutes 2003, Chapter 144

144.1203 Training; rulemaking.

The commissioner shall adopt rules to ensure that individuals handling or utilizing radioactive materials under the terms of a license issued by the commissioner under section 144.1202 have proper training and qualifications to do so. The rules adopted must be at least as stringent as federal regulations on proper training and qualifications adopted by the Nuclear Regulatory Commission. Rules adopted under this section may incorporate federal regulations by reference.

HIST: 1999 c 245 art 2 s 18

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144.1204 Surety requirements.

Subdivision 1. Financial assurance required. The commissioner may require an applicant for a license under section 144.1202, or a person who was formerly licensed by the Nuclear Regulatory Commission and is now subject to sections 144.1201 to 144.1204, to post financial assurances to ensure the completion of all requirements established by the commissioner for the decontamination, closure, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with activities related to licensure. The financial assurances posted must be sufficient to restore the site to unrestricted future use and must be sufficient to provide for surveillance and care when radioactive materials remain at the site after the licensed activities cease. The commissioner may establish financial assurance criteria by rule. In establishing such criteria, the commissioner may consider:

- (1) the chemical and physical form of the licensed radioactive material;
- (2) the quantity of radioactive material authorized;
- (3) the particular radioisotopes authorized and their subsequent radiotoxicity;
- (4) the method in which the radioactive material is held, used, stored, processed, transferred, or disposed of; and
- (5) the potential costs of decontamination, treatment, or disposal of a licensee's equipment and facilities.

Subd. 2. Acceptable financial assurances. The commissioner may, by rule, establish types of financial assurances that meet the requirements of this section. Such financial assurances may include bank letters of credit, deposits of cash, or deposits of government securities.

Subd. 3. Trust agreements. Financial assurances must be established together with trust agreements. Both the financial assurances and the trust agreements must be in a form and substance that meet requirements established by the commissioner.

Subd. 4. Exemptions. The commissioner is authorized to exempt from the requirements of this section, by rule, any category of licensee upon a determination by the commissioner that an exemption does not result in a significant risk to the public health or safety or to the environment and does not pose a financial risk to the state.

Subd. 5. Other remedies unaffected. Nothing in this section relieves a licensee of a civil liability incurred, nor may this section be construed to relieve the licensee of obligations to prevent or mitigate the consequences of improper handling or abandonment of radioactive materials.

HIST: 1999 c 245 art 2 s 19

Minnesota Statutes 2003, Chapter 144

144.1205 Radioactive material; source and special nuclear material; fees; inspection.

Subdivision 1. Application and license renewal fee. When a license is required for radioactive material or source or special nuclear material by a rule adopted under section 144.1202, subdivision 2, an application fee according to subdivision 4 must be paid upon initial application for a license. The licensee must renew the license 60 days before the expiration date of the license by paying a license renewal fee equal to the application fee under subdivision 4. The expiration date of a license is the date set by the United States Nuclear Regulatory Commission before transfer of the licensing program under section 144.1202 and thereafter as specified by rule of the commissioner of health.

Subd. 2. Annual fee. A licensee must pay an annual fee at least 60 days before the anniversary date of the issuance of the license. The annual fee is an amount equal to 80 percent of the application fee under subdivision 4, rounded to the nearest whole dollar.

Subd. 3. Fee categories; incorporation of federal licensing categories. (a) Fee categories under this section are equivalent to the licensing categories used by the United States Nuclear Regulatory Commission under Code of Federal Regulations, title 10, parts 30 to 36, 39, 40, 70, 71, and 150, except as provided in paragraph (b).

(b) The category of "Academic, small" is the type of license required for the use of radioactive materials in a teaching institution. Radioactive materials are limited to ten radionuclides not to exceed a total activity amount of one curie.

Subd. 4. Application fee. A licensee must pay an application fee as follows:

Radioactive material, source and special material	Application Fee	U.S. Nuclear Regulatory Commission licensing category as reference
Type A broadscope	\$20,000	Medical institution type A
Type B broadscope	\$15,000	Research and development type B
Type C broadscope	\$10,000	Academic type C
Medical use	\$4,000	Medical Medical institution Medical private practice
Mobile nuclear medical laboratory	\$4,000	Mobile medical laboratory
Medical special use sealed sources	\$6,000	Teletherapy High dose rate remote afterloaders Stereotactic radiosurgery devices
In vitro testing	\$2,300	In vitro testing laboratories
Measuring gauge, sealed sources	\$2,000	Fixed gauges Portable gauges Analytical instruments
Gas chromatographs	\$1,200	Measuring systems - other Gas chromatographs
Manufacturing and distribution	\$14,700	Manufacturing and distribution - other

Distribution only	\$8,800	Distribution of radioactive material for commercial use only
Other services	\$1,500	Other services
Nuclear medicine pharmacy	\$4,100	Nuclear pharmacy
Waste disposal	\$9,400	Waste disposal service prepackage
		Waste disposal service
		processing/repackage
Waste storage only	\$7,000	To receive and store radioactive material waste
Industrial radiography	\$8,400	Industrial radiography fixed location
		Industrial radiography
		portable/temporary sites
Irradiator - self-shielded	\$4,100	Irradiators self-shielded less than 10,000 curies
		Irradiators less than 10,000 curies
Irradiator - less than 10,000 Ci	\$7,500	Irradiators greater than 10,000 curies
Irradiator - more than 10,000 Ci	\$11,500	
Research and development, no distribution	\$4,100	Research and development
Radioactive material possession only	\$1,000	Byproduct possession only
Source material	\$1,000	Source material shielding
Special nuclear material, less than 200 grams	\$1,000	Special nuclear material plutonium-neutron sources less than 200 grams
Pacemaker manufacturing	\$1,000	Pacemaker byproduct and/or special nuclear material - medical institution
General license distribution	\$2,100	General license distribution
General license distribution, exempt	\$1,500	General license distribution -certain exempt items
Academic, small	\$1,000	Possession limit of ten radionuclides, not to exceed a total of one curie of activity
Veterinary	\$2,000	Veterinary use
Well logging	\$5,000	Well logging

Subd. 5. Penalty for late payment. An annual fee or a license renewal fee submitted to the commissioner after the due date specified by rule must be accompanied by an additional amount equal to 25 percent of the fee due.

Subd. 6. Inspections. The commissioner of health shall make periodic safety inspections of the radioactive material and source and special nuclear material of a licensee. The commissioner shall prescribe the frequency of safety inspections by rule.

Subd. 7. Recovery of reinspection cost. If the commissioner finds serious violations of public health standards during an inspection under subdivision 6, the licensee must pay all costs associated with subsequent reinspection of the source. The costs shall be the actual costs incurred by the commissioner and include, but are not limited to, labor, transportation, per diem, materials, legal fees, testing, and monitoring costs.

Subd. 8. **Reciprocity fee.** A licensee submitting an application for reciprocal recognition of a materials license issued by another agreement state or the United States Nuclear Regulatory Commission for a period of 180 days or less during a calendar year must pay one-half of the application fee specified under subdivision 4. For a period of 181 days or more, the licensee must pay the entire application fee under subdivision 4.

Subd. 9. **Fees for license amendments.** A licensee must pay a fee to amend a license as follows:

(1) to amend a license requiring no license review including, but not limited to, facility name change or removal of a previously authorized user, no fee;

(2) to amend a license requiring review including, but not limited to, addition of isotopes, procedure changes, new authorized users, or a new radiation safety officer, \$200; and

(3) to amend a license requiring review and a site visit including, but not limited to, facility move or addition of processes, \$400.

HIST: 1Sp2001 c 9 art 1 s 29; 2002 c 379 art 1 s 113

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Minnesota Statutes 2003, Chapter 181

181.931 Definitions.

Subdivision 1. **Generally.** For the purpose of sections 181.931 to 181.935 the terms defined in this section have the meanings given them.

Subd. 2. **Employee.** "Employee" means a person who performs services for hire in Minnesota for an employer. Employee does not include an independent contractor.

Subd. 3. **Employer.** "Employer" means any person having one or more employees in Minnesota and includes the state and any political subdivision of the state.

HIST: 1987 c 76 s 1

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Minnesota Statutes 2003, Chapter 181

181.932 Disclosure of information by employees.

Subdivision 1. Prohibited action. An employer shall not discharge, discipline, threaten, otherwise discriminate against, or penalize an employee regarding the employee's compensation, terms, conditions, location, or privileges of employment because:

- (a) the employee, or a person acting on behalf of an employee, in good faith, reports a violation or suspected violation of any federal or state law or rule adopted pursuant to law to an employer or to any governmental body or law enforcement official;
- (b) the employee is requested by a public body or office to participate in an investigation, hearing, inquiry;
- (c) the employee refuses an employer's order to perform an action that the employee has an objective basis in fact to believe violates any state or federal law or rule or regulation adopted pursuant to law, and the employee informs the employer that the order is being refused for that reason; or
- (d) the employee, in good faith, reports a situation in which the quality of health care services provided by a health care facility, organization, or health care provider violates a standard established by federal or state law or a professionally recognized national clinical or ethical standard and potentially places the public at risk of harm.

Subd. 2. Disclosure of identity. The identity of any employee making a report to a governmental body or law enforcement official under subdivision 1, clause (a) or (d), is private data on individuals as defined in section 13.02. The identity of an employee providing information under subdivision 1, clause (b), is private data on individuals if:

- (1) the employee would not have provided the information without an assurance that the employee's identity would remain private, because of a concern that the employer would commit an action prohibited under subdivision 1 or that the employee would be subject to some other form of retaliation; or
- (2) the state agency, statewide system, or political subdivision reasonably believes that the employee would not have provided the data because of that concern.

If the disclosure is necessary for prosecution, the identity of the employee may be disclosed but the employee shall be informed prior to the disclosure.

Subd. 3. False disclosures. This section does not permit an employee to make statements or disclosures knowing that they are false or that they are in reckless disregard of the truth.

Subd. 4. Collective bargaining rights. This section does not diminish or impair the rights of a person under any collective bargaining agreement.

Subd. 5. **Confidential information.** This section does not permit disclosures that would violate federal or state law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by common law.

HIST: 1987 c 76 s 2; 1988 c 659 s 2; 1997 c 237 s 16; 1999 c 227 s 14

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Minnesota Statutes 2003, Chapter 181

181.933 Notice of termination.

Subdivision 1. Notice required. An employee who has been involuntarily terminated may, within 15 working days following such termination, request in writing that the employer inform the employee of the reason for the termination. Within ten working days following receipt of such request, an employer shall inform the terminated employee in writing of the truthful reason for the termination.

Subd. 2. Defamation action prohibited. No communication of the statement furnished by the employer to the employee under subdivision 1 may be made the subject of any action for libel, slander, or defamation by the employee against the employer.

HIST: 1987 c 76 s 3; 2001 c 95 s 1

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Minnesota Statutes 2003, Chapter 181

181.934 Employee notice.

The Department of Labor and Industry shall promulgate rules for notification of employees by employers of an employee's rights under sections 181.931 to 181.935.

HIST: 1987 c 76 s 4

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Minnesota Statutes 2003, Chapter 181

181.935 Individual remedies; penalty.

(a) In addition to any remedies otherwise provided by law, an employee injured by a violation of section 181.932 may bring a civil action to recover any and all damages recoverable at law, together with costs and disbursements, including reasonable attorney's fees, and may receive such injunctive and other equitable relief as determined by the court.

(b) An employer who failed to notify, as required under section 181.933 or 181.934, an employee injured by a violation of section 181.932 is subject to a civil penalty of \$25 per day per injured employee not to exceed \$750 per injured employee.

HIST: 1987 c 76 s 5

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4.1.2

Program Organization

4.1.2 PROGRAM ORGANIZATION

The enclosed five documents address the structure, organization, and history of the Minnesota radioactive materials program. *Background of the Minnesota Department of Health*, and *History of Radiation Control in Minnesota* give a brief description of radiation control in the state. *Radiation Control Organizational Description*, and the *Organizational Charts* give a description of the current structure of the program. The *Organizational Charts* include all organizational levels between the Governor and the State materials program staff. Individual discussions and cross-references to pertinent portions of the supporting information can be found in both the *Introduction to the Application* and in the introductory pages in each section. In addition, the *Intra-agency Lab Agreement* and the *University of Minnesota Interagency Disposal Agreement* have been included in this section to further explain the Radioactive Materials Program organization.

BACKGROUND OF THE MINNESOTA DEPARTMENT OF HEALTH

The Minnesota Department of Health's (MDH) mission is to protect, maintain and improve the health of all Minnesotans. The Department operates programs in the areas of disease prevention and control, health promotion, family and community health, environmental health, health care policy, and regulation of health care providers and facilities. Among its many duties, the department does the following:

- Investigates disease outbreaks, and works to prevent both chronic and infectious diseases.
- Protects the quality of the food in restaurants, the safety of public water supplies, and the air inside public places.
- Identifies and evaluates potential health hazards in the environment—from simple sanitation problems to the health risks associated with toxic waste sites.
- Provides sophisticated laboratory services, including techniques and procedures for screening biological and chemical samples that are available nowhere else in the state.
- Works to help people lower their health risks by giving them information and support for making healthier lifestyle choices.
- Safeguards the quality of our state's health care, and regulates many of the people and institutions responsible for providing that care.
- Develops and implements strategies to contain health care costs, while broadening access to affordable, high-quality health care coverage for all Minnesotans.

Improving health is not just MDH's job—it requires coordinated efforts on the part of all levels of government, the private sector, community groups, and citizens themselves. The public health system—MDH working together with local public health agencies across the state—plays a key role in building and supporting the partnerships needed to improve health for individuals and communities.

History:

Minnesota became the fourth state to establish a state board of health in 1872, preceded by Massachusetts, California, and Virginia. The labs were originally located in Red Wing, but were moved to the University of Minnesota campus in 1893. The following year the offices of the board were moved to the Pioneer Building in St. Paul.

In 1902, the legislature appropriated funds for a laboratory animal house. Additional space was provided in 1907 in what is now the University's psychology building.

Albert J. Chesley, M.D. served the longest term as Secretary and Executive Officer of the State Board of Health from May 13, 1921 until his death at the age of 78 on October 15, 1955. During his tenure the board had offices in the University's Westbrook and Eddy Halls from 1922-1938. The Board's Maternal and Child Health Unit was housed on the University's St. Paul campus, and from 1932-1969 the board also had offices in the State Capitol and the State Office Building.

A building on the University of Minnesota-Minneapolis campus was dedicated to the Board on July 13, 1969. This building now houses the laboratory, disease prevention and control and vital records, with other functions housed in other locations.

In 1977, the State Board of Health's name was changed to the Minnesota Department of Health (MDH), and the powers and duties were transferred to the commissioner of health. This position became a gubernatorial appointment and part of the governor's cabinet.

Environmental Health Division:

This division is responsible for protecting the public from potential health hazards associated with drinking water, food and beverage establishments, hotels and resorts, plumbing, swimming pools, lead, asbestos, radiation, and other forms of environmental exposure to potentially hazardous physical or chemical agents. The division oversees licensing programs and regulatory activity relating to these areas. It performs examinations and inspections for MDH and other government agencies to identify potential problems associated with chemical or physical agents, bacterial contamination, or exposure to radiation.

Radiation Control Unit:

The Radiation Control Unit registers and inspects all x-ray machines and other sources of ionizing radiation at medical, dental, veterinary, industrial and educational facilities on a four-year cycle. It annually inspects mammography facilities for compliance with the Federal Mammographic Quality Standards Act. The Unit also conducts environmental sampling statewide and near the state's two nuclear power plants. It regulates the transportation of naturally occurring or accelerator produced radioactive materials (NARM) within Minnesota and responds to accidents and emergencies involving radiation. In addition, the Unit provides technical assistance to the general public, answering consumer concerns about radiation.

HISTORY OF RADIATION CONTROL IN MINNESOTA

1938

- The Minnesota State Board of Health granted federal funds to begin the Industrial Health Division.

1939

- The Legislature authorized creation of the Industrial Health Division. At this time, medical and industrial use of radium was just becoming common. Immediate concerns included radium dial painters' exposure and the medical use of radium in therapy. The Industrial Health Division, in order to detect exposure, used ultraviolet light to determine whether or not radium dial painters were using proper handwashing techniques.
- The National Council of Radiation Protection and Measurements established a maximum permissible body burden (MPBB) for radium.
- Radiation protection measures for patients, staff, and the public were established.

1940's

- The Industrial Health Division conducted surveys of hospitals, clinics, and private offices to ensure proper radiation protection procedures were being followed in the handling and disposal of radium plaques and needles.

Late 1940's

- Foot fluoroscopes in shoe fitting became widespread. Consequently, the Industrial Health Division began frequent surveys and adjustments of foot fluoroscopes.
- The Industrial Health Division also began surveying x-ray equipment in hospitals and medical and dental offices, which necessitated the purchase of radiation detection and measurement instruments.

1950

- By 1950, 200 foot fluoroscopes had been inspected and adjusted.

1951

- Mobile x-ray units began operating throughout the state to test the public for tuberculosis. The Industrial Health Division began surveying these machines.
- A study began in Minnesota to determine the exposure of personnel operating x-ray machines.

1952

- The Industrial Health Division began assessing new medical buildings or additions to determine the effectiveness of radiation shielding construction.
- The Industrial Health Division also began accompanying the U.S. Atomic Energy Commission on inspections of isotope users in Minnesota.
- An organized effort was begun to survey every x-ray unit in hospitals and medical and dental facilities in Minnesota.

1953

- The Minnesota State Board of Health became aware of nuclear fallout and its dangers and began participation in the National Air Sampling Network
- A staff member of the Industrial Health Division participated as an off-site monitor for the Nevada Test Site.
- The State Board of Health participated in the U.S. Public Health Service National Radiation Surveillance Network for air, milk, and water.
- The Section of Radiation and Occupational Health (formerly the Industrial Health Division) began to collect and analyze environmental samples from western Minnesota after concerns arose about illness and unusual environmental findings.

1955

- The Elk River Cooperative Association applied to the Atomic Energy Commission for a permit to build a nuclear power reactor. Studies were conducted by the State Board of Health and the U.S. Public Health Service to determine the possible health hazards of such a facility.

1956

- The State Board of Health purchased more sophisticated and sensitive lab equipment to accommodate the amount and type of analyses being done.

1957

- The State Board of Health determined that the use of radiation had grown large enough to necessitate further controls and direction. In July of 1957, Governor Orville Freeman appointed a committee to study and advise on atomic development. This committee was known as the Minnesota Atomic Development Problems Committee, and was composed of 24 Minnesota citizens with special competence or ability in fields related to the utilization or development of nuclear energy.
- Legislature amended Statute 144.12 to include the handling, storage, transportation, use, and disposal of x-ray machines and radioactive materials. The Legislature also authorized the State Board of Health to adopt regulations for the control of sources of ionizing radiation.

1958

- The Ionizing Radiation Rules were adopted on December 4th by the State Board of Health. (Minnesota was one of the first states to have such regulations.)
- A detailed environmental radiation study program was initiated by the Section of Radiation and Occupational Health. A low background anticoincidence counter was purchased to assist in the sample analysis.
- Water surveillance expanded to monthly sampling and analysis of 40 surface waters and 20 ground water supplies.
- The environmental radiation study revealed the presence of Strontium-90 in milk. In a study supported by the U.S. Public Health Service, monthly milk samples were taken from five areas in Minnesota. The results indicated the amounts were well within the maximum permissible concentration levels.

- Additional environmental monitoring was conducted around the Elk River reactor site in accordance with the preoperational monitoring program.
- The Section of Radiation and Occupational Health staff expanded to include a radiochemist, a chemical engineer, two chemist aids, and a radiological health physicist on loan from U.S. Public Health Service.
- The Radiological Health Program expanded to include medical and industrial sources of radiation.

1959

- The Legislature appropriated \$25,000 per year for the development of the State Board of Health Radiological Health Program. Three additional technical staff were hired, as was a radiation physicist. The State Board of Health appointed a Radiation Safety Advisory Committee to advise the Board on matters related to the field of radiation. In addition, a radiochemical lab was constructed and equipped.
- State-wide surveys of operating conditions of x-ray & fluoroscopic installations were initiated.
- By 1959, most hospitals had chest x-ray programs for tuberculosis detection. SROH surveyed these machines and kept records on the exposures to determine patient and personnel exposure.

1962

- In August and September of 1962, Iodine-131 levels in milk had risen a significant amount. After meetings with representatives from the dairy industry, the Minnesota Department of Agriculture, and other concerned parties, an aged feeding program for fluid milk dairy herds was implemented to reduce the I-131 levels. Samples were collected on a 24-hour basis and verified that the technique was effective.

1965

- Because of the extreme hazards related to leaking radium from a sealed source, the Section of Radiation and Occupational Health increased the frequency of its leak testing to every six months.
- Concern about radiation emission from color televisions prompted the Section of Radiation and Occupational Health to conduct surveys of television receivers to determine radiation levels. The results did not indicate a need for further corrective action.
- At this point in time, environmental monitoring and x-ray surveys took up most of the Section's staff time.

1966

- In June of 1966, Iodine in eight milk sampling locations rose slightly following Chinese nuclear weapons testing in the previous month. The levels were found to be within established limits. The general trend for Strontium-90 and Cesium-137 in milk continued downward, but remained within the detectable range.

- Daily sampling of air particulates continued by the Public Health Service Radiation Surveillance Network. The results were published in "Radiological Health Data and Reports," a monthly bulletin distributed by the Public Health Service.
- The Rural Cooperative Power Association of Elk River and the Minnesota Department of Health began their biennial release of the "Survey of Environmental Radioactivity."
- A demonstration nuclear power plant was built near Elk River, and operated for the next two years. Pre-operational and operational environmental monitoring were performed by the University of Minnesota School of Public Health under the direction of the Governor's Committee on Atomic Problems. Various structural and radiation problems were discovered during operational period. Due to these problems, the company expected to purchase the plant declined the offer.
- In April of 1966, due to increasing demands, the Section of Radiation and Occupational Health divided into two sections—the Section of Radiation Control and the Section of Industrial Hygiene.
- After investigations to determine the safety of building a nuclear reactor near Red Wing, the State Board of Health submitted their approval on May 21st to a hearing board for the Prairie Island nuclear power plant.

1969

- Radiation Control had hired three additional staff members.
- The Atomic Energy Commission commissioned the Elk River Cooperative Power Association to dismantle & decontaminate the Elk River reactor. (This was one of first reactors in the country to be dismantled.)

1970

- The Elk River Cooperative Power Association met with Radiation Control to discuss plans for decommissioning the reactor. Also discussed were the responsibilities of the State Board of Health for conducting environmental monitoring.
- At this time, 7000 x-ray and radioactive material sources were used in approximately 2500 facilities.
- Because of the widespread use of x-ray and radioactive material sources, schools began using sources for educational purposes. 741 secondary schools and universities were requested to submit information about their sources. 200 schools reported possession. Most were small enough to be exempt from registration. Information was gathered to determine if significant hazards resulted from these sources.

1971

- The Monticello Nuclear Reactor began operation. An extensive environmental monitoring and sample analysis program had been initiated two years earlier. Northern States Power worked with the Minnesota Department of Health (formerly the State Board of Health) to provide monitoring in order to comply

with Nuclear Regulatory Commission (NRC) regulations. This arrangement dissolved a few years later.

- The Minnesota Department of Health (MDH) Ionizing Radiation Rules were revised after meetings and discussions with the Advisory Committee on Radiation Safety and other interested parties. The revised rules included regulations specific to radiation equipment and registration requirements.
- MDH began meeting with the Department of Public Safety, the Division of Civil Defense, and other state and local agencies to write the Minnesota Emergency Response plan for nuclear accidents. An emergency response team from MDH was trained and maintained in readiness.
- Pre-operational environmental monitoring and sample analysis began for the Prairie Island site.

1973

- Prairie Island began operation and continued monitoring.
- The Elk River reactor was fully decommissioned. Waste from the reactor was transported to a disposal site in Illinois, which is no longer active.

1974

- The Legislature authorized fee requirements for the registration of x-ray machines and radium and mandated a minimum four year inspection cycle.
- MDH entered into a contract with the U.S. Food and Drug Administration (FDA) to inspect new or refurbished x-ray system installations using FDA protocol for inspections.

1976

- The registration fee was incorporated.

1977

- China & India conducted aboveground nuclear bomb tests. Environmental monitoring detected additional radioactivity in Minnesota milk and air, but not in sufficient quantities to recommend protective actions.

1978

- The Commissioner of Health began requiring commissioner approval before performing x-ray screening for the public in an attempt to reduce public exposure from mobile chest x-rays for Tuberculosis set up at shopping centers around the state.
- Environmental monitoring was conducted following the nuclear accident at Three Mile Island. No related contamination was found in Minnesota.

1979

- Prairie Island had a loss of coolant accident caused by a rupture in the recirculating water pipe. The accident was controlled within a couple hours; nonetheless, MDH followed through with its emergency response plan. Environmental monitoring and samples were taken and the two-mile area

surrounding the plant was evacuated. Tests showed that the release consisted mostly of krypton, xenon, and a small amount of Iodine-131 that did not extend much beyond plant boundary.

1980

- By 1980, all Minnesota facilities owning x-ray machines or radioactive materials had been inspected.

1985

- Some Cobalt-60 was included as scrap metal that was used to make table legs sold all over country. When MDH was notified, dozens of restaurants and other facilities were already using the tables and many more were in storage. Radiation Control staff inspected each table.
- The same year, some Polonium-210 discs became dislodged from 3M anti-static devices, creating potentially contaminated areas. Many of these devices were located in manufacturing or processing facilities, but some were in food-processing establishments. NRC sent its staff to inspect these facilities, and Radiation Control assisted by conducting inspections in places like Hormel Meats in Austin and Baldinger Bakery in West St. Paul.

1986

- The Chernobyl accident in the Soviet Union (now Ukraine) required additional environmental monitoring. Radiation Control maintained contact with the U.S. Department of Energy the Environmental Protection Agency to get updates on the content and amount of the release. Some radioactivity was found in Minnesota environmental samples, but none were high enough to warrant special action.
- Fees for the registration of x-ray machines and radium increased for the first time in ten years.
- Minnesota became one of first states to initiate mammography inspections. Later, MDH collaborated with Medicare, the lead organization for mammography inspections.

1987

- Another radioactive source mixed with scrap metal was made into chain link fencing. Radiation Control staff was dispatched to inspect the fencing.

1988

- Staggered biennial renewal was initiated to make Radiation Control's workload more manageable.

1990

- The registration fees were increased to make Radiation Control self-supporting by 1995.

1991

- The Legislature gave Radiation Control the authority to issue Cease & Desist orders and Administrative Penalties; rules were drafted following the authorization.
- The Health Enforcement act was adopted to give MDH the ability to fine facilities and individuals for rule violations and noncompliance. The fine maximum was \$10,000 per inspection.
- In September, the Ionizing Radiation Rules were revised to incorporate Federal Performance requirements for x-ray systems, requirements for Quality Assurance, increased registrant responsibilities, and revised shielding rules for new buildings or major reconstruction projects.
- In August, 34 seminars on the new rules were held for vendors. The seminars were held September through November for registrants. Enforcement of the regulations on Quality Assurance was delayed to allow facilities to write their procedures and obtain necessary equipment.
- By 1991, there were 4500 facilities with over 12,000 x-ray systems operating in Minnesota.
- Inspection procedures were modified to accommodate FDA compliance tests, which assured not only compliance with MDH standards, but also with manufacturer's specifications.

1992

- Congress passed the Mammography Quality Standards Act (MQSA) and later charged the FDA with national mammography standards and inspection responsibilities. FDA contracted MDH to inspect 250 facilities and 15 mobile organizations in Minnesota.
- In August, Minnesota Public Utilities Commission issued an order permitting the storage of high-level nuclear waste at the Prairie Island Nuclear Generating Station. The order included the requirement that the utility consult with MDH and the Prairie Island Indian Community for the preparation of the radiation monitoring plan. The Commission also ordered the installation of two pressurized ionization chambers with telemetry links to the MDH office.

1993

- Rules for Quality Assurance became effective in July.

1997

- The Ionizing Radiation Rules were revised to specifically address certain radiation sources, such as radium in density meters and Cobalt-57 in x-ray fluorescent analyzers. Also added were requirements to maintain formal written procedures, rules for record keeping, and certified calibrations of radiation survey meters. Radiation Control staff conducted six workshops throughout the state to explain the new rules.

1998

- The Legislature authorized the negotiation of an agreement with the NRC to become agreement state, which would allow Minnesota to assume regulatory authority for non-power plant radioactive materials pursuant to section 274b of the Atomic Energy Act of 1954 as amended.

2000

- Huisken Meats introduced hamburgers irradiated with a SureBeam irradiator to kill food borne pathogens. Later that summer, the irradiated hamburger was available for public consumption at the Minnesota State Fair.
- Two PET cyclotron facilities began production of Fluorine-18. Mayo Clinic and a Roseville facility began production of F-18 for diagnostic screening. Radiation Control staff held meetings with the owners of these facilities before construction and Radiation Control staff made several visits during the construction.

2001

- Radiation Control updated its inspection procedures for CT scanners.

2002

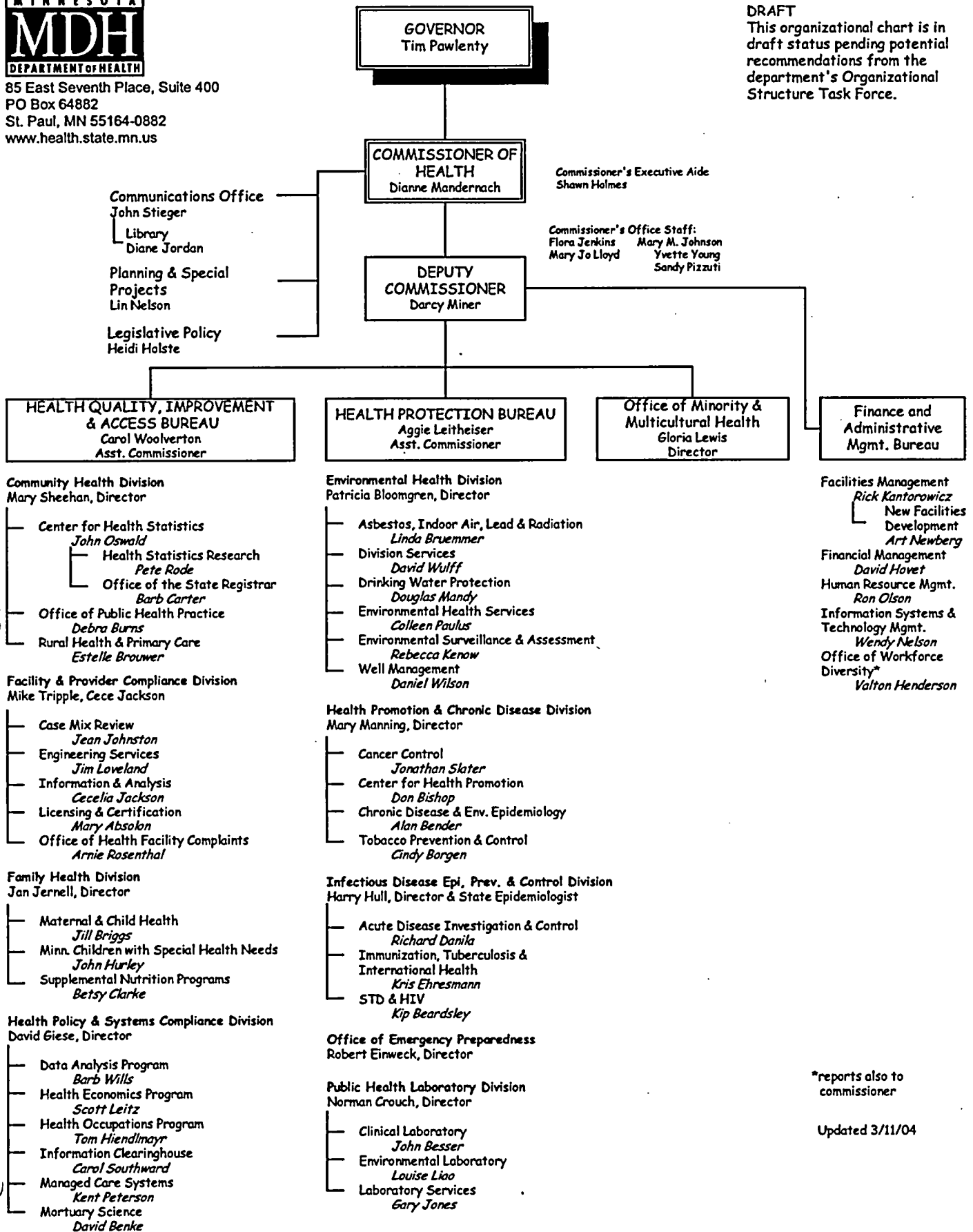
- MDH notified NRC of its intent to become an Agreement State. NRC completed its completeness review in September.

Organization Charts



85 East Seventh Place, Suite 400
 PO Box 64882
 St. Paul, MN 55164-0882
 www.health.state.mn.us

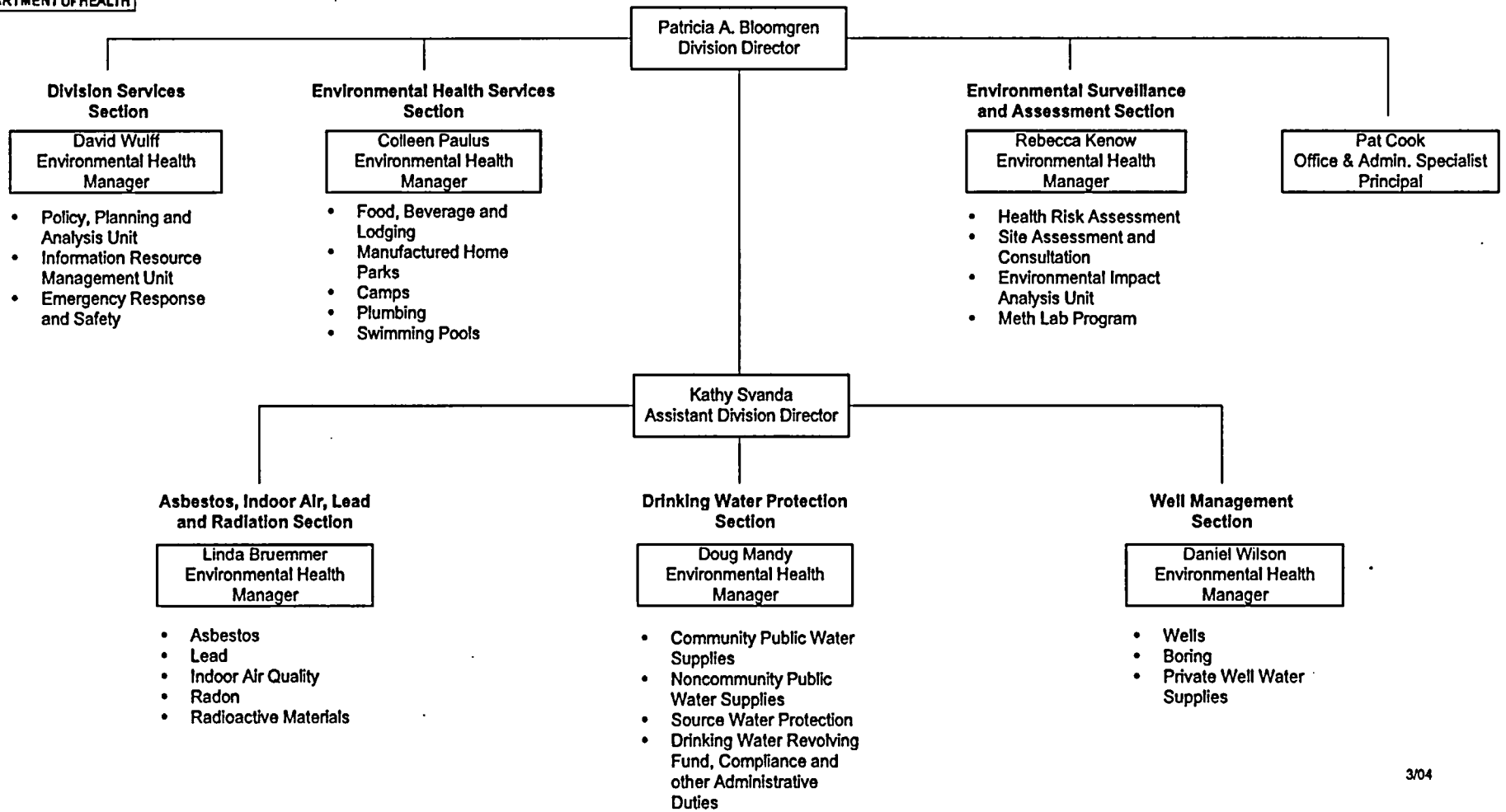
DRAFT
 This organizational chart is in draft status pending potential recommendations from the department's Organizational Structure Task Force.



*reports also to commissioner
 Updated 3/11/04



**Environmental Health Division
Minnesota Department of Health**



**Linda Bruemmer, Manager
Asbestos, Indoor Air, Lead, & Radiation Section**

**George Johns
Environmental Health Supervisor**

Radioactive Materials Group

**Susan McClanahan
Radiation Specialist 3**

**Timothy Donakowski
Health Physicist 1**

**John Goepferd
Radiation Specialist 2**

**Craig Verke
Radiation Specialist 2**

**Katherine Johnson
Radiation Specialist 1**

Support Staff

**Tina Leland
Office Administrative Specialist
Intermediate**

**Lisa Schuck
Office Administrative Specialist**

Memorandums of Understanding

**STATE OF MINNESOTA
INTRA-AGENCY AGREEMENT**

RADIATION ANNEX

This agreement is between the Radiation Control (RC) Unit of the Asbestos, Indoor Air, Lead, and Radiation (AILR) Section of the Division of Environmental Health (EH) and the Public Health Laboratory (PHL) within the Minnesota Department of Health (MDH).

AGREEMENT

1. Term of Agreement

- A. *Effective date:* July 1, 2004
- B. *Expiration date:* June 30, 2005 or until all obligations have been satisfactorily fulfilled, whichever occurs first.

2. Scope of Work

A. Public Health Laboratory's Responsibilities

- 1. Public Health Laboratory shall provide analytical services as prescribed in Attachment 1, which is incorporated into this agreement. Attachment 1 is a listing of RC's projected tests. RC may request any of the tests offered and is not limited to requesting only those in the projections.
- 2. PHL shall perform analyses using procedures required by Federal regulations. Where more than one method for analysis for radionuclides exists, and PHL has the capability for performing more than one method, PHL will use the least expensive method unless otherwise agreed upon by RC. For tests not regulated, PHL shall use procedures acceptable to RC. PHL shall make available to RC written test procedures upon request.
- 3. PHL will meet the analytical and report times prescribed in Attachment 2, which is incorporated into this agreement. Whenever PHL anticipates referenced times will be exceeded, PHL shall notify the RC liaison(s) of the situation, the specific samples affected, the reason(s) for not being able to meet analytical times, and the corrective action to be taken. PHL and RC liaisons will mutually agree on a method of resolution of the problem.
- 4. PHL will meet or exceed the Lower Limit of Detection (LLD) requirements in Attachment 3 for all analyses. These are based on the Technical Specifications for the Prairie Island and Monticello Nuclear Generating Plants and the U.S. Environmental Protection Agency's Environmental Radiation Ambient Monitoring System (ERAMS). PHL will notify RC on each analysis that does not meet the LLD with an explanation added to the data sheet (for example, sample size too small).
- 5. PHL will accept emergency response samples within a four-hour notice period on a 24-hour, year-round basis. PHL shall not refuse to accept emergency samples except when PHL determines that due to circumstances beyond its control, PHL cannot perform the analyses, or does not have the necessary safety procedures and safety equipment or facilities to safely handle and analyze the samples. If PHL cannot accept an emergency sample, PHL shall immediately inform RC of the reasons and assist RC in identifying alternative laboratories to perform the emergency analyses. Analysis of emergency samples shall commence within four hours of PHL's acceptance.

6. PHL shall maintain, within the cost recovery for analytical services contained herein, a quality assurance program that meets EPA certification requirements. PHL will provide quality assurance data summaries upon request that are suitable for use by RC personnel. The Program Liaison for PHL shall coordinate quality control as it relates to RC programs.
7. PHL shall collect all samples and prepare corresponding analysis request chain of custody forms to meet the sample collection, preservation, documentation and holding time requirements. RC will provide PHL with information on hazards of samples, if known.
8. PHL shall maintain procedures for chain of custody that are appropriate for acceptance, tracking possession and securing of samples submitted as standard, civil or criminal custody samples. PHL agrees to testify on results of samples analyzed by PHL in civil or criminal proceedings.
9. At no additional charge, PHL will provide sample containers and preservatives.
10. As necessary, PHL will ship samples for additional analysis, complying with all requirements for shipment. Shipment will be made within the timeframe specified by RC. PHL will retain documentation of shipments for RC reference.
11. PHL shall provide RC with monthly reports of RC's analyses requested to date and/or other status reports of any RC work.
12. PHL will dispose of samples submitted by RC that are part of the activities addressed in this agreement. When samples are hazardous and special disposal procedures need to be implemented, PHL may assess a disposal surcharge in an amount not to exceed PHL's actual cost associated with the special disposal procedures.
13. PHL will provide technical consultation, interpretation and guidance by the technical staff of PHL in matters of environmental testing conducted as part of this agreement.

B. Environmental Health's Responsibilities

1. RC shall provide workload projections to PHL one month prior to the start of a new Fiscal Year. RC will meet with PHL at that time to discuss specific sample type and volume requirements.
2. In the event that RC requires significant increases in testing which result in a change of more than 20% in projected workload, RC agrees to notify PHL as early as practicable.
3. RC will make a reasonable effort to maintain uniform loading of samples in the lab, with the understanding that field variability will not always allow uniform distribution of sample collection.
4. RC shall submit a request for priority or emergency status for RC samples to PHL by phone, with follow-up notification in writing (including e-mail) from the liaisons or program/project managers.
5. In the event of an environmental emergency, RC may make a request to a PHL program liaison or emergency contact for emergency testing services. The program liaisons or other contacts will coordinate information between PHL and RC staff.
6. RC liaisons will notify PHL of RC's intent to issue a Request for Proposal or to enter into a contract for laboratory services. RC liaisons will notify PHL of grants or proposals that RC is attempting to obtain involving work that may be performed by PHL.

7. RC will inform PHL regarding the classification of data created and maintained by PHL on behalf of RC programs.
8. EH will inform PHL regarding procedures for handling public requests for data generated and maintained on behalf of RC programs.

3. Considerations and Payment

Cost recovery for PHL analytical services shall be limited to the \$50,000.00 that has been permanently transferred into PHL account #4101 as of fiscal year '02. With this transfer, it becomes the responsibility of PHL to assure adequate funding for the current monitoring program and additional funding for any expanded program.

The cost to collect samples as specified in 2.A.6 shall be limited to \$10,000.00 that will be transferred upon execution of this agreement.

4. Authorized Representatives

Environmental Health's authorized representatives for the purposes of administration of this agreement are:

Principal Liaison: Patricia Bloomgren, Division Director, Environmental Health Division
Program Liaisons: Linda B. Bruemmer, Manager, Asbestos, Indoor Air, Lead, and Radiation
George F. Johns, Jr., Supervisor, Radiation Control Unit
Timothy Donakowski, Health Physicist

Public Health Laboratory's authorized representatives for the purposes of administration of this agreement are:

Principal Liaison: Norman Crouch, Director, Public Health Laboratory Division
Program Liaisons: Louise Liao, Manager, Environmental Laboratory Section
Jean Kahilainen, Assistant Manager, Environmental Laboratory Section

5. Amendments

Any amendment to this agreement must be in writing and will not be effective until it has been executed and approved by the same parties who executed and approved the original agreement, or their successors in office.

6. Liability

Each party will be responsible for its own acts and behavior and the results thereof.

7. Termination

This agreement may be terminated through mutual agreement between the authorized representatives. In the event of such a termination PHL shall be entitled to payment for work or services satisfactorily performed. All funds received by PHL as indicated in Section 3 of this agreement for work not performed shall be transferred back to RC.

Public Health Laboratory

By: _____

Title: _____

Date: _____

Environmental Health

By: _____

Title: _____

Date: _____

Attachment 1

RC's Projected Tests

FISCAL YEAR ENVIRONMENTAL MONITORING SAMPLE ANALYSIS														
Sample Type	Analysis Type	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Total Samples
Air-MDH	1, 2	4	4	5	4	4	5	4	4	5	4	5	4	52
Air-Power Plant	1, 2	4	4	5	4	4	5	4	4	5	4	5	4	52
Milk	1, 5	2	2	2	2	2	2	2	2	2	2	2	2	24
Surface Water	1, 3, 4, 6	4	4	4	4	4	4	2	2	2	4	4	4	42
Well Water	1, 3, 4	1	0	0	1	0	0	1	0	0	1	0	0	4
Sediment	1, 7	0	0	2	0	0	0	0	0	0	0	0	0	2
Vegetation	1, 7	2	2	2	2	0	0	0	0	0	0	2	2	12
Crop/Food	1, 7	2	2	2	2	2	2	2	2	2	2	2	2	24
Total Samples		19	18	22	19	16	18	15	14	16	17	20	18	212

ANALYSIS TYPE	
1	Gamma scan
2	Gross Alpha and Beta - Air
3	Gross Alpha and Beta - Water
4	Tritium
5	Sr-90 - Milk
6	Sr-90 - Water
7	Initial Prep

Attachment 2

Analytical and Report Times

TEST	MATRIX	REFERENCE METHOD	YEARLY VOLUME	REPORT TIME
Gamma	Water, Milk, Air, Vegetation, Sediment	Standard Methods 7120	212	30 days
Alpha/Beta	Water	EPA 900.0	46	45 days
Alpha/Beta	Air	EPA 900.0	104	45 days
Strontium	Milk	EPA 520/ 5-84-006	24	90 days
Strontium	Water	EPA 905.0	42	60 days
Tritium	Water	EPA 906.0	46	60 days

Attachment 3

GAMMA SCAN NUCLIDES AND LOWER LIMIT OF DETECTION (LLD)			
Nuclide	Air pCi/m ³	Liquids pCi/l	Solids pCi/g
Barium-140	0.01	15	0.08
Beryllium-7	0.02	20	0.2
Bismuth-212	0.03	81	0.2
Bismuth-214	0.01	16	0.1
Cerium-144	0.01	54	0.1
Cesium-134	0.003	7	0.02
Cesium-137	0.004	4	0.03
Chromium-51	0.02	16	0.2
Cobalt-58	0.003	2	0.03
Cobalt-60	0.003	7	0.02
Iodine-131	0.003	1	0.02
Iodine-132	0.002	3	0.2
Iodine-133	0.004	3	0.03
Iodine-134	0.004	4	0.7
Iodine-135	0.03	20	0.3
Iron-59	0.001	17	0.2
Krypton-88	0.006	9	0.004
Lead-210	0.005	20	0.004
Lead-212	0.006	13	0.06
Lead-214	0.008	17	0.005
Manganese-54	0.003	4	0.03
Niobium-95	0.004	5	0.03
Potassium-40	1	140	1
Radium-224	0.1	100	0.6
Radium-226	0.007	120	0.5
Ruthenium-103	0.002	5	0.02
Ruthenium-106	0.03	36	0.2
Strontium-91	0.03	40	0.2
Tellurium-132	0.002	4	0.02
Thallium-208	0.006	13	0.06
Thorium-228	0.1	400	1
Thorium-230	0.4	1700	4
Xenon-133	0.007	7	0.04
Xenon-135	0.005	4	0.05
Zinc-65	0.01	15	0.07
Zirconium-95	0.004	8	0.03

Lower limits of detection (LLD) for gross alpha analyses are 0.0005 pCi per cubic meter of air and 1 pCi per liter of water. LLD for gross beta analyses are 0.001 pCi per cubic meter for air and 1 pCi per liter for water.

Separate analyses are made for tritium (hydrogen-3) and radioactive strontium. The LLD for tritium is 150 pCi per liter. The LLD for Sr-89 is 0.8 pCi per liter, and for Sr-90, it is 0.8 pCi per liter.

Minnesota Department of Health
Division of Environmental Health
Asbestos, Indoor Air, Lead & Radiation Section
Radiation Control Unit

Snelling Office Park
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

**INTERAGENCY AGREEMENT
BETWEEN
THE MINNESOTA DEPARTMENT OF HEALTH
AND
UNIVERSITY OF MINNESOTA
DEPARTMENT OF ENVIRONMENTAL HEALTH AND SAFETY**

The Minnesota Department of Health (MDH) and University of Minnesota, Department of Environmental Health and Safety (DEHS), enter into an Interagency Agreement to assure that the MDH has radiological waste disposal support.

Delineation of Agency Responsibilities

This document applies to providing radiological technical assistance and radiological waste disposal services to the MDH by University of Minnesota, Department of Environmental Health and Safety.

The MDH is responsible for regulating radiation machines and radioactive materials in the state. MDH has established rules relating to: prescribing radiation safety criteria, licensing radioactive material, registering radiation machines, inspecting facilities to assure adherence to the safety standards, and collecting fees. Under this law, persons must register their radiation machines and have a license from the MDH for the use, manufacture, production, distribution, sale, transport, transfer, installation, repair, receipt, acquisition, ownership, or possession of any radioactive material except as exempted under Ionizing Radiation and Radioactive Materials Rules, Chapter 4731.

In carrying out the duties outlined above, the MDH may need radiological waste disposal services.

Agreement

It is hereby agreed that each of the affected agencies will perform the following functions:

A. Minnesota Department of Health

Collect, package and transport radiological waste to The University of Minnesota for storage treatment or disposal. The waste will be limited to small amounts collected from educational facilities, scrap yards and metal processing facilities, and abandoned

radioactive material. The treatment or storage of large radioactive sources (such as density gauges and radiography sources) will require specific negotiations between The University of Minnesota and The Minnesota Department of Health.

B. University of Minnesota; Department of Environmental Health and Safety

1. Upon receipt and as appropriate, store, treat, package or dispose of radioactive material collected by the MDH.
2. Provide radiological technical assistance as requested by MDH.

Funding

1. The MDH will exempt all fees for the broad scope license held by University of Minnesota in exchange for the radiological waste disposal that The University's Department of Environmental Health and Safety will provide to the MDH.
2. If, in the future, it is determined that this agreement is not equitable for either party, negotiations will take place to determine an equitable arrangement.

Liaison Designations

George F. Johns, Jr., Minnesota Department of Health, Radiation Control Unit
Jerome W. Staiger, University of Minnesota, Department of Environmental Health and Safety

Modification, Termination and Extension

This agreement will be reviewed yearly and may be revised at any time by mutual consent of both parties. This agreement shall continue in effect until terminated by either party upon sixty-(60) days written notice to the other party.

Jerome W. Staiger, Assistant Director
University of Minnesota
Department of Environmental Health and Safety

Date

Patricia Bloomgren, Director
Minnesota Department of Health
Division of Environmental Safety

Date

4.1.3

Content of Agreement

4.1.3
CONTENT OF AGREEMENT

The following document is the *Proposed Agreement* between the U.S. Nuclear Regulatory Commission and the State of Minnesota. It follows the format and content of the standard Agreement in Exhibit 1 of MD 5.8, Handbook.

**AN AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE STATE OF MINNESOTA
FOR THE
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY
AND
RESPONSIBILITY WITHIN THE STATE PURSUANT TO
SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED**

WHEREAS, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, The Governor of the State of Minnesota is authorized under §144.1202 Subdivision 1, Minnesota Statutes, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the State of Minnesota certified on [date], that the State of Minnesota (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

WHEREAS, The Commission found on [date] that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

WHEREAS, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

WHEREAS, The Commission and the State recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the State acting in behalf of the State as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- A. Byproduct materials as defined in Section 11e.(1) of the Act;
- B. Source materials;
- C. Special nuclear materials in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:

- A. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
- B. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
- C. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear materials waste as defined in the regulations or orders of the Commission;
- D. The regulation of the disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed without a license from the Commission;
- E. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.
- F. The regulation of the land disposal of by-product, source, or special nuclear material waste received from other persons;
- G. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

ARTICLE III

With the exception of those activities identified in Article II.A through D, this Agreement may be amended, upon application by the State and approval by the Commission, to include one or more of the additional activities specified in Article II, paragraphs E, F, and G, whereby the State may then exert regulatory authority and responsibility with respect to those activities.

ARTICLE IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE V

This Agreement shall not affect the authority of the Commission under Subsection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that Commission and State programs for protection against hazards of radiation will be coordinated and compatible. The State agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

ARTICLE VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State. Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

ARTICLE VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

ARTICLE IX

This Agreement shall become effective on [date], and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State] this [date] day of [month], [year].

FOR THE UNITED STATES NUCLEAR
REGULATORY COMMISSION

_____, Chairman

FOR THE STATE OF MINNESOTA

_____, Governor

4.2.1 Radiation Protection Standards

4.2.1

RADIATION PROTECTION STANDARDS

Minnesota's standards for protection against radiation can be found in the *Minnesota Rules Chapter 4731*, primarily in Part 2000. These rules address dose limits for occupationally exposed persons and members of the public; limits on the concentrations and quantity of materials released to the environment; and technical definitions and terminology, units of radioactivity and radiation dose, and radiation symbols, labels and warning signs.

4.2.2

Transboundary Requirements

4.2.2

TRANSBOUNDARY REQUIREMENTS

Regulatory requirements with significant transboundary implications can be found in various parts of the *Minnesota Rules Chapter 4731*. To assure that Minnesota's rules have minimal transboundary implications, all "A," "B," "C," and "H&S" language has been preserved with the exception the "Commission" has been replaced with "commissioner" where appropriate. Furthermore, all "D" compatibility items remain essentially the same as NRC regulations if adopted.

The *Compatibility Chart* provides a cross reference to NRC regulations. It also includes the compatibility, which is in accordance with SA-200, for each rule part.

MN Rule Part	Title	10 CFR	Compatibility
	Definitions		
4731.0100	Definitions		
Subpart 1	Scope		
Subp. 2	A ₁	71.4	A
Subp. 3	A ₂	71.4	A
Subp. 4	Absorbed dose	20.1003	A
Subp. 5	Active maintenance	61.2	DH&S
Subp. 6	Activity	20.1003	A
Subp. 7	Acute		
Subp. 8	Address of use	35.2	D
Subp. 9	Adult	20.1003	A
Subp. 10	Agreement State	30.4, 40.4, 150.3	B
Subp. 11	Air-purifying respirator	20.1003	A
Subp. 12	Airborne radioactive material	20.1003	A
Subp. 13	Airborne radioactivity area	20.1003	A
Subp. 14	Alert	30.3, 40.4	A
Subp. 15	Annual limit on intake or ALI	20.1003	A
Subp. 16	Annual refresher safety training or safety review	34.3, 39.2	C
Subp. 17	Area of use	35.2	D
Subp. 18	As low as reasonably achievable or ALARA	20.1003, 34.3	A
Subp. 19	Assigned protection factor or APF	20.1003	B
Subp. 20	Associated equipment	34.3	B
Subp. 21	Atmosphere-supplying respirator	20.1003	B
Subp. 22	Authorized medical physicist	35.2	B
Subp. 23	Authorized nuclear pharmacist	35.2	B
Subp. 24	Authorized user	35.2.	B
Subp. 25	Background radiation	20.1003	A
Subp. 26	Becquerel or Bq.	20.1005, 34.3	A
Subp. 27	Bioassay or radiobioassay	20.1003	A

MN Rule Part	Title	10 CFR	Compatibility
Subp. 28	Boring		
Subp. 29	Brachytherapy	35.2	D
Subp. 30	Brachytherapy source	35.2	D
Subp. 31	Broad scope license	33.11	D
Subp. 32	By-product material	30.4, 40.4, 150.3	A
Subp. 33	Carrier	71.4	B
Subp. 34	Certifying entity or independent certifying organization	34.3	B
Subp. 35	Chelating agent	61.2	B
Subp. 36	Class, inhalation class, or lung class	20.1003	A
Subp. 37	Client's address	35.2.	D
Subp. 38	Collective dose	20.1003	A
Subp. 39	Collimator	34.3	B
Subp. 40	Commencement of construction	30.4,40.4,61.2	D
Subp. 41	Commissioner		
Subp. 42	Committed dose equivalent or $H_{T,50}$	20.1003, 32.2	A
Subp. 43	Committed effective dose equivalent or $H_{E,50}$	20.1003	A
Subp. 44	Constraint or dose constraint	20.1003	C
Subp. 45	Contiguous sites	70.4	D
Subp. 46	Control cable or drive cable	34.3	B
Subp. 47	Control drive mechanism	34.3	B
Subp.48	Control tube	34.3	B
Subp. 49	Controlled area	20.1003	D
Subp. 50.	Critical group	20.1003	B
Subp. 51	Curie or Ci.	20.1005, 30.4	A
Subp. 52	Declared pregnant woman	20.1003	A
Subp. 53	Decommission	20.1003, 30.4	C
Subp. 54	Dedicated check source	35.2	D
Subp. 55	Deep dose equivalent or H_d	20.1003	A
Subp. 56	Demand respirator	20.1003	B

MN Rule Part	Title	10 CFR	Compatibility
Subp. 57	Depleted uranium	40.4, 71.4	A
Subp. 58	Derived air concentration or DAC	20.1003	A
Subp. 59	Derived air concentration-hour or DAC-hour	20.1003	A
Subp. 60	Disposable respirator	20.1003	B
Subp. 61	Distinguishable from background	20.1003	B
Subp. 62	Distribution		
Subp. 63	Distributor		
Subp. 64	Dose or radiation dose	20.1003	D
Subp. 65	Dose equivalent or H _T	20.1003	A
Subp. 66	Dose limits or limits	20.1003	A
Subp. 67	DOT		
Subp. 68	Doubly encapsulated sealed source	36.2	D
Subp. 69	Effective dose equivalent or H _E	20.1003, 30.4	A
Subp. 70	Effective kilogram	40.4	D
Subp. 71	Electron-beam generator		
Subp. 72	Embryo-fetus	20.1003	A
Subp. 73	Energy compensation source or ECS	39.2	B
Subp. 74	Enriched uranium	71.4	B
Subp. 75	Entrance or access point	20.1003	C
Subp. 76	Exclusive use	71.4	B
Subp. 77	Exposure	20.1003	D
Subp. 78	Exposure head or source stop	34.3	B
Subp. 79	Exposure rate		
Subp. 80	External dose	20.1003	D
Subp. 81	Extremity	20.1003	A
Subp. 82	Field station	39.2, 34.2	B
Subp. 83	Filtering facepiece or dust mask	20.1003	B
Subp. 84	Fissile material	71.4	B
Subp. 85	Fit factor	20.1003	B

MN Rule Part	Title	10 CFR	Compatibility
Subp. 86	Fit test	20.1003	B
Subp. 87	Freshwater aquifer	39.2	D
Subp. 88	General license	30.31	C
Subp. 89	Geologic repository		
Subp. 90	Government agency	20.1003, 30.4	D
Subp. 91	Gray or Gy	20.1004	A
Subp. 92	Guide tube or projection sheath	34.3	B
Subp. 93	Hands-on experience	34.3	B
Subp. 94	Hazardous waste	61.2	C
Subp. 95	Helmet	20.1003	B
Subp. 96	High dose-rate remote afterloader	35.2	D
Subp. 97	High radiation area	20.1003	A
Subp. 98	Hood	20.1003	B
Subp. 99	Inadvertent intruder	61.2	C
Subp. 100	Incident		
Subp. 101	Individual	20.1003	A
Subp. 102	Individual monitoring	20.1003	A
Subp. 103	Individual monitoring devices	20.1003	C
Subp. 104	Industrial radiographer or radiographer	34.3	C
Subp. 105	Industrial radiographer certification or radiographer certification	34.3	B
Subp. 106	Industrial radiographer's assistant or radiographer's assistant	34.3	D
Subp. 107	Industrial radiography or radiography	34.3	B
Subp. 108	Injection tool	39.2	D
Subp. 109	Internal dose	20.1003	A
Subp. 110	Intruder barrier	61.2	C
Subp. 111	Irradiation		
Subp. 112	Irradiator	36.2	C
Subp. 113	Irradiator operator	36.2	C
Subp. 114	Irretrievable well logging source	39.2	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 115	Land disposal facility	61.2	B
Subp. 116	Lay-barge radiography	34.3	D
Subp. 117	Lens dose equivalent or eye dose equivalent	20.1003	A
Subp. 118	License	20.1003, 30.4	D
Subp. 119	Licensee	20.1003	D
Subp. 120	Licensed material	20.1003, 39.2	D
Subp. 121	Licensed practitioner of the healing arts	35.2	D
Subp. 121a	Licensing state		
Subp. 122	Logging assistant	39.2	D
Subp. 123	Logging supervisor	39.2	C
Subp. 124	Logging tool	39.2	D
Subp. 125	Loose-fitting facepiece	20.1003	B
Subp. 126	Lost or missing licensed material	20.1003	B
Subp. 127	Lot tolerance percent defective	32.2	B
Subp. 128	Low dose-rate remote afterloader	35.2	D
Subp. 129	Low specific activity material or LSA	71.4	B
Subp. 130	Low specific activity material group I	71.4	B
Subp. 131	Low specific activity material group II	71.4	B
Subp. 132	Low specific activity material group III	71.4	B
Subp. 133	Low toxicity alpha emitters	71.4	B
Subp. 134	Management	35.2	D
Subp. 135	Manual brachytherapy	35.2	D
Subp. 136	Maximum normal operating pressure	71.4	B
Subp. 137	Medical event	35.2	D
Subp. 138	Medical institution	35.2	D
Subp. 139	Medical use	30.4, 35.2	C
Subp. 140	Medium dose-rate remote afterloader	35.2	D
Subp. 141	Member of the public	20.1003	A
Subp. 142	Microcurie or Ci	30.4	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 143	Millicurie or mCi	30.4	D
Subp. 144	Minor	20.1003	A
Subp. 145	Mobile medical service	35.2	D
Subp. 146	Monitoring	20.1003, 61.2	A
Subp. 147	National voluntary laboratory accreditation program or NVLAP		
Subp. 148	Natural thorium	71.4	B
Subp. 149	Natural uranium	71.4	B
Subp. 150	Naturally occurring or accelerator-produced radioactive material or NARM		
Subp. 151	Negative pressure respirator (tight fitting)	20.1003	B
Subp. 152	Neutron generator		
Subp. 153	Non-stochastic effect or deterministic effect	20.1003	A
Subp. 154	Normal form radioactive material	71.4	B
Subp. 154a	NRC	20.1003	D
Subp. 155	Occupational dose	20.1003	A
Subp. 156	Offshore platform radiography	34.3	D
Subp. 157	Offshore waters	150.3	B
Subp. 158	Output	35.2	D
Subp. 159	Package	71.4	B
Subp. 160	Packaging	71.4	B
Subp. 161	Panoramic dry-source-storage irradiator	36.2	D
Subp. 162	Panoramic irradiator	36.2	D
Subp. 163	Panoramic wet-source-storage irradiator	36.2	D
Subp. 164	Patient intervention	35.2	D
Subp. 165	Permanent radiographic installation	34.3	C
Subp. 166	Person	20.1003, 150.3	C
Subp. 167	Personal supervision	39.2	D
Subp. 168	Pharmacist	35.2, 40.4	D
Subp. 169	Planned special exposure	20.1003	D
Subp. 170	Pool irradiator	36.2	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 171	Positive pressure respirator	20.1003	B
Subp. 172	Powered air-purifying respirator	20.1003	B
Subp. 173	Practical examination	34.3	C
Subp. 174	Preceptor	35.2	D
Subp. 175	Prescribed dosage	35.2	C
Subp. 176	Prescribed dose	35.2	C
Subp. 177	Pressure demand respirator	20.1003	B
Subp. 178	Principal activities	30.4, 40.4	D
Subp. 179	Product conveyor system	36.2	D
Subp. 180	Public dose	20.1003	A
Subp. 181	Pulsed dose-rate remote afterloader	35.2	D
Subp. 182	Qualitative fit test	20.1003	B
Subp. 183	Quality factor	20.1004	A
Subp. 184	Quantitative fit test	20.1003	B
Subp. 185	Quarter	20.1003	D
Subp. 186	Rad	20.1004	A
Subp. 187	Radiation	20.1003	A
Subp. 188	Radiation area	20.1003	A
Subp. 189	Radiation detector or detector		
Subp. 190	Radiation hazard		
Subp. 191	Radiation protection		
Subp. 192	Radiation room	36.2	D
Subp. 193	Radiation safety officer or RSO	34.3, 35.2, 36.2	B
Subp. 194	Radioactive marker	39.2	D
Subp. 195	Radioactive material		
Subp. 196	Radioactive waste or waste	61.2	B
Subp. 197	Radiographic exposure device	34.3	B
Subp. 198	Radiographic operations	34.3	C
Subp. 199	Reference man	20.1003	A

MN Rule Part	Title	10 CFR	Compatibility
Subp. 200	Registrant		
Subp. 201	Rem	20.1004	A
Subp. 202	Research and development	30.4, 70.4	D
Subp. 203	Residual radioactivity	20.1003	B
Subp. 204	Respiratory protective device	20.1003	C
Subp. 205	Restricted area	20.1003	A
Subp. 206	Roentgen or R		
Subp. 207	S-tube	34.3	B
Subp. 208	Sanitary sewerage	20.1003	A
Subp. 209	Sealed source	30.4,35.2,36.2	B
Subp. 210	Sealed source and device registry	35.2	D
Subp. 211	Self-contained breathing apparatus	20.1003	B
Subp. 212	Shallow dose equivalent of H _S	20.1003	A
Subp. 213	Shielded position	34.3	C
Subp. 214	SI		
Subp. 215	Sievert or Sv	20.1004	A
Subp. 216	Site area emergency	30.4,40.4, 70.4	A
Subp. 217	Site boundary	20.1003	D
Subp. 218	Source		
Subp. 219	Source assembly	34.3	B
Subp. 220	Source changer	34.3	B
Subp. 221	Source holder	39.2	D
Subp. 222	Source material	20.1003,150.3	A
Subp. 223	Source of radiation		
Subp. 224	Special form radioactive material	71.4	B
Subp. 225	Special nuclear material	20.1003, 30.4	A
Subp. 226	Specific activity	71.4	B
Subp. 227	Stereotactic radiosurgery	35.2	D
Subp. 228	Stochastic effect	20.1003	A

MN Rule Part	Title	10 CFR	Compatibility
Subp. 229	Storage area	34.3	C
Subp. 230	Storage container	34.3	C
Subp. 231	Structured educational program	35.2	D
Subp. 232	Subsurface tracer study	39.2	D
Subp. 233	Supplied-air respirator or airline respirator	20.1003	B
Subp. 234	Surface casing for protecting freshwater aquifers	39.2	D
Subp. 235	Surface contaminated object or SCO	71.4	B
Subp. 236	Survey or radiation safety survey	20.1003	A
Subp. 237	Target		
Subp. 238	Teletherapy	35.2	D
Subp. 239	Temporary job site	34.3, 35.2, 39.2	B
Subp. 240	Therapeutic dosage	35.2	D
Subp. 241	Therapeutic dose	35.2	D
Subp. 242	Tight-fitting facepiece	20.1003	B
Subp. 243	Total effective dose equivalent or TEDE	20.1003	A
Subp. 244	Traceable to a standard		
Subp. 245	Transient shipment	40.4, 70.4	D
Subp. 246	Transport index	71.4	B
Subp. 247	Treatment site	35.2	C
Subp. 248	Tritium neutron generator target source	39.2	B
Subp. 249	Type A quantity	71.4	B
Subp. 250	Type B quantity	71.4	B
Subp. 251	Type of use	35.2	D
Subp. 252	Underwater irradiator	36.2	D
Subp. 253	Underwater radiography	34.3	B
Subp. 254	Unit dosage	35.2	D
Subp. 255	Unrefined and unprocessed ore	40.4	B
Subp. 256	Unrestricted area	20.1003	A
Subp. 257	Uranium sinker bar	39.2	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 258	User seal check or fit check	20.1003	B
Subp. 259	Very high radiation area	20.1003	A
Subp. 260	Week	20.1003	D
Subp. 261	Weighting factor or W_T	20.1003	A
Subp. 262	Well	39.2	D
Subp. 263	Well logging or logging	39.2	D
Subp. 264	Whole body	20.1003	A
Subp. 265	Worker	19.3	C
Subp. 266	Working level	20.1003	A
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4731.0270	Modification and revocation of licenses	30.61, 40.71	D
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4731.0790	License expiration and termination; decommissioning	40.42	DH&S
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4731.0815	Transfer of radioactive material	40.51	C
4731.0820	Reporting requirements	40.60	C
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4731.3035	Exemption; resins containing Scandium-46; sand-consolidation in oil wells	30.16	B
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4731.3045	Exemption; self-luminous products containing Tritium, Krypton-85 or Promethium-147	30.19	B
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4731.3320	Specific license; Resins containing Scandium-46; manufacture or initial transfer	32.17	B
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4731.3365	Specific license; calibration or reference sources, manufacture or initial transfer		
4731.3365, subp. 1	Approval criteria	32.57	B
4731.3365, subp. 2	Labeling requirements	32.58	B
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4731.3390	Specific license; material for in vitro clinical or laboratory testing; manufacture and distribution	32.71	B
4731.3395	Specific license; radioactive drugs for medical use; manufacture, preparation, or transfer	32.72	B
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4731.3405	Prototype tests for luminous safety devices for aircraft	32.101	B
4731.3410	Prototype tests; calibration or reference sources containing Americium-241, Plutonium, or Radium-226	32.102	B
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4731.3500,	Specific domestic licenses of broad scope for radioactive material		
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4731.3530	Type A specific license of broad scope	33.13	D
4731.3540	Type B specific license of broad scope	33.14	D
4731.3550	Type C specific license of broad scope	33.15	D

MN Rule Part	Title	10 CFR	Compatibility
4731.3560	Application for other specific licenses	33.16	D
4731.3570	Specific licenses of broad scope; conditions	33.17	D
4731.3580	Limits for broad scope licenses	33.100	D
	Uses of Radioactive Material in Industrial Radiography		
4731.4000	Licenses for industrial radiography and radiation safety requirements for industrial radiographic operations	34.1	D
4731.4010	Specific license; application	34.11	D
4731.4020	Specific license; industrial radiography	34.13	C
4731.4030	Performance requirements; industrial radiography equipment	34.20	B
4731.4030, subp. 1	ANSI standard		
4731.4030, subp. 2	Additional requirements		
4731.4030, subp. 3	Removable sources and source changers; requirements		
4731.4030, subp. 4	Exception		
4731.4040	Limits on external radiation levels	34.21	B
4731.4050	Locking of radiographic exposure devices, storage containers and source changers	34.23	B
4731.4060	Radiation survey instruments	34.25	C
4731.4060, subp. 1	Required instruments		
4731.4060, subp. 2	Calibration		
4731.4060, subp. 3	Record keeping		
4731.4070	Leak testing, replacement, and other modifications of sealed sources	34.27	C
4731.4080	Quarterly inventory	34.29	C
4731.4090	Equipment inspection and maintenance	34.31	C
4731.4100	Permanent radiographic installations; entrance controls	34.33	DH&S
4731.4110	Labeling; packaging; security	34.35	B
4731.4120	Conducting industrial radiographic operations	34.41	B
4731.4130	Radiation safety officer for industrial radiography	34.42	C
4731.4140	Radiographer training	34.43	B
4731.4150	Operating and emergency procedures	34.45, 34.81	C

MN Rule Part	Title	10 CFR	Compatibility
4731.4160	Supervision of radiographers' assistants	34.46	B
4731.4170	Personnel monitoring	34.47	C
4731.4180	Radiation surveys	34.49	C
4731.4190	Surveillance	34.51	C
4731.4200	Posting	34.53	C
4731.4210	Records; specific license for industrial radiography	34.61	D
4731.4220	Records; receipt and transfer of sealed sources	34.63	C
4731.4240	Records; leak testing	34.67	C
4731.4250	Records; quarterly inventory	34.69	C
4731.4260	Utilization logs	34.71	B
4731.4270	Records; inspection and maintenance	34.73	C
4731.4290	Records of training and certification	34.79	C
4731.4310	Records; personnel monitoring	34.83	C
4731.4330	Location of documents and records	34.89	C
4731.4350	Notifications	34.101	C
4731.4360	Radiographer certification	Appendix A	B
	Medical Use of Radioactive Material		
4731.4400	Applicability for the use of radioactive materials in the healing arts	35.1	D
4731.4401	Protection of human research subjects	35.6	C
4731.4402	Implementation	35.10	D
4731.4403	Specific license; medical use of radioactive materials	35.11	C
4731.4403, subp. 1	Specific license required	35.11	C
4731.4403, subp. 2	Application for license, amendment or renewal	35.12	D
4731.4403, subp. 3	License amendments	35.13	D
4731.4403, subp. 4	Notifications of changes	35.14	D
4731.4403, subp. 5	Exemptions; Type A specific license of broad scope	35.15	D
4731.4403, subp. 6	License issuance	35.18	D
4731.4403, subp. 7	Specific exemptions	35.19	D

MN Rule Part	Title	10 CFR	Compatibility
4731.4403, subp. 8	Other medical uses of radioactive material or radiation from radioactive material	35.1000	D
4731.4405	Radiation protection program		
4731.4405, subp. 1	Authority and responsibilities for the radiation protection program	35.24	DH&S
4731.4405, subp. 2	Radiation protection program changes	35.26	D
4731.4407	Supervised individuals	35.27	DH&S
4731.4408	Written directives	35.40	DH&S
4731.4409	Procedures for administrations requiring a written directive	35.41	DH&S
4731.4410	Suppliers for sealed sources or devices for medical use	35.49	C
4731.4411	Radiation safety officer training	35.50	B
4731.4412	Authorized medical physicist training	35.51	B
4731.4413	Authorized nuclear pharmacist training	35.55	B
4731.4414	Training; experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist	35.57	B
4731.4415	Recentness of training	35.59	B
4731.4420	Measuring activity of unsealed radioactive material; instruments required	35.60	DH&S
4731.4421	Calibration of survey instruments	35.61	DH&S
4731.4422	Determination of dosages; unsealed radioactive material	35.63	DH&S
4731.4423	Authorization for calibration, transmission and reference use	35.65	D
4731.4424	Possession of sealed source and brachytherapy sources, requirements	35.67	DH&S
4731.4425	Labeling of vials and syringes	35.69	DH&S
4731.4426	Surveys of ambient radiation exposure rate	35.70	DH&S
4731.4427	Release of individuals containing unsealed radioactive material or implants	35.75	C
4731.4428	Mobile medical service	35.80	DH&S
4731.4429	Decay-in-storage	35.92	DH&S
4731.4432	Unsealed radioactive material; uptake, dilution, and excretion studies	35.100	DH&S
4731.4433	Uptake, dilution, and excretion studies; training	35.190	B
4731.4434	Unsealed radioactive material; imaging and localization studies	35.200	DH&S
4731.4435	Permissible molybdenum-99 concentrations	35.204	DH&S
4731.4436	Imaging and localization studies; training	35.290	B

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4731.4440	Unsealed radioactive material; written directive required	35.300	DH&S
4731.4441	Safety instructions	35.310	DH&S
4731.4442	Safety precautions	35.315	DH&S
4731.4443	Unsealed radioactive material; written directive required; training	35.390	B
4731.4444	Administration of sodium iodide; quantities less than or equal to 33 millicuries (1.22 GBq); training	35.392	B
4731.4445	Administration of sodium iodide; quantities greater than 33 millicuries (1.22 GBq); training	35.394	B
4731.4450	Use of sources for manual brachytherapy	35.400	C
4731.4451	Surveys after source implant and removal	35.404	DH&S
4731.4452	Brachytherapy sources accountability	35.406	DH&S
4731.4453	Brachytherapy: Safety instructions	35.410	DH&S
4731.4454	Brachytherapy: Safety precautions	35.415	DH&S
4731.4455	Brachytherapy; calibration measurements	35.432	DH&S
4731.4456	Decay of strontium-90 sources for ophthalmic treatments	35.433	DH&S
4731.4457	Therapy-related computer systems	35.457	DH&S
4731.4458	Manual brachytherapy training	35.490	B
4731.4459	Ophthalmic use of Strontium-90; training	35.491	B
4731.4460	Use of sealed sources for diagnosis	35.500	C
4731.4461	Sealed sources for Diagnosis: Training	35.590	B
4731.4463	Use of a sealed source; remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit	35.600	C
4731.4464	Treatment with remote afterloader unit; surveys	35.604	DH&S
4731.4465	Installation, maintenance, adjustment and repair requirements	35.605	DH&S
4731.4466	Remote afterloader units, teletherapy units, and gamma stereotactic units; safety procedures and instructions	35.610	DH&S
4731.4467	Remote afterloader units, teletherapy units, and gamma stereotactic units; Safety precautions	35.615	DH&S
4731.4468	Dosimetry equipment	35.630	DH&S

MN Rule Part	Title	10 CFR	Compatibility
4731.4469	Teletherapy units; full calibration	35.632	DH&S
4731.4470	Remote afterloader units; full calibration	35.633	DH&S
4731.4471	Gamma stereotactic radiosurgery units; full calibration	35.635	DH&S
4731.4472	Teletherapy units; periodic spot checks	35.642	DH&S
4731.4473	Remote afterloader units; periodic spot checks	35.643	DH&S
4731.4474	Gamma stereotactic radiosurgery units; periodic spot checks	35.645	DH&S
4731.4475	Mobile remote afterloader units; additional requirements	35.647	DH&S
4731.4476	Radiation surveys	35.652	DH&S
4731.4477	Teletherapy and gamma stereotactic radiosurgery units; five-year inspection	35.655	DH&S
4731.4478	Teletherapy and gamma stereotactic computer systems	35.657	DH&S
4731.4479	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.690	DH&S
4731.4500	Radiation protection program records		
4731.4500, subp. 1	Records of authority and responsibilities for radiation protection programs	35.2024	D
4731.4500, subp. 2	Records of radiation protection program changes	35.2026	D
471.4500	Written directive records		
4731.4501, subp. 1	Records of written directives	35.2040	D
4731.4501, subp. 2	Records for procedures for administrations requiring a written directive	35.2041	D
4731.4502	Instrument calibration records		
4731.4502, subp. 1	Activity measurement instruments	35.2060	D
4731.4502, subp. 2	Survey instruments	35.2061	D
4731.4503	Dosage records	35.2063	D
4731.4504	Leak test and inventory records	35.2067	D
4731.4505	Survey records; ambient radiation exposure	35.2070	D
4731.4506	Release records; individuals containing radioactive material or implants	35.2075	D
4731.4507	Mobile medical service records	35.2080	D
4731.4508	Decay-in-storage records	35.2092	D
4731.4509	Molybdenum-99 records	35.2204	D
4731.4510	Safety Instruction records	35.2310	D

MN Rule Part	Title	10 CFR	Compatibility
4731.4511	Survey records; source implant and removal	35.2404	D
4731.4512	Brachytherapy source accountability records	35.2406	D
4731.4513	Brachytherapy source calibration records	35.2432	D
4731.4514	Strontium-90 decay records	35.2433	D
4731.4515	Installation, maintenance, adjustment, and repair records	35.2605	D
4731.4516	Safety procedures records	35.2610	D
4731.4517	Dosimetry equipment Records	35.2630	D
4731.4518	Calibration records; teletherapy, remote afterloader, and gamma stereotactic radiosurgery units	35.2632	D
4731.4519	Spot check records; teletherapy units	35.2642	D
4731.4520	Spot check records; remote afterloader units	35.2643	D
4731.4521	Spot check records; gamma stereotactic radiosurgery units	35.2645	D
4731.4522	Operability records; mobile remote afterloader units	35.2647	D
4731.4523	Survey records; therapeutic treatment units	35.2652	D
4731.4524	Inspection records; teletherapy and gamma stereotactic radiosurgery units	35.2655	D
4731.4525	Medical event; report and notification	35.3045	D
4731.4526	Dose to an embryo/fetus or child; report and notification	35.3047	C
4731.4527	Report of a leaking source	35.3067	C
	Irradiators		
4731.6000	Purpose and scope	36.1	C
4731.6010	Specific license; application	36.11	D
4731.6020	Specific license; approval	36.13	DH&S
4731.6030	Start of construction	36.15	D
4731.6040	Application for exemptions	36.17	D
4731.6050	Performance criteria; sealed sources	36.21	B
4731.6060	Access control	36.23	DH&S
4731.6070	Shielding	36.25	DH&S
4731.6080	Fire protection	36.27	DH&S

MN Rule Part	Title	10 CFR	Compatibility
4731.6090	Radiation monitors	36.29	DH&S
4731.6100	Control of source movement; panoramic irradiators	36.31	DH&S
4731.6110	Irradiator pools	36.33	DH&S
4731.6120	Source rack protection	36.35	D
4731.6130	Power failures	36.37	DH&S
4731.6140	Design requirements	36.39	DH&S
4731.6150	Construction monitoring and acceptance testing	36.41	DH&S
4731.6160	Training	36.51	DH&S
4731.6170	Operating and emergency procedures	36.53	DH&S
4731.6180	Personnel monitoring	36.55	D
4731.6190	Radiation surveys	36.57	DH&S
4731.6200	Detection of leaking sources	36.59	DH&S
4731.6210	Inspection and maintenance	36.61	DH&S
4731.6220	Pool water purity	36.63	DH&S
4731.6230	Attendance during operation	36.65	DH&S
4731.6240	Entering and leaving the radiation room	36.67	DH&S
4731.6250	Irradiation of explosive or flammable materials	36.69	DH&S
4731.6260	Records and retention periods	36.81	D
4731.6270	Reports	36.83	C
	Well Logging		
4731.7000	Licenses and radiation safety requirements for well logging	39.1	D
4731.7010	Application	39.11	D
4731.7020	Specific license; well logging	39.13	DH&S
4731.7030	Agreement with well owner or operator	39.15	C
4731.7040	Request for written statements	39.17	D
4731.7050	Labels, security and transportation precautions	39.31	C
4731.7060	Radiation detection instruments	39.33	C
4731.7070	Leak testing; sealed sources	39.35	C

MN Rule Part	Title	10 CFR	Compatibility
4731.7080	Physical inventory	39.37	DH&S
4731.7090	Records of material use	39.39	C
4731.7100	Design and performance criteria for sources	39.41	B
4731.7110	Inspection and maintenance; opening source or source holder	39.43	C
4731.7120	Subsurface tracer studies	39.45	C
4731.7130	Radioactive markers	39.47	D
4731.7140	Uranium sinker bars	39.49	C
4731.7150	Use without a surface casing	39.51	D
4731.7160	Energy compensation source	39.53	C
4731.7170	Tritium neutron generator target source	39.55	C
4731.7200	Training	39.61	B
4731.7200, subp. 1	Logging supervisor		
4731.7200, subp. 2	Logging assistant		
4731.7200, subp. 3	Safety reviews		
4731.7200, subp. 4	Records		
4731.7200, subp. 5	Training subjects		
4731.7210	Operating and emergency procedures	39.63	C
4731.7220	Personnel monitoring	39.65	C
4731.7230	Radiation surveys	39.67	C
4731.7240	Radioactive contamination control	39.69	C
4731.7250	Security	39.71	C
4731.7260	Documents and records; field stations	39.73	C
4731.7270	Documents and records; temporary jobsites	39.75	C
4731.7280	Notification of incidents and lost sources; abandonment procedures	39.77	C

4.2.3

Orderly Pattern of Regulation or Health and Safety Significance

4.2.3

ORDERLY PATTERN OF REGULATION OR HEALTH AND SAFETY SIGNIFICANCE

Minnesota's regulations for the Radioactive Materials Program can be found in the *Minnesota Rules Chapter 4731*. To provide a reasonable harmony of Minnesota Rules Chapter 4731 with NRC rules, all compatibility codes A, B, C and D/H&S rules were included in Chapter 4731. A list of the ways in which Minnesota's rules are compatible can be found in the *Compatibility Index* to the rules.

MN Rule Part	Title	10 CFR	Compatibility
	Definitions		
4731.0100	Definitions		
Subpart 1	Scope		
Subp. 2	A ₁	71.4	A
Subp. 3	A ₂	71.4	A
Subp. 4	Absorbed dose	20.1003	A
Subp. 5	Active maintenance	61.2	DH&S
Subp. 6	Activity	20.1003	A
Subp. 7	Acute		
Subp. 8	Address of use	35.2	D
Subp. 9	Adult	20.1003	A
Subp. 10	Agreement State	30.4, 40.4, 150.3	B
Subp. 11	Air-purifying respirator	20.1003	A
Subp. 12	Airborne radioactive material	20.1003	A
Subp. 13	Airborne radioactivity area	20.1003	A
Subp. 14	Alert	30.3, 40.4	A
Subp. 15	Annual limit on intake or ALI	20.1003	A
Subp. 16	Annual refresher safety training or safety review	34.3, 39.2	C
Subp. 17	Area of use	35.2	D
Subp. 18	As low as reasonably achievable or ALARA	20.1003, 34.3	A
Subp. 19	Assigned protection factor or APF	20.1003	B
Subp. 20	Associated equipment	34.3	B
Subp. 21	Atmosphere-supplying respirator	20.1003	B
Subp. 22	Authorized medical physicist	35.2	B
Subp. 23	Authorized nuclear pharmacist	35.2	B
Subp. 24	Authorized user	35.2	B
Subp. 25	Background radiation	20.1003	A
Subp. 26	Becquerel or Bq.	20.1005, 34.3	A
Subp. 27	Bioassay or radiobioassay	20.1003	A

MN Rule Part	Title	10 CFR	Compatibility
Subp. 28	Boring		
Subp. 29	Brachytherapy	35.2	D
Subp. 30	Brachytherapy source	35.2	D
Subp. 31	Broad scope license	33.11	D
Subp. 32	By-product material	30.4, 40.4, 150.3	A
Subp. 33	Carrier	71.4	B
Subp. 34	Certifying entity or independent certifying organization	34.3	B
Subp. 35	Chelating agent	61.2	B
Subp. 36	Class, inhalation class, or lung class	20.1003	A
Subp. 37	Client's address	35.2	D
Subp. 38	Collective dose	20.1003	A
Subp. 39	Collimator	34.3	B
Subp. 40	Commencement of construction	30.4,40.4,61.2	D
Subp. 41	Commissioner		
Subp. 42	Committed dose equivalent or $H_{T,50}$	20.1003, 32.2	A
Subp. 43	Committed effective dose equivalent or $H_{E,50}$	20.1003	A
Subp. 44	Constraint or dose constraint	20.1003	C
Subp. 45	Contiguous sites	70.4	D
Subp. 46	Control cable or drive cable	34.3	B
Subp. 47	Control drive mechanism	34.3	B
Subp.48	Control tube	34.3	B
Subp. 49	Controlled area	20.1003	D
Subp. 50.	Critical group	20.1003	B
Subp. 51	Curie or Ci.	20.1005, 30.4	A
Subp. 52	Declared pregnant woman	20.1003	A
Subp. 53	Decommission	20.1003, 30.4	C
Subp. 54	Dedicated check source	35.2	D
Subp. 55	Deep dose equivalent or H_d	20.1003	A
Subp. 56	Demand respirator	20.1003	B

MN Rule Part	Title	10 CFR	Compatibility
Subp. 57	Depleted uranium	40.4, 71.4	A
Subp. 58	Derived air concentration or DAC	20.1003	A
Subp. 59	Derived air concentration-hour or DAC-hour	20.1003	A
Subp. 60	Disposable respirator	20.1003	B
Subp. 61	Distinguishable from background	20.1003	B
Subp. 62	Distribution		
Subp. 63	Distributor		
Subp. 64	Dose or radiation dose	20.1003	D
Subp. 65	Dose equivalent or H _T	201003	A
Subp. 66	Dose limits or limits	20.1003	A
Subp. 67	DOT		
Subp. 68	Doubly encapsulated sealed source	36.2	D
Subp. 69	Effective dose equivalent or H _E	20.1003, 30.4	A
Subp. 70	Effective kilogram	40.4	D
Subp. 71	Electron-beam generator		
Subp. 72	Embryo-fetus	20.1003	A
Subp. 73	Energy compensation source or ECS	39.2	B
Subp. 74	Enriched uranium	71.4	B
Subp. 75	Entrance or access point	20.1003	C
Subp. 76	Exclusive use	71.4	B
Subp. 77	Exposure	20.1003	D
Subp. 78	Exposure head or source stop	34.3	B
Subp. 79	Exposure rate		
Subp. 80	External dose	20.1003	D
Subp. 81	Extremity	20.1003	A
Subp. 82	Field station	39.2, 34.2	B
Subp. 83	Filtering facepiece or dust mask	20.1003	B
Subp. 84	Fissile material	71.4	B
Subp. 85	Fit factor	20.1003	B

MN Rule Part	Title	10 CFR	Compatibility
Subp. 86	Fit test	20.1003	B
Subp. 87	Freshwater aquifer	39.2	D
Subp. 88	General license	30.31	C
Subp. 89	Geologic repository		
Subp. 90	Government agency	20.1003, 30.4	D
Subp. 91	Gray or Gy	20.1004	A
Subp. 92	Guide tube or projection sheath	34.3	B
Subp. 93	Hands-on experience	34.3	B
Subp. 94	Hazardous waste	61.2	C
Subp. 95	Helmet	20.1003	B
Subp. 96	High dose-rate remote afterloader	35.2	D
Subp. 97	High radiation area	20.1003	A
Subp. 98	Hood	20.1003	B
Subp. 99	Inadvertent intruder	61.2	C
Subp. 100	Incident		
Subp. 101	Individual	20.1003	A
Subp. 102	Individual monitoring	20.1003	A
Subp. 103	Individual monitoring devices	20.1003	C
Subp. 104	Industrial radiographer or radiographer	34.3	C
Subp. 105	Industrial radiographer certification or radiographer certification	34.3	B
Subp. 106	Industrial radiographer's assistant or radiographer's assistant	34.3	D
Subp. 107	Industrial radiography or radiography	34.3	B
Subp. 108	Injection tool	39.2	D
Subp. 109	Internal dose	20.1003	A
Subp. 110	Intruder barrier	61.2	C
Subp. 111	Irradiation		
Subp. 112	Irradiator	36.2	C
Subp. 113	Irradiator operator	36.2	C
Subp. 114	Irretrievable well logging source	39.2	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 115	Land disposal facility	61.2	B
Subp. 116	Lay-barge radiography	34.3	D
Subp. 117	Lens dose equivalent or eye dose equivalent	20.1003	A
Subp. 118	License	20.1003, 30.4	D
Subp. 119	Licensee	20.1003	D
Subp. 120	Licensed material	20.1003, 39.2	D
Subp. 121	Licensed practitioner of the healing arts	35.2	D
Subp. 121a	Licensing state		
Subp. 122	Logging assistant	39.2	D
Subp. 123	Logging supervisor	39.2	C
Subp. 124	Logging tool	39.2	D
Subp. 125	Loose-fitting facepiece	20.1003	B
Subp. 126	Lost or missing licensed material	20.1003	B
Subp. 127	Lot tolerance percent defective	32.2	B
Subp. 128	Low dose-rate remote afterloader	35.2	D
Subp. 129	Low specific activity material or LSA	71.4	B
Subp. 130	Low specific activity material group I	71.4	B
Subp. 131	Low specific activity material group II	71.4	B
Subp. 132	Low specific activity material group III	71.4	B
Subp. 133	Low toxicity alpha emitters	71.4	B
Subp. 134	Management	35.2	D
Subp. 135	Manual brachytherapy	35.2	D
Subp. 136	Maximum normal operating pressure	71.4	B
Subp. 137	Medical event	35.2	D
Subp. 138	Medical institution	35.2	D
Subp. 139	Medical use	30.4, 35.2	C
Subp. 140	Medium dose-rate remote afterloader	35.2	D
Subp. 141	Member of the public	20.1003	A
Subp. 142	Microcurie or Ci	30.4	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 143	Millicurie or mCi	30.4	D
Subp. 144	Minor	20.1003	A
Subp. 145	Mobile medical service	35.2	D
Subp. 146	Monitoring	20.1003, 61.2	A
Subp. 147	National voluntary laboratory accreditation program or NVLAP		
Subp. 148	Natural thorium	71.4	B
Subp. 149	Natural uranium	71.4	B
Subp. 150	Naturally occurring or accelerator-produced radioactive material or NARM		
Subp. 151	Negative pressure respirator (tight fitting)	20.1003	B
Subp. 152	Neutron generator		
Subp. 153	Non-stochastic effect or deterministic effect	20.1003	A
Subp. 154	Normal form radioactive material	71.4	B
Subp. 154a	NRC	20.1003	D
Subp. 155	Occupational dose	20.1003	A
Subp. 156	Offshore platform radiography	34.3	D
Subp. 157	Offshore waters	150.3	B
Subp. 158	Output	35.2	D
Subp. 159	Package	71.4	B
Subp. 160	Packaging	71.4	B
Subp. 161	Panoramic dry-source-storage irradiator	36.2	D
Subp. 162	Panoramic irradiator	36.2	D
Subp. 163	Panoramic wet-source-storage irradiator	36.2	D
Subp. 164	Patient intervention	35.2	D
Subp. 165	Permanent radiographic installation	34.3	C
Subp. 166	Person	20.1003, 150.3	C
Subp. 167	Personal supervision	39.2	D
Subp. 168	Pharmacist	35.2, 40.4	D
Subp. 169	Planned special exposure	20.1003	D
Subp. 170	Pool irradiator	36.2	D

MN Rule Part	Title	10 CFR	Compatibility
Subp. 171	Positive pressure respirator	20.1003	B
Subp. 172	Powered air-purifying respirator	20.1003	B
Subp. 173	Practical examination	34.3	C
Subp. 174	Preceptor	35.2	D
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4731.3075	Terms and conditions of licenses	30.34	C
4731.3080	Financial assurance and recordkeeping for decommissioning	30.35	DH&S
4731.3080, subp. 1	Decommissioning funding plan required		
4731.3080, subp. 2	Plan or financial assurance required		
4731.3080, subp. 3	Date-specific requirements		
4731.3080, subp. 4	Financial assurance; amounts (table)		
4731.3080, subp. 5	Funding plan requirements		
4731.3080, subp. 6	Financial assurance requirements		
4731.3080, subp. 7	Record keeping		
4731.3085	License expiration and termination; decommissioning	30.36	DH&S
4731.3090	Renewal and amendment of licenses		
4731.3105	Transfer of radioactive material	30.41	C
4731.3110	Reporting requirements	30.50	C
4731.3110, subp. 1	Immediate notification required		
4731.3110, subp. 2	24- hour notification required		
4731.3110, subp. 3	Preparation and submission of reports		
4731.3115	Records	30.51	C
4731.3120	Inspections and tests	30.52	D
4731.3120, subp. 1	Material and premises inspection		
4731.3120, subp. 2	Record inspections		
4731.3120, subp. 3	Testing	30.53	D
4731.3130	Modification and revocation of licenses	30.61	D
4731.3135	Withholding or recall of radioactive material	30.62	D
4731.3140	Exempt concentrations, schedule A	30.70	B
4731.3145	Exempt quantities, schedule B	30.71	B
4731.3150	Radioactive materials; Emergency plan quantities	30.72	DH&S

MN Rule Part	Title	10 CFR	Compatibility
4731.3155	Assuring decommissioning funds; parent company guarantees	Appendix A	D
4731.3160	Quantities of licensed material requiring labeling for decommissioning	Appendix B	B
4731.3165	Assuring decommissioning funds; self-guarantees; bond rating	Appendix C	D
4731.3170	Assuring decommissioning funds; self-guarantee; no outstanding rated bonds	Appendix D	D
4731.3175	Assuring decommissioning funds; nonprofit entities; colleges and hospitals	Appendix E	D
	General Domestic Licenses for Radioactive Material		
4731.3200	General domestic licenses for radioactive material	31.1; 31.2	D
4731.3210	General license; static elimination and ion-generating devices	31.3	B
4731.3215	General license; detecting, measuring, gauging, controlling, and other devices	31.5	D
4731.3220	General license; installation of generally licensed devices	31.6	C
4731.3225	General license; luminous safety devices for aircraft	31.7	B
4731.3230	General license; calibration or reference sources	31.8	D
4731.3235	General license; owning radioactive material	31.9	C
4731.3240	General license; strontium 90 in ice detection devices	31.10	B
4731.3245	General license; in vitro clinical or laboratory testing use	31.11	D
	Specific Domestic Licensing of Radioactive Material		
4731.3300	Specific licenses to manufacture or transfer certain items containing radioactive material	32.1	D
4731.3305	Specific license; introduction of radioactive material in exempt concentrations; transfer of ownership or possession	32.11, 32.12	B & C
4731.3315	Prohibition of introduction	32.13	C
4731.3320	Specific license; Resins containing Scandium-46; manufacture or initial transfer	32.17	B
4731.3325	Organ doses	32.24	B
4731.3330	Specific licenses; certain devices containing radioactive materials; manufacture or initial transfer	32.51	B
4731.3345	Specific license; luminous safety devices; manufacture, assemble, repair or initially transfer	32.53	B

MN Rule Part	Title	10 CFR	Compatibility
4731.3345, subp. 1	Approval criteria		
4731.3345, subp. 2	Labeling requirements	32.54	B
4731.3345, subp. 3	Alternative labeling		
4731.3345, subp. 4	Quality assurance; prohibition of transfer	32.55	B
4731.3345, subp. 5	Transfer reports	32.56	B
4731.3365	Specific license; calibration or reference sources, manufacture or initial transfer		
4731.3365, subp. 1	Approval criteria	32.57	B
4731.3365, subp. 2	Labeling requirements	32.58	B
4731.3365, subp. 3	Leak testing	32.59	B
4731.3380	Specific license; Ice detection devices; manufacture or initial transfer	32.61. 32.62	B
4731.3390	Specific license; material for in vitro clinical or laboratory testing; manufacture and distribution	32.71	B
4731.3395	Specific license; radioactive drugs for medical use; manufacture, preparation, or transfer	32.72	B
4731.3400	Specific license; sources or devices for medical use; manufacture and distribution	32.74	B
4731.3405	Prototype tests for luminous safety devices for aircraft	32.101	B
4731.3410	Prototype tests; calibration or reference sources containing Americium-241, Plutonium, or Radium-226	32.102	B
4731.3415	Prototype tests; ice detection devices containing Strontium-90	32.103	B
4731.3420	Acceptance sampling procedures	32.110	B
	Specific Domestic License of Broad scope for Radioactive Materials		
4731.3500,	Specific domestic licenses of broad scope for radioactive material		
4731.3500, subp. 1	Applicability	33.1	D
4731.3500, subp. 2	Types of specific licenses of broad scope	33.11	D
4731.3520	Specific license of broad scope; application	33.12	D
4731.3530	Type A specific license of broad scope	33.13	D
4731.3540	Type B specific license of broad scope	33.14	D
4731.3550	Type C specific license of broad scope	33.15	D

MN Rule Part	Title	10 CFR	Compatibility
4731.3560	Application for other specific licenses	33.16	D
4731.3570	Specific licenses of broad scope; conditions	33.17	D
4731.3580	Limits for broad scope licenses	33.100	D
	Uses of Radioactive Material in Industrial Radiography		
4731.4000	Licenses for industrial radiography and radiation safety requirements for industrial radiographic operations	34.1	D
4731.4010	Specific license; application	34.11	D
4731.4020	Specific license; industrial radiography	34.13	C
4731.4030	Performance requirements; industrial radiography equipment	34.20	B
4731.4030, subp. 1	ANSI standard		
4731.4030, subp. 2	Additional requirements		
4731.4030, subp. 3	Removable sources and source changers; requirements		
4731.4030, subp. 4	Exception		
4731.4040	Limits on external radiation levels	34.21	B
4731.4050	Locking of radiographic exposure devices, storage containers and source changers	34.23	B
4731.4060	Radiation survey instruments	34.25	C
4731.4060, subp. 1	Required instruments		
4731.4060, subp. 2	Calibration		
4731.4060, subp. 3	Record keeping		
4731.4070	Leak testing, replacement, and other modifications of sealed sources	34.27	C
4731.4080	Quarterly inventory	34.29	C
4731.4090	Equipment inspection and maintenance	34.31	C
4731.4100	Permanent radiographic installations; entrance controls	34.33	DH&S
4731.4110	Labeling; packaging; security	34.35	B
4731.4120	Conducting industrial radiographic operations	34.41	B
4731.4130	Radiation safety officer for industrial radiography	34.42	C
4731.4140	Radiographer training	34.43	B
4731.4150	Operating and emergency procedures	34.45, 34.81	C

MN Rule Part	Title	10 CFR	Compatibility
4731.4160	Supervision of radiographers' assistants	34.46	B
4731.4170	Personnel monitoring	34.47	C
4731.4180	Radiation surveys	34.49	C
4731.4190	Surveillance	34.51	C
4731.4200	Posting	34.53	C
4731.4210	Records; specific license for industrial radiography	34.61	D
4731.4220	Records; receipt and transfer of sealed sources	34.63	C
4731.4240	Records; leak testing	34.67	C
4731.4250	Records; quarterly inventory	34.69	C
4731.4260	Utilization logs	34.71	B
4731.4270	Records; inspection and maintenance	34.73	C
4731.4290	Records of training and certification	34.79	C
4731.4310	Records; personnel monitoring	34.83	C
4731.4330	Location of documents and records	34.89	C
4731.4350	Notifications	34.101	C
4731.4360	Radiographer certification	Appendix A	B
	Medical Use of Radioactive Material		
4731.4400	Applicability for the use of radioactive materials in the healing arts	35.1	D
4731.4401	Protection of human research subjects	35.6	C
4731.4402	Implementation	35.10	D
4731.4403	Specific license; medical use of radioactive materials	35.11	C
4731.4403, subp. 1	Specific license required	35.11	C
4731.4403, subp. 2	Application for license, amendment or renewal	35.12	D
4731.4403, subp. 3	License amendments	35.13	D
4731.4403, subp. 4	Notifications of changes	35.14	D
4731.4403, subp. 5	Exemptions; Type A specific license of broad scope	35.15	D
4731.4403, subp. 6	License issuance	35.18	D
4731.4403, subp. 7	Specific exemptions	35.19	D

MN Rule Part	Title	10 CFR	Compatibility
4731.4403, subp. 8	Other medical uses of radioactive material or radiation from radioactive material	35.1000	D
4731.4405	Radiation protection program		
4731.4405, subp. 1	Authority and responsibilities for the radiation protection program	35.24	DH&S
4731.4405, subp. 2	Radiation protection program changes	35.26	D
4731.4407	Supervised individuals	35.27	DH&S
4731.4408	Written directives	35.40	DH&S
4731.4409	Procedures for administrations requiring a written directive	35.41	DH&S
4731.4410	Suppliers for sealed sources or devices for medical use	35.49	C
4731.4411	Radiation safety officer training	35.50	B
4731.4412	Authorized medical physicist training	35.51	B
4731.4413	Authorized nuclear pharmacist training	35.55	B
4731.4414	Training; experienced radiation safety officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist	35.57	B
4731.4415	Recentness of training	35.59	B
4731.4420	Measuring activity of unsealed radioactive material; instruments required	35.60	DH&S
4731.4421	Calibration of survey instruments	35.61	DH&S
4731.4422	Determination of dosages; unsealed radioactive material	35.63	DH&S
4731.4423	Authorization for calibration, transmission and reference use	35.65	D
4731.4424	Possession of sealed source and brachytherapy sources, requirements	35.67	DH&S
4731.4425	Labeling of vials and syringes	35.69	DH&S
4731.4426	Surveys of ambient radiation exposure rate	35.70	DH&S
4731.4427	Release of individuals containing unsealed radioactive material or implants	35.75	C
4731.4428	Mobile medical service	35.80	DH&S
4731.4429	Decay-in-storage	35.92	DH&S
4731.4432	Unsealed radioactive material; uptake, dilution, and excretion studies	35.100	DH&S
4731.4433	Uptake, dilution, and excretion studies; training	35.190	B
4731.4434	Unsealed radioactive material; imaging and localization studies	35.200	DH&S
4731.4435	Permissible molybdenum-99 concentrations	35.204	DH&S
4731.4436	Imaging and localization studies; training	35.290	B

MN Rule Part	Title	10 CFR	Compatibility
4731.4440	Unsealed radioactive material; written directive required	35.300	DH&S
4731.4441	Safety instructions	35.310	DH&S
4731.4442	Safety precautions	35.315	DH&S
4731.4443	Unsealed radioactive material; written directive required; training	35.390	B
4731.4444	Administration of sodium iodide; quantities less than or equal to 33 millicuries (1.22 GBq); training	35.392	B
4731.4445	Administration of sodium iodide; quantities greater than 33 millicuries (1.22 GBq); training	35.394	B
4731.4450	Use of sources for manual brachytherapy	35.400	C
4731.4451	Surveys after source implant and removal	35.404	DH&S
4731.4452	Brachytherapy sources accountability	35.406	DH&S
4731.4453	Brachytherapy: Safety instructions	35.410	DH&S
4731.4454	Brachytherapy: Safety precautions	35.415	DH&S
4731.4455	Brachytherapy; calibration measurements	35.432	DH&S
4731.4456	Decay of strontium-90 sources for ophthalmic treatments	35.433	DH&S
4731.4457	Therapy-related computer systems	35.457	DH&S
4731.4458	Manual brachytherapy training	35.490	B
4731.4459	Ophthalmic use of Strontium-90; training	35.491	B
4731.4460	Use of sealed sources for diagnosis	35.500	C
4731.4461	Sealed sources for Diagnosis: Training	35.590	B
4731.4463	Use of a sealed source; remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit	35.600	C
4731.4464	Treatment with remote afterloader unit; surveys	35.604	DH&S
4731.4465	Installation, maintenance, adjustment and repair requirements	35.605	DH&S
4731.4466	Remote afterloader units, teletherapy units, and gamma stereotactic units; safety procedures and instructions	35.610	DH&S
4731.4467	Remote afterloader units, teletherapy units, and gamma stereotactic units; Safety precautions	35.615	DH&S
4731.4468	Dosimetry equipment	35.630	DH&S

MN Rule Part	Title	10 CFR	Compatibility
4731.4469	Teletherapy units; full calibration	35.632	DH&S
4731.4470	Remote afterloader units; full calibration	35.633	DH&S
4731.4471	Gamma stereotactic radiosurgery units; full calibration	35.635	DH&S
4731.4472	Teletherapy units; periodic spot checks	35.642	DH&S
4731.4473	Remote afterloader units; periodic spot checks	35.643	DH&S
4731.4474	Gamma stereotactic radiosurgery units; periodic spot checks	35.645	DH&S
4731.4475	Mobile remote afterloader units; additional requirements	35.647	DH&S
4731.4476	Radiation surveys	35.652	DH&S
4731.4477	Teletherapy and gamma stereotactic radiosurgery units; five-year inspection	35.655	DH&S
4731.4478	Teletherapy and gamma stereotactic computer systems	35.657	DH&S
4731.4479	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.690	DH&S
4731.4500	Radiation protection program records		
4731.4500, subp. 1	Records of authority and responsibilities for radiation protection programs	35.2024	D
4731.4500, subp. 2	Records of radiation protection program changes	35.2026	D
471.4500	Written directive records		
4731.4501, subp. 1	Records of written directives	35.2040	D
4731.4501, subp. 2	Records for procedures for administrations requiring a written directive	35.2041	D
4731.4502	Instrument calibration records		
4731.4502, subp. 1	Activity measurement instruments	35.2060	D
4731.4502, subp. 2	Survey instruments	35.2061	D
4731.4503	Dosage records	35.2063	D
4731.4504	Leak test and inventory records	35.2067	D
4731.4505	Survey records; ambient radiation exposure	35.2070	D
4731.4506	Release records; individuals containing radioactive material or implants	35.2075	D
4731.4507	Mobile medical service records	35.2080	D
4731.4508	Decay-in-storage records	35.2092	D
4731.4509	Molybdenum-99 records	35.2204	D
4731.4510	Safety Instruction records	35.2310	D

MN Rule Part	Title	10 CFR	Compatibility
4731.4511	Survey records; source implant and removal	35.2404	D
4731.4512	Brachytherapy source accountability records	35.2406	D
4731.4513	Brachytherapy source calibration records	35.2432	D
4731.4514	Strontium-90 decay records	35.2433	D
4731.4515	Installation, maintenance, adjustment, and repair records	35.2605	D
4731.4516	Safety procedures records	35.2610	D
4731.4517	Dosimetry equipment Records	35.2630	D
4731.4518	Calibration records; teletherapy, remote afterloader, and gamma stereotactic radiosurgery units	35.2632	D
4731.4519	Spot check records; teletherapy units	35.2642	D
4731.4520	Spot check records; remote afterloader units	35.2643	D
4731.4521	Spot check records; gamma stereotactic radiosurgery units	35.2645	D
4731.4522	Operability records; mobile remote afterloader units	35.2647	D
4731.4523	Survey records; therapeutic treatment units	35.2652	D
4731.4524	Inspection records; teletherapy and gamma stereotactic radiosurgery units	35.2655	D
4731.4525	Medical event; report and notification	35.3045	D
4731.4526	Dose to an embryo/fetus or child; report and notification	35.3047	C
4731.4527	Report of a leaking source	35.3067	C
	Irradiators		
4731.6000	Purpose and scope	36.1	C
4731.6010	Specific license; application	36.11	D
4731.6020	Specific license; approval	36.13	DH&S
4731.6030	Start of construction	36.15	D
4731.6040	Application for exemptions	36.17	D
4731.6050	Performance criteria; sealed sources	36.21	B
4731.6060	Access control	36.23	DH&S
4731.6070	Shielding	36.25	DH&S
4731.6080	Fire protection	36.27	DH&S

MN Rule Part	Title	10 CFR	Compatibility
4731.6090	Radiation monitors	36.29	DH&S
4731.6100	Control of source movement; panoramic irradiators	36.31	DH&S
4731.6110	Irradiator pools	36.33	DH&S
4731.6120	Source rack protection	36.35	D
4731.6130	Power failures	36.37	DH&S
4731.6140	Design requirements	36.39	DH&S
4731.6150	Construction monitoring and acceptance testing	36.41	DH&S
4731.6160	Training	36.51	DH&S
4731.6170	Operating and emergency procedures	36.53	DH&S
4731.6180	Personnel monitoring	36.55	D
4731.6190	Radiation surveys	36.57	DH&S
4731.6200	Detection of leaking sources	36.59	DH&S
4731.6210	Inspection and maintenance	36.61	DH&S
4731.6220	Pool water purity	36.63	DH&S
4731.6230	Attendance during operation	36.65	DH&S
4731.6240	Entering and leaving the radiation room	36.67	DH&S
4731.6250	Irradiation of explosive or flammable materials	36.69	DH&S
4731.6260	Records and retention periods	36.81	D
4731.6270	Reports	36.83	C
	Well Logging		
4731.7000	Licenses and radiation safety requirements for well logging	39.1	D
4731.7010	Application	39.11	D
4731.7020	Specific license; well logging	39.13	DH&S
4731.7030	Agreement with well owner or operator	39.15	C
4731.7040	Request for written statements	39.17	D
4731.7050	Labels, security and transportation precautions	39.31	C
4731.7060	Radiation detection instruments	39.33	C
4731.7070	Leak testing; sealed sources	39.35	C

MN Rule Part	Title	10 CFR	Compatibility
4731.7080	Physical inventory	39.37	DH&S
4731.7090	Records of material use	39.39	C
4731.7100	Design and performance criteria for sources	39.41	B
4731.7110	Inspection and maintenance; opening source or source holder	39.43	C
4731.7120	Subsurface tracer studies	39.45	C
4731.7130	Radioactive markers	39.47	D
4731.7140	Uranium sinker bars	39.49	C
4731.7150	Use without a surface casing	39.51	D
4731.7160	Energy compensation source	39.53	C
4731.7170	Tritium neutron generator target source	39.55	C
4731.7200	Training	39.61	B
4731.7200, subp. 1	Logging supervisor		
4731.7200, subp. 2	Logging assistant		
4731.7200, subp. 3	Safety reviews		
4731.7200, subp. 4	Records		
4731.7200, subp. 5	Training subjects		
4731.7210	Operating and emergency procedures	39.63	C
4731.7220	Personnel monitoring	39.65	C
4731.7230	Radiation surveys	39.67	C
4731.7240	Radioactive contamination control	39.69	C
4731.7250	Security	39.71	C
4731.7260	Documents and records; field stations	39.73	C
4731.7270	Documents and records; temporary jobsites	39.75	C
4731.7280	Notification of incidents and lost sources; abandonment procedures	39.77	C

4.3.1

Materials Licensing

4.3.1 MATERIALS LICENSING

Minnesota's technical licensing procedures, standard review plans, checklists, and licensing guides can be found in this application. Procedures covering each type of license can be found in each of the *Regulatory Guides*. These *Regulatory Guides* address the applicants' facilities and safety equipment, training and experience in the use of the materials for the purpose requested, and proposed administrative controls.

Guidance for information exchange between the program's inspection staff and licensing staff can be found in both the *Licensing Procedures Manual* and the *Inspections Procedures Manual* under the titles, "Memorandum to License Reviewer," "Memorandum to License Inspector," and "Conversation Record." A copy of these documents can be found in this section.

The required qualifications of license reviewers can be found in the *Licensing and Inspections Qualification Journal*.

Qualifications for those directing the medical use of radioactive materials can be found in the *Minnesota Rules Chapter 4731.4400* and in each of the medical use *Regulatory Guides*. These qualifications include prescribed minimum training and experience in the medical use of radioisotopes or radiation, and are compatible with those in 10 CFR Part 35.

Procedures for evaluating the conditions of storage and use addressing security against unauthorized removal and safety equipment can be found in each *Regulatory Guide* under "Item 9: Facilities and Equipment." An example of Item 9 can be found in this section. Other procedures that address qualification of users, licensee operating and emergency procedures, appropriate surveys, personnel monitoring under the close supervision of technically competent individuals, preparations for transport, and decommissioning can be found in the appropriate sections of each regulatory guide.

Licensing Checklists are also included in this section.

SUMMARY

The licensing program is outlined in the combination of the *Licensing Procedures Manual* and the *Qualification Journal* to form the nucleus of the Radioactive Materials Regulatory program. The manuals provide the information necessary for licensing and inspection staff to process, manage, and track activities. These manuals are included as part of this application.

The *Qualification Journal* is the tool that documents the license reviewer's and the inspector's qualification progress as well as the steps taken to qualify that individual. This Journal contains an outline of the minimum activities expected by the Radiation Control supervisor and the Section Manager.

These activities are classified as the following:

1. Formal training
2. Self-study
3. Accompanied inspections
4. Licensing audits

Each of the Regulatory Guides developed by the Minnesota Department of Health, Radioactive Materials Program outlines the licensing directives and application directions. These guides include the following:

- Instruction Concerning Prenatal Radiation Exposure
- Instruction Concerning Risks From Occupational Radiation Exposure
- Regulatory Guide for Broad Scope Licenses
- Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments
- Regulatory Guide for Decommissioning
- Regulatory Guide for Diagnostic and Therapeutic Medical Procedures
- Regulatory Guide for Diagnostic Medical Procedures
- Regulatory Guide for Fixed Gauges
- Regulatory Guide for Gamma Stereotactic Radiosurgery
- Regulatory Guide for Gas Chromatographs and X-Ray Fluorescence Analyzers
- Regulatory Guide for High Dose Rate Afterloaders
- Regulatory Guide for Industrial Radiography
- Regulatory Guide for Mobile Nuclear Medical Service
- Regulatory Guide for Nuclear Pharmacies
- Regulatory Guide for Portable Gauges
- Regulatory Guide for Research and Development, Laboratory and Industrial Use of Small Quantities of Radioactive Material
- Regulatory Guide for Special Nuclear Material of Less Than Critical Mass Quantities
- Regulatory Guide for the Release of Patients Administered Radioactive Materials

The license reviewers and inspectors are required to use this information as they are reviewing applications, amendments and license renewals. Part of the license reviewers and inspectors continuing quality assurance is the ability to use these guides appropriately.

These guides are included in Volume III of this application.

**RADIOACTIVE MATERIALS UNIT
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

**MEMORANDUM TO LICENSE REVIEWER
AREA(S) THAT SHOULD BE ADDRESSED DURING THE NEXT LICENSE REVIEW**

Inspector:

Date:

Licensee:

License Number:

Specific license condition, application, or letter that needs to be reviewed. Identify type and date of document.

Provide a brief description of the issue associated with the license. If there are numerous issues, the items should be numbered. Use additional sheets if necessary.

**RADIOACTIVE MATERIALS UNIT
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

**MEMORANDUM TO LICENSE INSPECTOR
MATTER(S) TO BE REVIEWED DURING THE NEXT INSPECTION**

Staff Member:

Date:

Licensee:

License Number:

Type of matter to be reviewed during the next inspection:

Instructions or comments:

**RADIOACTIVE MATERIALS UNIT
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

CONVERSATION RECORD

- Outgoing call
- Incoming call

Date:

Licensee:

License Number:

Summary of Discussion:

Required actions:

Inspector:

Date:

The following has been excerpted from the *Regulatory Guide for Diagnostic and Therapeutic Medical Procedures*:

Item 9: Facilities And Equipment

Applications will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta emitters.

Applicants must describe the proposed facilities and equipment. The facility diagram should include the room or rooms and adjacent areas where radioactive material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

For use of unsealed radioactive material for uptake, dilution, or excretion, or for imaging and localization (4731.4432 or 4731.4433), applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described.

For radiopharmaceutical therapy and manual brachytherapy (4731.4440 and 4731.4450), applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 4731.4427. The discussion should include a description of shielding, if applicable.

For a remote afterloader, teletherapy unit, or gamma knife (4731.4463), the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room.

The applicant should demonstrate that the dose limits for individual members of the public (4731.2090) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

- Requesting prior MDH authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by MDH. If applicants elect to use portable shielding they should commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. The licensee should specify the electrical, mechanical, or other physical means (rather than administrative controls) used to limit movement or rotation of the unit (e.g., electrical or mechanical stops).

Annotated Drawings

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.
- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored.
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003.
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

Radiation Monitoring Instruments

All licensees should possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010 must include provisions for survey instrument calibration (4731.2200). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be conducted each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Qualified personnel must perform survey meter calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an MDH (or equivalent NRC or Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Provide one or both of the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."
- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 4731.2200 and that meet the requirements of 4731.4421." Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing."

Also provide both of the following:

- A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
Short Scientific, Inc.	LGD-310	1 - 100000 cpm

- A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

Dose Calibrator and Other Equipment Used To Measure Dosages of Unsealed Radioactive Material

As described in 4731.4422, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or a nuclear pharmacy and does not split, combine, or otherwise modify unit dosages, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- If the licensee performs direct measurements of dosages in accordance with 4731.4422 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused

by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.



Broadscope Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Radioactive Material listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Chemical/Physical form of each isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Maximum activity |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each sealed source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each sealed source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of each sealed source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Emergency Plan and Financial Assurance documentation submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 Appropriate purpose for materials listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 Individuals responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Organizational chart submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Executive Management |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Committee |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Officer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Office Staff |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8 Training Program submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Initial and annual refresher training provided to Authorized users, laboratory supervisors, and laboratory workers |
| | | | Authorized Users |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Bachelor level degree in physical or biological sciences |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | At least 40 hours of training and experience in the safe use of radioactive material |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Supplementary Continuing Education provided |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Performance based training provided |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Annual interviews with users by Radiation Safety |



Broadscope Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annual evaluation of lab personnel by Authorized Users
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9 Facilities Described
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Laboratory classification scheme provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Material storage and use in fume hoods specified
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Storage facility described
			10 Radiation Safety Program
			Audits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Management and RSC audits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Internal audits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Recordkeeping
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation detection and monitoring equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calibration methods described
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inventory, control and accountability program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Occupational dose
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Public dose
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe use of radionuclides
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	General safety procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bioassay samples
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak testing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transportation of RAM described
			Procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Approved packages
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate labeling
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Proper surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Shipping papers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Blocking and bracing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Training provided to drivers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Quarterly audits of transportation documentation



Broadscope Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures taken by driver
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transporting radioactive waste
			11 Waste Management
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Decay in storage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Release into sanitary sewerage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transfer to authorized recipient
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Alternative methods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Incineration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Waste volume reduction
			Appendices
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Field studies
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Delegation of authority
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radionuclides classified by toxicity
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Facility considerations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Audit Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Instrument Specifications
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Material receipt and accountability
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe Use of material and emergency procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation survey topics
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak testing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Laboratory animal and veterinary uses
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Waste management
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Certification

Reviewer Notes:



Fixed Gauge Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| | | | 5 Radioactive Material |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Each Isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer and model of calibration sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 Purpose of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 Individuals responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Officer listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If not a user, training adequate |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Duties listed (Appendix A) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Submitted training program for individuals, other than those listed in Item 7 that will work in the vicinity of the gauges (Appendix B) |
| | | | 8 |
| | | | 9 Facilities and Equipment |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Annotated drawing or description submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Environmental conditions |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If ambient temperature is less than operating specifications, cooling system described. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Procedures for cooling system failure |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Kay-Ray models 7062B, 7062BP vibration tests (Ref: NMSS Licensee Newsletter dated September 1999) |



Fixed Gauge Licensing Checklist



OK DEF N/A

10 Radiation Safety Program

Leak Test procedures Submitted
Appropriate leak test frequency (SS&D catalog)

Option 1- Engage Services of Consultant
Name, address, and license number of consultant

Option 2- Use of Commercial Leak Test Kit
Kit number, name, address, and license number of kit, the kit supplier and the company who will analyze the sample
Description of wipe test procedure

Option 3- Perform Entire Leak Test at Facility
Instrumentation adequate for analysis
Sample conversion of measurement data to microcuries

Commitment to lock-out procedures
Procedures given to personnel
Procedures posted

Maintenance information submitted (shutter checks)

Personnel dosimetry available
Name and address of supplier
NVLAP approved
Type and frequency of exchange

If servicing gauge, is survey instrument available
 Manufacturer's name
 Model number
 Type of radiation detected
 Range of instrument is adequate

Name, address, and license number of calibration service

Commitment to six-month inventories



Fixed Gauge Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annual audits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to follow manufacturer's procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Licensee submitted procedures (reference regulatory guide for specifics)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Operating procedures submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Do procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use of personnel monitoring
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Step-by-step procedures for use of device
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Storage of device
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Isolating gauge and immediate area
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveying radiation areas around gauge
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Verification of shielding
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Informing personnel of accident
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Obtaining manufacturer's assistance
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Notifying RSO and MDH
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management



Gas Chromatograph and XRF Licensing Checklist



OK	DEF	N/A	
			Facility Name:
			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Each Isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 Purpose of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 Individuals responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Officer listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If not a user, training adequate |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Duties listed (Appendix A) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8 Submitted training program for individuals, other than those listed in Item 7 that will work in the vicinity of the gauges |
| | | | 9 Facilities and Equipment |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Annotated drawing or description submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Adequate security (including during storage) |
| | | | 10 Radiation Safety Program |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Leak Test procedures Submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Appropriate leak test frequency (SS&D catalog) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Option 1- Engage Services of Consultant |
| | | | Name, address, and license number of consultant |



Gas Chromatograph and XRF Licensing Checklist



OK	DEF	N/A	
			Option 2- Use of Commercial Leak Test Kit
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Kit number, name, address, and license number of kit, the kit supplier and the company who will analyze the sample
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of wipe test procedure
			Option 3- Perform Entire Leak Test at Facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Instrumentation adequate for analysis
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sample conversion of measurement data to microcuries
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Maintenance information submitted
			Operations involving source removal, maintenance, and repair
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Specific operations listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Responsible individuals listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer's training provided to maintenance personnel
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name and affiliation of instructor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Outline of training received
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel dosimetry available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name and address of supplier
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NVLAP approved
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If servicing gauge, is survey instrument available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer's name
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Type of radiation detected
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Range of instrument is adequate
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, and license number of calibration service
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to six-month inventories
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annual audits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Operating procedures submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to follow manufacturer's procedures
			Do procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use of personnel monitoring
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Step-by-step procedures for use of device



Gas Chromatograph and XRF Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Storage of device
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures submitted
			Procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Isolating device and immediate area
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveying radiation adjacent areas
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Verification of shielding
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Informing personnel of accident
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Obtaining manufacturer's assistance
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Notifying RSO and MDH
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to transport device in accordance with DOT regulations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management



Industrial Radiography Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and mailing address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Physical address of use and/or storage |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Appropriate contact person |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Radioactive Material Listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Each isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer and model number of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer and model number of each radiographic device and changer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer and model number of calibration sources |
| | | | List SS&D Catalog number(s) in checklist notes |
| | | | NOTE : EACH SOURCE CHANGER SHOULD SPECIFY THE CORRESPONDING SOURCE |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 Purpose |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 Individual responsible for radiation safety program |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Organizational chart provided |
| | | | 8 Training |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Individual users listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Training adequate (4731.4140) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Officer listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Training adequate (4731.4130) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Training for other workers in the vicinity |
| | | | 9 Facilities and Equipment |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Annotated drawing or description of storage area |
| | | | Includes: |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Type, thickness of shielding in storage area (includes floor and roof) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Types of posting and location |



Industrial Radiography Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Location of access points
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description and distance to adjacent areas
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of Permanent Installation
			Includes:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of visible-audible signal system and its location(s)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation calculations or readings in adjacent areas
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Limitations of source position
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation detection instruments available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer's name and model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Type of radiation each instrument can detect
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sensitivity range of each instrument
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Frequency of calibration (6 month)
			Survey instrument calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, and license number of calibration facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calibration procedures if license to perform
			10 Radiation Safety Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test at appropriate intervals
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Six Months for Ir-192 and Co-60
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	One Year for Depleted Uranium
			<u>Option 1 (Consultant)</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test company name, address, and license number
			<u>Option 2 (Commercial Kit)</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, license #, and kit model#
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Details of test if licensee to perform
			<u>Option 3 (Licensee to perform)</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Submitted procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to Maintenance Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to transporting in accordance with DOT regulations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment for 6 month inventories
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Operating and Emergency Procedures submitted



Industrial Radiography Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Provided to each user
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer or other licensed facility for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management

Reviewer Notes:

Reviewer Notes: (Retain with license application)

EXPOSURE DEVICE MANUFACTURER	DEVICE MODEL NUMBER	SOURCE MANUFACTURER	SOURCE MODEL NUMBER	ISOTOPE	ACTIVITY	LEAK TEST INTERVAL	SEALED SOURCE AND DEVICE CATALOG NO.
A.							Camera: Source:
B.							Camera: Source:
C.							Camera: Source:
D.							Camera: Source:
E.							Camera: Source:
F.							Camera: Source:



Nuclear Pharmacy



OK DEF N/A

Facility Name:	License No.:
-----------------------	---------------------

- | | | | | |
|--------------------------|--------------------------|--------------------------|---|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 | Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 | Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 | Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 | Radioactive material listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Chemical/Physical form |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Maximum activity |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Manufacturer name of any sealed sources (i.e., calibration sources) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Model Number of any sealed sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Serial number of any sealed sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 | Appropriate purpose for materials listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Licensee will redistribute various items containing RAM (e.g., generators, reagent kits, sealed sources, etc.) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Licensee intends to provide services (e.g., survey meter calibration, wipe test analysis, etc.) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 | Individual(s) responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Organizational chart submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Radiation Safety Officer listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Present daily |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Duties listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8 | Training program submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Radiation Safety Officer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Authorized Nuclear Pharmacists |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Authorized Users |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Individuals frequenting restricted areas |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Occupationally exposed and ancillary personnel |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | HAZMAT package preparation and transportation training |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Training for persons preparing radiopharmaceuticals |



Nuclear Pharmacy



OK	DEF	N/A	
			9 Facilities and Equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annotated drawing or description submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Principal use of each room listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Shielding available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If the facility is under construction- estimated date of completion
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Additional safety equipment listed (i.e., L-blocks, fixed monitors, fume hoods, etc.)
			<i>(Note to have Xenon-133: Fume hood, negative pressure)</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Location of air supply and exhaust vents provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measured air flow provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Equipment and methods used to measure airflow
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Airflow checked every 6 months
			Other equipment and facilities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dose calibrator
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey meters
			<i>Note: Range (must cover range from 0.1 mR/hr to 1000 mR/hr)</i>
			Manufacturer name
			Model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Method of calibrating survey meters submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey meters calibrated annually
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Equipment for analyzing wipes listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Licensee intends to provide services (e.g., survey meter calibration, wipe test analysis, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Multi-tenant Building
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Outline agreement with other tenants provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey method for common walls provided (e.g., survey on opposite side of wall or film badge attached to common wall)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Common wall survey frequencies provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Common wall film badge processing frequency
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Air circulation system provided (common air space ceiling tile, central air return)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Special Equipment for Handling Iodine
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Will be performed in fume hoods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Airflow checked every six months
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Airflow check procedures provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of system to maintain release to the general public below limits. (i.e., charcoal systems)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Release calculations provided
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bioassay program submitted (within 72 hrs if $\geq 30\text{mCi}$)



Nuclear Pharmacy



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Duties of the RSO (Appendix A)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for Dose Calibrator (Appendix B)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiopharmacy Audit Checklist (Appendix C)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ordering and receiving (Appendix D)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedure for opening packages (Appendix E)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model personnel Exposure Program (Appendix F)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe use of radiopharmaceuticals (Appendix G)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Spill procedures and action limits (Appendix H)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Area survey procedures (Appendix I)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to noble gases (Appendix J.1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating public dose to airborne effluent (Appendix J.2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calculating clearance times (Appendix J.3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak Test Procedures (Appendix K)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Return of Waste from Customers (Appendix L)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sealed Source Inventory
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Proper records maintained
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Records retained for three years
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for Retrieving Waste
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Retrieve only items that contain licensee supplied RAM
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Provided the detailed instructions given to customers
			Operations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Assurance provided that the products distributed are FDA approved
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Nuclear Pharmacy is licensed by the State Board of Pharmacy
			Commitment to distribute radiopharmaceuticals to only facilities authorized to receive and prescribed by an authorized user on the customer's license
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to maintain current copies of customer's license
			Product Labels
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Two labels provided one on container and the other on the unit dose syringe or vial
			Labels for container
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient information to prevent misadministration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unique identifier (patient's name or prescription number)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tc-99m radiopharmaceuticals contain the concentration of Mo-99 and expiration time that the radiopharmaceutical will contain >1µCi of Mo-99 per millicurie of Tc-99m per single dose



Nuclear Pharmacy



OK DEF N/A

Labels for Syringe

Label Contains the radiation caution symbol, the words "CAUTION- RADIOACTIVE MATERIAL," and patient's name or prescription number

Product Shielding

State maximum activity for each type of container

Description of type and thickness of shielding

Maximum radiation level to be expected at the surface of each shielded container

Description or mechanism submitted for:

Approved packages

Appropriate Labeling

Proper surveys

Complete and accurate shipping papers

Blocking and Bracing

Security

Emergency Procedures

Training of drivers

Quarterly audits of transportation documents

Emergency Procedures

Procedures for handling radioactive waste

Reviewer Comments:



Portable Gauge Licensing Checklist



OK DEF N/A

Facility Name:	License No.:
-----------------------	---------------------

- | | | | | |
|--------------------------|--------------------------|--------------------------|---|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 | Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 | Location of use or stored |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 | Licensee contact |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 | Each isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Manufacturer and model number of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Activity of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Manufacturer and model number of each device |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Manufacturer and model number of calibration sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 | Purpose adequate |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 | Individuals responsible for the radiation safety program listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Radiation Safety Officer listed (Appendix A) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | If not a user, is adequate training submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Duties listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Individual users listed |
| | | | 8 | Training |
| | | | | <u>If using manufacturer's training</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Have successfully completed manufacturer's course |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Received copies and training in licensee's operating and emergency procedures |
| | | | | <u>IF USING SUBMITTED TRAINING FOR REVIEW</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Description submitted (Appendix B) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Name and qualifications of instructor |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Submitted training program for individuals that work in the vicinity of the gauges |



Portable Gauge Licensing Checklist



OK	DEF	N/A	
			9 Facilities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annotated drawing or description submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Storage area described
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security (While in storage and in the field)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If the facility is under construction - estimated date of completion
			10 Radiation Safety Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak Test procedures Submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate leak test frequency (SS&D catalog)
			Option 1- Engage Services of Consultant
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, and license number of consultant
			Option 2- Use of Commercial Leak Test Kit
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Kit number, name, address, and license number of the kit supplier and company who will analyze test.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of wipe test procedure (Appendix E.1)
			Option 3- Perform Entire Leak Test at Facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Instrumentation adequate for analysis
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sample conversion of measurement data to microcuries
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Licensee to perform maintenance
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name and qualifications of individual performing maintenance submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate procedures submitted (Appendix C)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If servicing gauge, is survey instrument available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer's name
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Type of radiation detected
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Range of instrumentation adequate
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, and license number of calibration service
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel dosimetry available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name and address of supplier
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NVLAP approved
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Type and frequency of exchange



Portable Gauge Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to 6-month inventories
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Audit Program
			Operating and Emergency procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to manufacturer's training; or
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Submitted their own
			Do the procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use of personnel monitoring
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Step-by-step procedures for use of device
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Storage of device
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transportation
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Provided to users
			Commitment to transport gauges in accordance with DOT regulations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee Submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Signed and dated by licensee's management

NOTES: Troxler 3400 series gauges only include models 3430, 3430-M, 3440, and 3440-M. These should be specified in Item 8 of the license. Campbell Pacific (CPN) is now owned by Boart Longyear and listed as such in the SSD.



**RESEARCH AND DEVELOPMENT, LABORATORY,
AND INDUSTRIAL USE OF SMALL QUANTITIES OF BY-PRODUCT LICENSING CHECKLIST**



OK	DEF	N/A		
			Facility Name:	License No.:

- | OK | DEF | N/A | | |
|--------------------------|--------------------------|--------------------------|----|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 | Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 | Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 | Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Telephone number |
| | | | 5 | Radioactive Material |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Radioactive Material listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Chemical/Physical form |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Maximum activity |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Manufacturer name of sealed sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Model number of sealed sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Activity of sealed sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Financial Assurance documentation |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 | Appropriate purpose for materials listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 | Individuals responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Organizational chart submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Radiation Safety Officer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Authorized users |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8 | Training Program submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Initial and annual refresher training provided to Authorized Users, laboratory supervisors, and laboratory workers |
| | | | | Authorized Users |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Bachelor level degree in physical or biological |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | At least 40 hours of training and experience |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9 | Facilities Described |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Material storage and use in fume hoods specified |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Storage facility described |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10 | Radiation Safety Program |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | Audits |



**RESEARCH AND DEVELOPMENT, LABORATORY,
AND INDUSTRIAL USE OF SMALL QUANTITIES OF BY-PRODUCT LICENSING CHECKLIST**



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation detection and monitoring equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calibration methods described
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inventory, control, and accountability program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Occupational dose
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Public dose
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe use of radionuclides
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	General safety procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bioassay samples
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak testing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transportation of RAM described
			Procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Approved packages
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate labeling
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Proper surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Shipping papers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Blocking and bracing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Training provided to drivers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Quarterly audits of transportation documentation
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures taken by driver
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for transporting radioactive waste
			11 Waste Management
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Decay in storage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Release into sanitary sewerage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Transfer to authorized recipient
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Alternative methods
			Appendices
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Guidance on decommissioning funding plan and financial assurance
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RSO Responsibilities



**RESEARCH AND DEVELOPMENT, LABORATORY,
AND INDUSTRIAL USE OF SMALL QUANTITIES OF BY-PRODUCT LICENSING CHECKLIST**



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model Training Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Audits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Facility considerations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Material receipt and accountability
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe Use of material and emergency procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe handling of radioactive material
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak testing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Laboratory animal and veterinary uses
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Certification

Reviewer Notes:



Special Nuclear Material Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and Address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Each Isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer and model of calibration sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 Purpose of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 Individuals responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Officer listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If not a user, training adequate |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Duties listed (Appendix B) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Specific instruction given to students |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8 Submitted training program for individuals, other than those listed in item 7, that work in the vicinity of the radioactive material |
| | | | 9 Facilities and Equipment |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Annotated drawing or description submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Environmental conditions |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The number, type, and length of remote handling tools |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Storage containers and facilities (location, shielding) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Physical plant, laboratory, or work area |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Security |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation detection instruments available |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer's name |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number |



Special Nuclear Material Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Type of radiation each instrument can detect
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sensitivity range of each instrument
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Frequency of calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, and license number of calibration facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calibration procedures if license to perform
			10 Radiation Safety Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel monitoring available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If none, justification (measurement or calculation)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NVLAP approved processor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adequate radiation survey program (Appendix D)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ordering and receiving procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveys performed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test at appropriate intervals
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test kit
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test company name, address, and license number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Details of test if licensee to perform (Appendix E)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Submitted emergency and operating procedures
			Operating procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use of personnel monitoring
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Step by step safety procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for storage of material
			Emergency procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Securing ventilation system
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Evaluation of area
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Reentry
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for containment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name and telephone numbers of responsible individuals
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to performing six month inventory
			11 Waste management procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management



Diagnostic and Therapeutic Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Radioactive Materials |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radioactive Material listed |
| | | | Unsealed materials in 4731.4432 |
| | | | Uptake, dilution, and excretion studies |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Unsealed materials in 4731.4434 |
| | | | Imaging and localization studies |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Sources in 4731.4450 |
| | | | Manual brachytherapy |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Isotope |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source manufacturer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source model |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source serial number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Sealed sources in 4731.4460 |
| | | | Sealed sources for diagnosis |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source manufacturer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source model |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Isotope |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source serial number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |



Diagnostic and Therapeutic Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Users authorized for materials
			Sealed sources in 4731.4463
			Remote afterloader, teletherapy, gamma knife
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Device manufacturer
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Device model
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Isotope
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Source manufacturer
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Source model
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Possession limits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Users authorized for materials
			Materials in 4731.4404
			Other medical uses
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Isotope
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Chemical/Physical form
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Possession limits
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Users authorized for materials
			For Materials Not Listed in 4731.4400
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Chemical/Physical form
			<i>Note: This includes Tc-99m for Quality Control</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Maximum activity
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer name
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Activity of sources > 30 mCi
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6 Appropriate purpose for materials listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7 Individual(s) responsible listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Organizational chart submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Authorized users for medical use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Certification appropriate for uses
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Non-certified; training appropriate
			Authorized users for non-medical use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate training submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation Safety Officer listed



Diagnostic and Therapeutic Licensing Checklist



OK DEF N/A

If not an authorized user; training submitted
Sufficient time to fulfill duties
Commitment from management for authority
Duties listed (Appendix B)

8 Training program submitted for individual working in or
frequenting restricted areas
Ancillary Personnel included
Consistent with Appendix E

9 Facilities and Equipment
Annotated drawing or description submitted
Principal use of each room listed
Shielding available
If the facility is under construction - estimated date of completion
Additional safety equipment listed (i.e., L-blocks, fixed monitors,
fume hoods, etc.)

Note: Fume hood and negative pressure required for Xenon-133

Other equipment and facilities
Survey meters
Manufacturer name
Model number
Adequate range
Note: Must cover range from 0.1 mR/hr to 1000 mR/hr
Dose calibrator (Appendix C)

Mobile Nuclear Medicine Services
Location of Use

Base Hot Lab in Medical Facility
Indicate applicant is medical institution's management
If not, letter from management of authorization

Base Hot Lab in Non-medical Facility
(Private Residential Locations)

Justification why residential vs. commercial
Contractual agreement between parties
Confirmation from local authorities (meets code)
Specific description of facility



Diagnostic and Therapeutic Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Demonstration of compliance with 4731.4428
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of scope of activities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of security measures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>Commercial Location of Base Hot Lab</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Indication of management body
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Contractual agreement between parties
			<u>Temporary Job Sites</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for sitting van at temporary job sites
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diagram of van
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Demonstrate compliance with radiation levels outside van
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Describe procedures for compliance with 4731.4428
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Describe survey procedures for compliance with 4731.4428
			<u>Transportation</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	In accordance with DOT regulations
			Description or mechanism submitted for:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Approved packages
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate Labeling
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Proper surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Complete and accurate shipping papers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Blocking and Bracing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Training of drivers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for handling radioactive waste
			10 Radiation safety program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ALARA program (Appendix A)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model procedures for dose calibrator (Appendix C)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel monitoring (Appendix D)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	RSC Charter/RSO Delegation of Authority (Appendix E)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test procedures (Appendix F)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe use of radiopharmaceuticals (Appendix G)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Spill procedures and action limits (Appendix H)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ordering and receiving radioactive materials (Appendix I)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for opening packages (Appendix J)



Diagnostic and Therapeutic Licensing Checklist



OK	DEF	N/A	
			Records (Appendix K)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unit dosage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Multiuse vial
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mo-99 concentration generators only
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Inventory of implant sources
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Area survey procedures (Appendix L)
			Monitoring and controlling airborne concentrations (Appendix M)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to noble gases (Appendix M.1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to aerosols (Appendix M.2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to aerosols and gas (Appendix M.3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calculating clearance times (Appendix M.4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedure for iodine therapy (Appendix N)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for implant therapy (Appendix O)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for Sr-90 eye applicators (Appendix Q)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model annual audit (Appendix R)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management



Diagnostic Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| | | | 5 Radioactive Materials |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radioactive Material listed |
| | | | Unsealed materials in 4731.4432 |
| | | | Uptake, dilution, and excretion studies |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Unsealed materials in 4731.4434 |
| | | | Imaging and localization studies |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Sealed sources in 4731.4460 |
| | | | Sealed sources for diagnosis |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source manufacturer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source model |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Isotope |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source serial number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | For Materials Not Listed in 4731.4400 |
| | | | Chemical/Physical form |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <i>Note: This includes Tc-99m for Quality Control</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Maximum activity |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer name |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of sources > 30 mCi |



Diagnostic Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6 Appropriate purpose for materials listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7 Individual(s) responsible listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Organizational chart submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Authorized users for medical use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Certification appropriate for uses
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Non-certified; training appropriate
			Authorized users for non-medical use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate training submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation Safety Officer listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If not an authorized user; training submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient time to fulfill duties
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment from management for authority
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Duties listed (Appendix B)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 Training program submitted for individual working in or frequenting restricted areas
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ancillary Personnel included
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Consistent with Appendix E
			9 Facilities and Equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annotated drawing or description submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Principal use of each room listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Shielding available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If the facility is under construction - estimated date of completion
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Additional safety equipment listed (i.e., L-blocks, fixed monitors, fume hoods, etc.)
			<i>Note: Fume hood and negative pressure required for Xenon-133</i>
			Other equipment and facilities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey meters
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer name
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adequate range
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Note: Must cover range from 0.1 mR/hr to 1000 mR/hr</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dose calibrator
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Note: Not required except for orders with written directives</i>



Diagnostic Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mobile Nuclear Medicine Services
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Location of Use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>Base Hot Lab in Medical Facility</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Indicate applicant is medical institution's management
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If not, letter from management of authorization
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>Base Hot Lab in Non-medical Facility</u>
			(Private Residential Locations)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Justification why residential vs. commercial
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Contractual agreement between parties
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Confirmation from local authorities (meets code)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Specific description of facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Demonstration of compliance with 4731.4428
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of scope of activities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of security measures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>Commercial Location of Base Hot Lab</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Indication of management body
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Contractual agreement between parties
			<u>Temporary Job Sites</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for sitting van at temporary job sites
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diagram of van
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Demonstrate compliance with radiation levels outside van
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Describe procedures for compliance with 4731.4428
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Describe survey procedures for compliance with 4731.4428
			<u>Transportation</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	In accordance with DOT regulations
			Description or mechanism submitted for:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Approved packages
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate Labeling
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Proper surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Complete and accurate shipping papers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Blocking and Bracing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures



Diagnostic Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Training of drivers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for handling radioactive waste
			10 Radiation safety program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ALARA program (Appendix A)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model procedures for dose calibrator (Appendix C)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel monitoring (Appendix D)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test procedures (Appendix E)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe use of radiopharmaceuticals (Appendix F)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Spill procedures and action limits (Appendix G)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ordering and receiving radioactive materials (Appendix H)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for opening packages (Appendix I)
			Records (Appendix J)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unit dosage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Multiuse vial
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mo-99 concentration generators only
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Area survey procedures (Appendix K)
			Monitoring and controlling airborne concentrations (Appendix L)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to noble gases (Appendix L.1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to aerosols (Appendix L.2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to aerosols and gas (Appendix L.3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calculating clearance times (Appendix L.4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management



Special Nuclear Material Licensing Checklist



OK	DEF	N/A	
Facility Name:			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and Address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Each Isotope listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each source listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of each source |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer and model of calibration sources |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6 Purpose of each device listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7 Individuals responsible listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety Officer listed |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | If not a user, training adequate |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Duties listed (Appendix B) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Specific instruction given to students |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8 Submitted training program for individuals, other than those listed in item 7, that work in the vicinity of the radioactive material |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9 Facilities and Equipment |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Annotated drawing or description submitted |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Environmental conditions |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | The number, type, and length of remote handling tools |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Storage containers and facilities (location, shielding) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Physical plant, laboratory, or work area |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Security |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radiation detection instruments available |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer's name |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number |



Special Nuclear Material Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Type of radiation each instrument can detect
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sensitivity range of each instrument
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Frequency of calibration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name, address, and license number of calibration facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calibration procedures if license to perform
			10 Radiation Safety Program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel monitoring available
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If none, justification (measurement or calculation)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NVLAP approved processor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adequate radiation survey program (Appendix D)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ordering and receiving procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Surveys performed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test at appropriate intervals
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test kit
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test company name, address, and license number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Details of test if licensee to perform (Appendix E)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Submitted emergency and operating procedures
			Operating procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Use of personnel monitoring
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Step by step safety procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for storage of material
			Emergency procedures include:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Securing ventilation system
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Evaluation of area
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Reentry
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for containment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Name and telephone numbers of responsible individuals
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment to performing six month inventory
			11 Waste management procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management



Mobile Nuclear Medical Licensing Checklist



OK	DEF	N/A	
			Facility Name:
			License No.:

- | OK | DEF | N/A | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2 Applicant's name and address |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3 Location of use |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4 Person to be contacted about application |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Telephone number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5 Radioactive Materials |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Radioactive Material listed |
| | | | Unsealed materials in 4731.4432 |
| | | | Uptake, dilution, and excretion studies |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Unsealed materials in 4731.4434 |
| | | | Imaging and localization studies |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | Sealed sources in 4731.4460 |
| | | | Sealed sources for diagnosis |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source manufacturer |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source model |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Isotope |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Source serial number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Possession limits |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Users authorized for materials |
| | | | For Materials Not Listed in 4731.4400 |
| | | | Chemical/Physical form |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <i>Note: This includes Tc-99m for Quality Control</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Maximum activity |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Manufacturer name |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Model number |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | Activity of sources > 30 mCi |



Mobile Nuclear Medical Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6 Appropriate purpose for materials listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7 Individual(s) responsible listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Organizational chart submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Authorized users for medical use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Certification appropriate for uses
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Non-certified; training appropriate
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation Safety Officer listed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If not an authorized user; training submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient time to fulfill duties
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Commitment from management for authority
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Duties listed (Appendix B)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 Training program submitted for individual working in or frequenting restricted areas
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ancillary Personnel included
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9 Facilities and Equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Annotated drawing or description submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Additional safety equipment listed (i.e., L-blocks, fixed monitors, fume hoods, etc.)
			<i>Note: Fume hood and negative pressure required for Xenon-133</i>
			Other equipment and facilities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Survey meters
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Manufacturer name
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model number
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adequate range
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Note: Must cover range from 0.1 mR/hr to 1000 mR/hr</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dose calibrator
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>Base Hot Lab in Medical Facility</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Indicate applicant is medical institution's management
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If not, letter from management of authorization
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>Base Hot Lab in Non-medical Facility</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(Private Residential Locations)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Justification why residential vs. commercial



Mobile Nuclear Medical Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Contractual agreement between parties
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Confirmation from local authorities (meets code)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Specific description of facility
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Demonstration of compliance with 4731.4428
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of scope of activities
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Description of security measures
			<u>Commercial Location of Base Hot Lab</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Indication of management body
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Contractual agreement between parties
			<u>Temporary Job Sites</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for sitting van at temporary job sites
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diagram of van
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Demonstrate compliance with radiation levels outside van
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Describe procedures for compliance with 4731.4428
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Describe survey procedures for compliance with 4731.4428
			<u>Transportation</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	In accordance with DOT regulations
			Description or mechanism submitted for:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Approved packages
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriate Labeling
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Proper surveys
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Complete and accurate shipping papers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Blocking and Bracing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Security
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Training of drivers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Emergency Procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for handling radioactive waste
			10 Radiation safety program
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ALARA program (Appendix A)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Model procedures for dose calibrator (Appendix C)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Personnel monitoring (Appendix D)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Leak test procedures (Appendix E)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Safe use of radiopharmaceuticals (Appendix F)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Spill procedures and action limits (Appendix G)



Mobile Nuclear Medical Licensing Checklist



OK	DEF	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Ordering and receiving radioactive materials (Appendix H)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for opening packages (Appendix I)
			Records (Appendix J)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unit dosage
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Multiuse vial
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Mo-99 concentration generators only
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Area survey procedures (Appendix K)
			Monitoring and controlling airborne concentrations (Appendix L)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to noble gases (Appendix L.1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to aerosols (Appendix L.2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Estimating dose to aerosols and gas (Appendix L.3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Calculating clearance times (Appendix L.4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11 Commitment to return device to manufacturer for disposal
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12 Appropriate fee submitted
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Application signed and dated by member of management

4.3.5

Licensing

Quality

Assurance

4.3.5

LICENSING QUALITY ASSURANCE

The State's procedures addressing peer review, supervisory review, and other methods assuring licensing quality assurance can be found in the *Licensing Procedures Manual* under "Peer Review Process," excerpted below. This information can also be found in the "Licensing and Inspection Tracking Form" located in both the *Licensing Procedures Manual* and the *Inspection Procedures Manual*. These tracking sheets have also been added to this section. In addition, the *Licensing Procedures Manual* and the *Inspection Procedures Manual* have a checklist to determine whether or not significant licensing action has taken place that may require an additional onsite inspection. This form has been excerpted and included in this section.

The following is an example of the peer review process section in both the *Licensing Procedures Manual* and the *Inspection Procedures Manual*:

Peer Review Process

The quality assurance for licensing procedures and licensing review is a three-fold process. The first involves cross training for both the licensing individuals and the individuals who will be the inspectors in the program. Second is the process of using a checklist to complete the license review process. Third, a follow-up peer review process has been implemented. This consists of a peer review and supervisory review. Peer reviews provide the following benefits:

- Consistency in licensing actions
- Quality assurance
- Educational opportunities for less experienced licensing staff
- Communication between licensing and inspection staff

The 30-day completion objective should always be met when licensing actions involve health and safety related issues. However, the quality review and approval will always take precedence over an arbitrary completion deadline.

A supervisory review of new, amended, and renewed licenses is required. A supervisory review is not required for deficiency letters.

CHECKLIST FOR DETERMINING WHEN SIGNIFICANT LICENSING ACTION HAS TAKEN PLACE THAT MAY REQUIRE AN ADDITIONAL ONSITE INSPECTION

If recent licensing actions have resulted in one of the following, Radioactive Materials Group staff should determine the need for performing an onsite inspection before the next routine inspection:

1. Does the licensing action result in increased authorization for types and quantities of radioactive material that could result in a significant potential for increased radiation exposure to the public and occupational workers?

No
 Yes (*Describe*)

Note: This can be identified by a change to a higher priority (i.e., from a Priority 2 to a Priority 1 license) or an increase in the authorized quantity from a millicurie amount to a curie amount.

2. Does the licensing action authorize a physical move of a facility or authorize use at a temporary job site(s)?

No
 Yes (*Describe*)

3. Does the licensing action authorize satellite facilities where material will be used or stored?

No
 Yes (*Describe*)

4. Does the licensing action increase the types of uses or disposal (incineration) of radioactive materials?

No
 Yes (*Describe*)

5. Does the licensing action significantly increase the number of authorized users?

No
 Yes (*Describe*)

4.3.6

Licensing
Administrative
Procedures

4.3.6

LICENSING ADMINISTRATIVE PROCEDURES

Minnesota's administrative procedures for licensing that address receipt of licensing actions, assignment of licensing actions to technical evaluators, license document preparation, tracking of action progress, signing of completed licenses, transmittal of signed license to the licensee, and license file maintenance can be found in the *Licensing Procedures Manual*. Procedures for the transfer of licenses from NRC to the State can be found in the *Licensing Procedures Manual* under the section, "License Transition from NRC to MDH." This document has been excerpted and included in this section.

All documents related to the licensing and inspection of radioactive material in Minnesota will be kept in secure filing cabinets in a restricted area of the Minnesota Department of Health. All electronic files are kept on the Radiation Control Unit's password-protected network, which also has restricted access.

MINNESOTA FEE SCHEDULE

Currently, the NRC has approximately 160 licenses in Minnesota. Conservatively, the annual income from these facilities is \$725,000. It should be noted that some licensees are authorized to use radioactive materials in Minnesota but have licenses issued to the corporate offices in another state. Their licenses were not included in the current inventory. On the other hand, some facilities may wish to dispose of the radioactive materials and cancel their licenses rather than having to have a separate license for Minnesota. This is occurring in Wisconsin.

Establishing a fee structure that is 80 percent of the annual NRC fees will produce an annual income of approximately \$580,000 for the Minnesota program. Using the following table, the estimated salary costs (base salary plus benefits and overhead) is \$495,000.

POSITION	SALARY	EMPLOYEES	TOTAL
SUPERVISOR	70,000	1	70,000
LEAD	60,000	1	60,000
WORKING POSITIONS	55,000	3	165,000
STAFF ASSISTANT	35,000	1	35,000
TOTAL WAGES			330,000
BENEFITS (30%)			99,000
OVERHEAD (20%)			66,000
TOTAL			495,000

The *Licensing Procedures Manual* included in this application provides the licensing staff and other appropriate staff members with basic administrative procedures for processing, managing, and tracking licensing actions from the time each action is received by the Radioactive Materials Group until the action is completed. It includes procedures for acknowledging requests for specific licensing actions, tracking the progress of actions, maintaining files electronically, preparing licenses, distributing documents, and other miscellaneous administrative activities. Much of the information needed by MDH licensing staff is provided in the appendices of the manual. Inspectors should note the following information:

- Appendix A contains standard forms used to complete licensing actions.
- Appendix B contains standard letters that may be edited to meet case-by-case requirements.
- Appendix C contains the list of standard license conditions.

A licensing tracking system, called the Radioactive Materials Information System (RAMIS), is the MDH computer system for tracking each license application from its receipt to completion. This system supports a standardized review process and provides licensing and inspection management reports. RAMIS allows the Radioactive Materials Group to provide timely responses to inquiries and specialized, ad hoc queries.

Consequently, all incoming licensing documents will be entered into this license tracking system. Support staff and the license reviewer are responsible for the timely processing of materials license applications. All materials licenses are assigned unique numbers that are tracked in the RAMIS database for the life of the licenses. For initial applicants, a new license number will be assigned. However, this number will not be referenced in communications with the licensee until the license has been finalized. (The computer system permits licensee identification using many different queries including a facility name as well as a license number.) Each licensing action is tracked in the RAMIS database from receipt of a request for licensing action to completion.

The Radioactive Materials Group will complete an acceptance review, as defined in the manual, and take the following actions:

- Issue a "deemed timely" letter (for renewals only) within five working days of the actions receipt. This "deemed timely" letter serves to notify the licensee that their license will not expire until final licensing action has been taken.
- Confirm that all necessary sections of the application are completed and that the application has been signed by the applicant's certifying official.
- Confirm that attachments identified by the applicant are, in fact, included in the submittal.
- Identify any requests for expedited review for safety-significant concerns (e.g., change in the Radiation Safety Officer or amendment requests resulting from identification of safety-significant violations) or for business reasons (e.g., change in ownership, bankruptcy).

The Group's objective is to complete all licensing actions within 30 days of receipt. Therefore, a well-prepared application (complete and accurate) should be processed, signed, and issued

within that time. Likewise, the license reviewer should have identified any need for additional information or clarification and issued a deficiency letter within 30 days of the receiving a licensing action with flaws. When the response to the deficiency letter arrives, the 30-day timeframe begins again.

- The previous discussion established the time constraints for processing a licensing action. Peer review and supervisory review are included in that timeframe.

The 30-day completion objective should always be met when licensing actions involve health and safety related issues. However, the quality review and approval will always take precedence over an arbitrary completion deadline. A supervisory review of new, amended, and renewed licenses is required. A supervisory review is not required for deficiency letters.

The license reviewer will ensure that the correct program code is assigned to the license. When it becomes necessary to assign more than one program code to a license, the code with the highest inspection priority (shortest inspection cycle) will be designated the primary code.

To standardize and simplify the review process, reviewers will use all available tools, including process, criteria, and checklists, when reviewing license applications. These are included in the licensing procedures manual appendices and attachments.

An example of a Minnesota Radioactive Materials License is included on the following pages.

Radioactive Materials Information System

The Radioactive Material Information System (RAMIS) development project was created at the request of the Radiation Control Unit. RAMIS is an interactive database application used by the Radiation Control Unit to meet the requirements of the NRC as an agreement state. Per department standards for large system development, this system utilizes an Oracle client-server database. The database is currently under development and should be completed near the end of 2004. Many of the components are similar to the X-ray database, which is scheduled for completion in August of this year.

The system is designed to track radioactive materials licenses and inspections. In addition to the expiration date most recent amendment number, RAMIS tracks standard license information including the licensee's name and address, location(s) of use, program codes, possession limits, and devices (if applicable).

Inspection intervals consistent with NRC Inspection Manual 2800 will be incorporated to develop inspection schedules. The application will manage the essential inspection and compliance activity information, based on the statute and program implementation of it, for a program. The system will be able to notify personnel when items are due and allow personnel to examine past compliance activities to ensure that their currently contemplated activity is consistent with past similar activities. The system will accomplish the following:

- Standardized recording of inspection and compliance activity information without the necessity of the regulatory program maintaining its own tracking system structure.
- Provide the ability to examine past inspection and compliance activity information to promote consistent use of compliance tools.
- Provide, if desired, the system notify staff of dates when responses to compliance communications are due.
- Report information, in a controlled, standardized manner, of activities when such information is requested by parties outside the division without the necessity of manual compilation of the requested information.
- Provide a report of staff activities for performance review purposes.

Consistent with MDH policy, RAMIS is designed to capture licensee staff and their associated roles. For example, the names of a medical broad scope licensee's administrator, radiation safety officer, medical physicist, nuclear pharmacist, as well as the authorized users will accessible to Radiation Control staff.

Finally, billing and payments is an integral component of the system.

The following has been excerpted from the *Licensing Procedures Manual*:

License Authorization

When complete, each license must be signed by the license reviewer and submitted for signature of the Unit Supervisor and Section Manager.

Issuance of Final Licensing Action

A cover letter and the original license should be sent for all completed licensing actions. The cover letter may be a form letter or individual letter. A sample cover letter is provided in Appendix B.

Many licensing actions require specific information to be included in the cover letter related to the individual case. All information may be combined into a single cover letter, or license reviewers may elect to use attachments. For licenses that are amended frequently, it is acceptable to include the standard information with every licensing action; or, if deemed appropriate, the information may be deleted if it was provided in a recent previous communication.

Record Retention

Paper and electronic records of inspection reports, enforcement actions, licensing documents, and routine correspondence are kept on the premises of the Minnesota Department of Health Radiation Unit. Paper documents are saved and filed according to license number and are stored in a secured entry resource room. Electronic files are kept in the radioactive materials database and on a network accessible to the Unit. All records are periodically archived to effectively utilize space.



RADIOACTIVE MATERIALS LICENSE

Pursuant to Minnesota Statute 144.12 and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the rules. This license is subject to all applicable rules and orders of the Minnesota Department of Health including the Minnesota Radioactive Materials Rules, Chapter 4731, now or hereafter in effect, and to any conditions specified below.

Licensee 1. 2.	In accordance with the application dated _____, the Minnesota Department of Health Radioactive Materials License is issued to read as follows:	
	3. License Number:	
	4. Expiration Date:	
	Primary:	Program Code Secondary:

5. Byproduct, Source Special Nuclear and/or Natural Occurring or Accelerator Produced Radioactive Material	6. Chemical and/or Physical Form	7. Maximum Amount that Licensee May Possess At Any One Time Under This License
A.	A.	A.
B.	B.	B.
C.	C.	C.
D.	D.	D.

8. **AUTHORIZED USE**

A.

B.

C.

D.

CONDITIONS

RADIOACTIVE MATERIALS LICENSE

SUPPLEMENTARY SHEET

LICENSE NO.

- 11.
- 12.
- 13.
- 14.
- 15.
- 16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Minnesota Department of Health's rules shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the rules.

A. Application dated .

B. Letter dated .

For the Minnesota Department of Health

Date: _____

By: _____

Radioactive Materials Group

Approval

Date: _____

By: _____

Radiation Control Unit Supervisor

Concurrence

Date: _____

By: _____

Section Manager

The following has been excerpted from the *Licensing Procedures Manual*:

LICENSE TRANSITION FROM NRC TO MDH

Upon completion of the Agreement, all active NRC licenses¹ issued to facilities in Minnesota will be recognized as Minnesota Department of Health licenses.

MDH will issue a one-page licensing document with all information in items 1 through 4 completed. A new license number (if appropriate) and expiration date will be included.

The document will contain the following statements:

This license authorizes receipt, acquisition, possession, and transfer of byproduct, source, and/or special nuclear material; the authorized use(s); purposes; and the places of use as designated on the NRC license.

The licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in the NRC license. The Minnesota Department of Health rules shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the rules.

Electronic copies of the licenses shall be transferred and stored on the Radioactive Materials Group site. Hard copies of licenses shall be stored in file cabinets.

¹ Nuclear power plants and licenses for facilities in areas of exclusive federal jurisdiction (e.g., Veterans Administration Hospitals) will remain NRC licenses.

4.4.1

Inspection Procedures

4.4.1 INSPECTION PROCEDURES

Inspection procedures, including report formats, checklists, and status reports are included in the *Inspection Procedures Manual* and the *Inspection Report Forms*. These procedures cover all NRC license program codes of licensees that will transfer to Minnesota. In addition, Minnesota's priority schedule for inspections by program code and reciprocity inspections can be found in the *Inspection Procedures Manual* and the *Licensing Procedures Manual* under the title, "Program Codes and Inspection Frequencies." This document has been excerpted in this section. Attached also is the *MDH Instrument Inventory* and the *MDH Laboratory Facility Description*.

SUMMARY

The inspection procedures are outlined in the *Inspection Procedures Manual*, which includes the general policy for the inspection program, priorities for conducting inspections, and the achieving a consistent method of conducting inspections. The *Inspection Procedures Manual* is included in the application for review.

The inspections are broken down into routine, non-routine and reciprocity categories. Each of these categories has a frequency, timing and requirements that will be met by the inspectors based on the *Inspection Procedures Manual*.

Inspection priorities

The inspection priority assigned to a license is based on the potential hazard of the regulated activities and this is accomplished at the time of the license application approval process. The inspections of licenses are conducted at intervals in years corresponding to the priority.

- Priority 1 = every year
- Priority 2 = 2 years
- Priority 3 = 3 years
- Priority 4 = 4 years
- Priority 5 = 5 years
- Priority 6 = 6 years

In addition, some inspection priorities are "Priority T." These are contacts, made by telephone and documented in the file, to determine the status of the licensees' activities, to assess compliance of Priority T licensees, or to exchange information with the licensee. Examples such as reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an inspection, or calling to determine whether the licensee actively possesses licensed material are types of telephonic contacts.

Types of routine inspections

In the *Inspection Procedures Manual*, the types of inspections, routine, non-routine, and reciprocity, are identified. Each of these inspections has a list of requirements that the inspectors will follow. This includes timelines, frequency issues and reporting requirements. An example of what is in the manual follows:

1. **Initial Inspections.** These shall be conducted between six months and one year after licensed material is received and operations have begun.
2. **Periodic Inspections.** These inspections shall be conducted at intervals in years corresponding to the inspection priority.
3. **Follow-up Inspections.** These inspections should occur within six months of the most recent inspection, should be conducted when numerous violations were identified during a previous inspection, for repeated poor performance, or, where there has been a significant breakdown in management control.

The intervals between inspections is addressed in the manual, other than initial inspections, to achieve the goal of cost saving and efficient use of staff time, inspections may be performed at a frequency other than that defined by the priority system. However, the frequency of inspection of a licensee should not fall outside the following points:

<u>Type of Inspection</u>	<u>Acceptable Frequency</u>
Initial Inspection	Within one year after operations have begun.
Inspection of licenses in Priorities 1, 2, and 3	Interval between inspections may vary by no more than 25 percent.
Inspection of licenses in Priorities 4, 5, 6, and 7	Interval between inspections may vary by a year.

Inspections of General Licenses are not required on a routine basis. However, inspections should be made to resolve allegations, complaints, or other indications of an unsafe practice, or when the inspection is directly pertinent to an inspection involving a specific license. As MDH staff develops, some General Licenses will be incorporated into an inspection program. The Radiation Control Unit will identify which type of General Licenses should be inspected and establish inspection frequencies.

Types of non-routine inspections

In the Inspection Procedure Manual, the types of non-routine inspections are addressed in reference to types, timelines, frequency and reporting requirements. An example of what is in the manual follows:

1. **Telephone Contacts and Inspections.** Contact by telephone is a good way of keeping in touch with licensees who have never been inspected or are inspected infrequently. Telephone contacts should be limited to General Licensees and Priority T licensees. A telephone questionnaire may be useful during this type of communication. After such contact, a licensee should be sent written documentation describing the findings.

MDH has established telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection has been completed and the inspector has determined that the licensee is satisfactorily implementing the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at five-year intervals for the duration of the license.

2. Telephone Inquiries. Telephone inquiries are made for a variety of reasons. These may include: (a) reminding a licensee that its license is about to expire; (b) determining if a licensee has an active program that would warrant an inspection. A previous visit may have determined that no licensed material had been received or, (c) determining if a licensee is still maintaining its licensed material in secure storage.

3. Expired or Terminated Licenses. Notification that a license has expired or is being processed for termination will require prompt action to ensure that licensed material has been properly disposed and areas where material was used can be safely released for unrestricted use.

4. Abandonment of Licensed Material or Licensed Activities. Often, the fact that a licensee has moved from the location specified in the license is first discovered when the post office returns mail. On other occasions, inspectors have gone to the designated location and found it abandoned.

5. Allegations. Occasionally, the Department will receive telephone calls or written communication from individuals who claim they are being exposed to hazardous radioactive materials at work. In other cases, they claim someone is releasing radioactive material into the environment or a company that works with radioactive material was involved in a serious radiation incident and did not report it.

6. Reactive Inspections. Because these inspections are reactive, they cannot be scheduled on a routine basis. They typically result in response to a licensee's report of an incident.

Reciprocity inspections

It is the Radioactive Materials Unit's objective to inspect all Priority 1 and 50 percent of all Priority 2 and 3 licensees entering the state under reciprocal recognition of an NRC or another Agreement State's license each calendar year.

Preparation for an inspection is outlined in the Inspection Procedures Manual because no matter how skilled an inspector might be, a quality inspection can never be performed without an in-depth preparation for that inspection. This applies equally to both entry level and senior inspectors

Announced vs. unannounced inspections

One of the questions that must be answered even before the review process begins is, "Should this inspection be conducted on an announced or unannounced basis?" The answer depends on the type of inspection that is going to be conducted and why the inspection is being conducted.

The Inspection Procedures Manual addresses many other topics such as the "Format for Narrative Reports" in section III and "Processing Inspection Reports" in section IV.

The Inspection Procedures Manual is to assist the inspector in creating an inspection report that can be an effective enforcement tool, the inspection report must be completed in a timely manner. This is especially true if violations have been identified. The inspectors are expected to be familiar with the procedure requirements outlined in the manual.

Appendix A of the manual includes examples of the forms to be used by the inspector. These may be reviewed, as the Inspection Procedure Manual is included in the application package.

Equipment

Calibration equipment used by the Radiation Control Unit is calibrated or response-tested annually by the following agency:

Iowa Homeland Security Emergency Management
Radiation Maintenance and Calibration Shop
Building W-20, Camp Dodge
7700 Northwest Beaver Drive
Johnston, Iowa 50131-1902

The Exploranium meters will be calibrated by the following company:

Exploranium G.S. Limited
6108 Edwards Boulevard
Mississauga, Ontario L5T 2V7

MDH INSTRUMENT INVENTORY

TAB	INSTRUMENT MFGR.	MODEL	SERIAL NO.	LAST CAL. DATE
1	ICN	DMC2000X	254690	06/17/03
2	ICN	DMC2000X	245770	06/17/03
3	ICN	DMC2000X	258846	06/17/03
4	ICN	DMC2000X	258862	06/17/03
5	Eberline	RO-2A	1159	08/03/03
6	Eberline	PAC 1SA	5004	08/20/03
7	Eberline	E-520 w/ HP 270 probe	4115	08/01/03
8	Eberline	E-520 w/ HP 270 probe	2242	07/15/03
9	Eberline	E-520 w/ HP 270 probe	4117	07/15/03
10	Eberline	E-520 w/ HP 270 probe	4112	03/01/04
11	Eberline	E-520 w/ HP 270 probe	4113	03/01/04
12	Eberline	E-520 w/ HP 270 probe	4114	03/01/04
13	Eberline	E-520 w/ HP 270 probe	2233	03/01/04
14	Eberline	E-520 w/ HP 270 probe	2245	03/01/04
15				
16	Eberline	ASP-1 w/ 2" Scintillation probe	332	08/21/03
17	Eberline	ASP-1 w/ alpha probe	2890	08/03/03
18	Exploranium	GR-135 MINISPECT	2595	12/13/03
19	Exploranium	GR-135 MINISPECT	2596	10/23/03
20	Exploranium	GR-130 MINISPECT	9612	12/12/03
21	Exploranium	GR-130 MINISPECT	9913	10/17/03
22	NDS Products	RA-500	44036	06/11/04
23	NDS Products	RA-500	44037	06/11/04
24	NDS Products	RA-500	44038	06/11/04
25	NDS Products	RA-500	44039	06/11/04
26	Radiation Alert	Inspector	05588	08/20/03
27	Victoreen	190	107367	06/27/03
28	Victoreen	190	107737	07/14/03
29	Victoreen	190	107738	07/14/03
30	Victoreen	450P	1126	07/15/03
31	Victoreen	450P	2363	08/22/03
32	Victoreen	450P	2378	06/11/04
33	Victoreen	450P	2381	06/11/04
34	Reuter-Stokes	100 mR/hr HPIC	N-4510	11/10/00
35	Reuter-Stokes	100 mR/hr HPIC	N-4518	02/01/99

**CAPACITY FOR RADIATION CHEMISTRY ANALYSES
BY THE MINNESOTA DEPARTMENT OF HEALTH
PUBLIC HEALTH LABORATORY**

The Public Health Laboratory of the Minnesota Department of Health is responsible for providing laboratory services and technical support to Radiation Control and Drinking Water Protection in the Environmental Health Division of the Minnesota Department of Health, as well as the Minnesota Department of Public Safety, in the event of an accident at either of the two nuclear power plants in Minnesota. The laboratory maintains an emergency response capability in the event of a large-scale nuclear power plant accident. In such an emergency, a large number of environmental and food samples would be rapidly measured to evaluate the accident's impact on public health and the protective actions needed.

The responsibility of the Public Health Laboratory in this program is three-fold. First, the laboratory maintains a radiochemical unit that monitors field samples routinely to determine if radioactive materials have been released from a nuclear power plant in the event of a minor accident (or indeed during routine operation) by monitoring sites adjacent to the power plants. The laboratory monitors air, surface water, vegetation, milk, and foodstuffs to identify and quantify man-made radionuclides, such as the beta emitters: strontium-89, strontium-90, and tritium, and the gamma emitters: cobalt-60, cesium-137, and iodine-131.

Secondly, the Public Health Laboratory conducts state and federally mandated radioactivity analyses in public drinking water. Chemists in our radiation chemistry unit routinely screen for low natural radioactivity gross alpha measurements and trace levels of natural radioisotopes such as radium, radon and uranium in public drinking water. This routine work is essential for maintaining proficiency, expertise, and equipment in a state of readiness.

Thirdly, the Public Health Laboratory provides trained personnel that constitute the Laboratory Nuclear Power Generating Plant Emergency Response Team. Team members could provide 24-hour coverage in the event of a release of radioactive material from a nuclear power plant. They are trained in sample receipt, screening, triaging, documenting, performing, and reporting laboratory analyses. These analyses would be critical to determining if a release occurred, the area of impact, which radioisotopes were involved (and what protective action is appropriate), and progress toward recovery and remediation. The laboratory's emergency response team participates in refresher training and practical sessions annually.

In 2004, the Public Health Laboratory's radiation chemistry unit has one supervisor and 2.5 analysts. Equipment includes: two liquid scintillation counters which are used to quantify radon and tritium; three gas-proportional counters to identify and quantify alpha and beta emitters (and one of these also measures gross-gamma emissions); and four high-purity germanium gamma detectors to identify and quantify gamma emitters.

The Public Health Laboratory is certified by the Environmental Protection Agency (EPA) and is routinely inspected by the Nuclear Regulatory Commission and the EPA. The laboratory maintains a comprehensive quality assurance program.

4.4.2

Inspections
Quality
Assurance

4.4.2

INSPECTIONS QUALITY ASSURANCE

Minnesota's procedures addressing peer review, supervisory review, and other methods to assure the quality of inspections and inspection reports can be found in both the *Inspection Procedures Manual* and the *Licensing Procedures Manual* under the section "Peer Review Process." This section is excerpted and included in this section of the application. The State's written procedures for guiding program staff can be found in the aforementioned documents as well as in the *Licensing and Inspections Qualification Journal* and the *Emergency Response Manual*.

SUMMARY

The inspector or the team leader in the case of a team inspection, are responsible for submitting the final report to the Unit Supervisor for final review. If the inspection was a team inspection, each of the team members gets a copy of the report at the same time as the Unit Supervisor for review.

Appendix A of the enclosed Inspection Procedure Manual includes examples of the communication tools used to share information with the other inspectors, license reviewers and Unit Supervisor. This is all part of the internal quality assurance procedure that ensures all inspectors and license reviewers are using the correct procedures and are involved in the entire process.

The following is an example of the peer review process section in both the *Inspection Procedures Manual* and the *Licensing Procedures Manual*:

Peer Review Process

The quality assurance for licensing procedures and licensing review is a three-fold process. The first involves cross training for both the licensing individuals and the individuals who will be the inspectors in the program. Second is the process of using a checklist to complete the license review process. Third, a follow-up peer review process has been implemented. This consists of a peer review and supervisory review. Peer reviews provide the following benefits:

- Consistency in licensing actions
- Quality assurance
- Educational opportunities for less experienced licensing staff
- Communication between licensing and inspection staff

The 30-day completion objective should always be met when licensing actions involve health and safety related issues. However, the quality review and approval will always take precedence over an arbitrary completion deadline.

A supervisory review of new, amended, and renewed licenses is required. A supervisory review is not required for deficiency letters.

4.4.3

Inspection
Administrative
Procedures

4.4.3

INSPECTION ADMINISTRATIVE PROCEDURES

Minnesota's inspection program administrative procedures can be found in the *Inspection Procedures Manual*.

The procedure for the format of the inspection reports is included in Section III of the Inspection Procedures Manual. Narrative reports must include the following information:

General information

- Type of inspection (announced or unannounced)
- Notification of, and accompaniment by, representatives from other agencies
- Person interviewed

Inspection history

- Brief summary of results of previous inspections

Program

- Type of program
- Uses for the material
- Form of isotopes
- Physical inventory of isotopes with quantity
- Rate of procurement and use
- Method of control

Other issues are also taken into consideration, such as organization, administrative control, facilities, equipment, personnel monitoring and exposure determination, radiation surveys and/or evaluations, posting and labeling, transportation, leak tests, waste disposal, reports of theft and loss, reports of overexposures and excessive levels or concentrations, records, independent measurements, license conditions and a management discussion.

The above topics are to be included in a narrative report of an inspection in some form that any reviewer or the Unit Supervisor will be able to comprehend the inspection.

The processing of the inspection reports found in Section IV of the Inspection Procedures Manual deals with how the report must be completed in a timely manner. Violations must be documented and the report completed within 30 days. This time frame also includes time for the Administrative Penalty Order to be issued within 30 days of the inspection date.

The communication forms for the inspections and the forms for intra-unit review are found in Appendix A of the Inspection Procedures Manual, which has been excerpted and included in the following pages.

Radioactive Materials Information System

The Radioactive Material Information System (RAMIS) development project was created at the request of the Radiation Control Unit. RAMIS is an interactive database application used by the Radiation Control Unit to meet the requirements of the NRC as an agreement state. Per department standards for large system development, this system utilizes an Oracle client-server database. The database is currently under development and should be completed near the end of 2004. Many of the components are similar to the X-ray database, which is scheduled for completion in August of this year.

The system is designed to track radioactive materials licenses and inspections. In addition to the expiration date most recent amendment number, RAMIS tracks standard license information including the licensee's name and address, location(s) of use, program codes, possession limits, and devices (if applicable).

Inspection intervals consistent with NRC Inspection Manual 2800 will be incorporated to develop inspection schedules. The application will manage the essential inspection and compliance activity information, based on the statute and program implementation of it, for a program. The system will be able to notify personnel when items are due and allow personnel to examine past compliance activities to ensure that their currently contemplated activity is consistent with past similar activities. The system will accomplish the following:

- Standardized recording of inspection and compliance activity information without the necessity of the regulatory program maintaining its own tracking system structure.
- Provide the ability to examine past inspection and compliance activity information to promote consistent use of compliance tools.
- Provide, if desired, the system notify staff of dates when responses to compliance communications are due.
- Report information, in a controlled, standardized manner, of activities when such information is requested by parties outside the division without the necessity of manual compilation of the requested information.
- Provide a report of staff activities for performance review purposes.

Consistent with MDH policy, RAMIS is designed to capture licensee staff and their associated roles. For example, the names of a medical broad scope licensee's administrator, radiation safety officer, medical physicist, nuclear pharmacist, as well as the authorized users will be accessible to Radiation Control staff.

Finally, billing and payments is an integral component of the system.

**RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

**MEMORANDUM TO LICENSE REVIEWER
AREA(S) THAT SHOULD BE ADDRESSED DURING THE NEXT LICENSE REVIEW**

Inspector:

Date:

Licensee:

License Number:

Specific license condition, application, or letter that needs to be reviewed. Identify type and date of document.

Provide a brief description of the issue associated with the license. If there are numerous issues, the items should be numbered. Use additional sheets if necessary.

**RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

**MEMORANDUM TO LICENSE INSPECTOR
MATTER(S) TO BE REVIEWED DURING THE NEXT INSPECTION**

Staff Member:

Date:

Licensee:

License Number:

Type of matter to be reviewed during the next inspection:

Instructions or comments:

**RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

CONVERSATION RECORD

- Outgoing call
- Incoming call

Date:

Licensee:

License Number:

Summary of Discussion:

Required actions:

Inspector:

Date:

Licensing and Inspection Tracking Form

Originator:	<input type="checkbox"/> New License <input type="checkbox"/> Renewal <input type="checkbox"/> Amendment	No.:	<input type="checkbox"/> Deficiency Letter <input type="checkbox"/> Inspection Report <input type="checkbox"/> Other
-------------	--	------	--

Facility:

License Number:

	Initials	Date
Draft Completed		
Draft Typed		
Originator		
First Reviewer		
Originator		
Final Typed		
To GFJ for Review		

Notes:

Inspections	Date of Inspection:			
Number of non-compliance items:				
Pre-inspection preparation time:				
On-site time:				
Travel time:				
Off-site report preparation time:				
Review plan of correction:				
Total hours:				

Licensing Activities				
New License				
Amendment				
Renewal				

4.5.1
Routine
Enforcement
Procedures

4.5.1

ROUTINE ENFORCEMENT PROCEDURES

Minnesota's procedures for assuring the fair and impartial administration of regulatory law can be found in the *Enforcement Applications Manual*. This manual also establishes standard methods of communicating sanctions to the licensee. Also included in this section are a *Sample Notice of Violation* and *Sample Cover Letter*.

SUMMARY

The MDH enforcement program is designed to assure compliance with the public health and safety issues when dealing with radioactive materials. Inspections are intended to be educational opportunities for licensees, and the emphasis for any enforcement program should be on compliance rather than on punishment. Based on this thought, the Enforcement Applications Manual was designed and is included in this application for review. It is intended to provide information relevant to the radioactive materials aspect of the Department's mission. It should also, provide additional information for radioactive materials inspectors. The Administrative Penalty Plan provides the "penalty" aspects of the enforcement program.

There are two categories of enforcement actions. The first category is a routine enforcement action and is the sanction of choice for inspections performed in which violation have been identified. Routine enforcement is taken whenever identified violations are of Severity Level IV or V. The civil penalties for Severity Level IV or V violations are "forgivable." Therefore, the licensee will only receive a "Notice of Violation (NOV)."

Severity Level III violations are the threshold of the escalated enforcement program, which is the second category. Escalated enforcement is the sanction of choice for less than one percent of all inspections in which violations have been identified. Further escalated enforcement issues are discussed in Section 4.5.2 of this application.

The principal criteria for determining whether routine enforcement, addressed in a NOV, or escalated enforcement actions, addressed in a APO, is appropriate is to determine the Severity Level of each violation identified during an inspection. Referring to each specific violation in the Minnesota Enforcement Applications Manual can aid in making this determination.

One of the first and absolutely essential things the inspector must do before considering any enforcement action is determine precisely what a licensee or registrant did or did not do that *appears* to violate a regulatory requirement.

It should be emphasized that a regulatory department must prove a licensee or registrant has violated a regulatory requirement. It is NOT the licensee's responsibility to prove it is innocent.

The inspector makes a persuasive argument to demonstrate a licensee or registrant has violated one or more regulatory requirement by identifying and address, in detail, several essential elements which are described in the Minnesota Enforcement Applications Manual.

How does an inspector make a persuasive argument to demonstrate a licensee or registrant has violated one or more regulatory requirements? The inspector must identify and address, in detail, several essential elements.

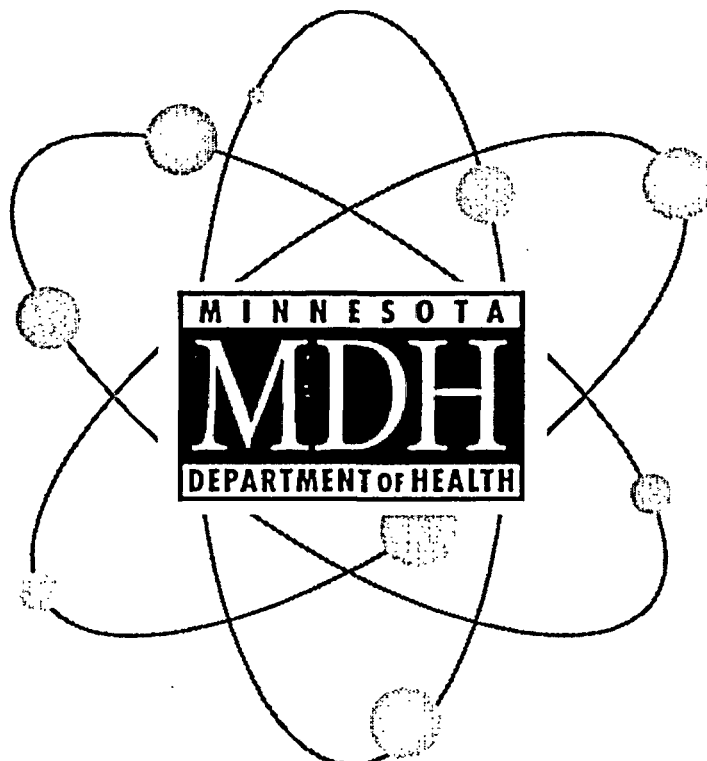
- What happened (description of the event)?
- When did it happen (showing exact date or dates)?
- How or why it happened (equipment failure, human error)?
- How many times it happened (were violations repetitive)?
- How do we know it happened (e.g., inspector saw it happen, a licensee's or registrant's records documented the occurrence, the licensee or registrant told us what happened)? In other words, on what basis did we conclude a violation occurred?

Each of these elements will be addressed in a Draft Inspection Report Form by the inspector. Routine enforcement actions are taken whenever the violations identified are either Severity Level IV or V and, in some cases, Severity Level III. There is an exception to this principle; a significant number of Severity level IV or V violations that collectively demonstrate a persistent break down in the licensee's management program, which has allowed the series of violations to occur.

The severity of violations, factors used in the characterization of violations, enforcement actions involving individuals, escalated enforcement options, corrective action, licensee performance, prior opportunity to identify, multiple occurrences, duration, orders, impoundment, and enforcement conferences are some of the facets of the enforcement plan that the license reviewers and inspectors will be knowledgeable and have a good understanding of. These facets of the enforcement plan are outlined further in the Enforcement Applications Manual.

The explanation of the Severity Categories for Health Physics, Transportation of Radioactive Materials, Certain uses of Radioactive Materials, and Miscellaneous Matters are all found in Part IV of the Enforcement Applications Manual.

MINNESOTA DEPARTMENT OF HEALTH



ENFORCEMENT APPLICATIONS MANUAL

The logo is circular with the text "Radioactive Materials Group" at the top, "Minnesota Department of Health" at the bottom, and "RAM" in the center. In the center is a stylized black and white illustration of a moose or elk head.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

FOREWORD

Despite all attempts to make a smooth transition of the radioactive materials programs from federal to state control, the process will not be seamless. The biggest change to the regulated community will be in the enforcement portion of the Minnesota Department of Health's program. For example, although it would seem intuitive to sequence the severity of violations with Severity Level I as the least egregious, the radioactive materials users have been working under the opposite numbering system for many years. The Radioactive Materials Group's Enforcement Applications Manual accommodates this long-standing numbering practice because it was deemed more appropriate to reduce the impact on the regulated community than to force change simply to conform to existing MDH terminology. Nevertheless, occasionally "Notices of Violation" will become "Administrative Penalty Orders" and the licensees must deal with forgivable and non-forgivable civil penalties.

To place things in perspective: the Radioactive Materials Group started with an Enforcement Applications Manual, which mirrored the U.S. Nuclear Regulatory Commission's enforcement program. The Enforcement Applications Manual was modified to incorporate the Division of Environmental Health's *Plan for the Use of Administrative Penalty and Cease and Desist Authority*. Both are designed to assure compliance with the Minnesota Department of Health's rules.

For the most part, the documents are compatible and the underlying philosophies similar:

- a. Inspections are intended to be educational opportunities for licensees.
- b. The emphasis for any enforcement program should be on compliance rather than on punishment.

The Enforcement Applications Manual is intended to provide information relevant to the radioactive materials aspect of the Department's mission. In addition, it should provide additional information for radioactive materials inspectors. The Plan provides the "penalty" aspects of the enforcement program. Therefore, as often as possible, the text of The Plan has been included.

Hopefully, in a few years this page can be removed – discarded as ancient history. If so, we all have met our objectives.

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PART 1 - INTRODUCTION

GENERAL

The Minnesota Department of Health's (MDH) rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation.

One of the more significant activities regulated by the State is the possession and use of radioactive material or of radiation producing machines. Issuing a "Specific License" or "General License" accomplishes this for the radioactive material and a "Registration" is issued for radiation producing machines. The State of Minnesota also regulates persons who enter the State under a reciprocity agreement and are using radioactive material that is regulated in accordance with the provisions of a Specific License issued by another Agreement State or by the Nuclear Regulatory Commission. Reciprocity is also granted for persons bringing radiation producing devices into the state.

THE PURPOSE OF THE ENFORCEMENT APPLICATIONS MANUAL

Agencies have developed a variety of programs and written documents to assist in issuing licenses, registrations, or permits to practice and for conducting inspections of these programs.

A review of enforcement programs throughout the country shows that many elements of the enforcement process are not clearly understood by regulatory personnel. In many cases, regulatory agencies have not been able to demonstrate, based on responses from licensees, registrants, and certificate holders that, after enforcement action had been taken, prompt and adequate corrective action had resulted.

Little formal training in enforcement activities has been available to Agreement State regulatory personnel. This scarcity of information or training has resulted in a need to create an Enforcement Application Manual that would make information available and help Agreement State personnel carry out an effective enforcement program.

This manual is written, in part, as a tutorial and rather than a textbook. It discusses enforcement principles and explains not only what to do when enforcement action is indicated, but also how it is to be done. **This manual is based on, and should be used in conjunction with, the Environmental Health Division of the Minnesota Department of Health *Plan for the Use of Administrative Penalty and Cease and Desist Authority (The Plan)*.**

TYPES OF ENFORCEMENT ACTIONS

There are two categories of enforcement actions. The first category is a routine enforcement action and is the sanction of choice for inspections performed in which violations have been identified. Routine enforcement is taken whenever identified violations are of Severity Level IV or V. The civil penalties for Severity Level IV and V violations are "forgivable." Therefore, the licensee will only receive a *Notice of Violation (NOV)*.

Severity Level III violations are the threshold of the escalated enforcement program, which is the second category. Escalated enforcement is the sanction of choice for less than one percent of all inspections in which violations have been identified. Deficiencies of this severity are addressed in an *Administrative Penalty Order (APO)*. For Severity Level III violations, the Radioactive Materials Group staff must review the inspection report to determine if the penalty should be forgivable or non-forgivable in accordance with The Plan.

Non-forgivable enforcement action should be taken whenever the identified violations are of Severity Level II or I.

As noted above, the principal criteria for determining whether routine enforcement (addressed in a NOV) or escalated enforcement action (addressed in an APO) is appropriate is to determine the Severity Level of each violation identified during an inspection. Referring to each specific violation in the Minnesota Enforcement Applications Manual can aid in making this determination.

A VIOLATION vs. AN ENFORCEMENT ACTION

One of the first and absolutely essential things the inspector must do before considering any enforcement action is determine precisely what a licensee or registrant did or did not do that "appears" to violate a regulatory requirement. Herein lies the weakest link in the entire inspection and enforcement process.

It should be emphasized that a regulatory Department must prove a licensee or registrant has violated a regulatory requirement. It is *not* the licensee's or registrant's responsibility to prove it is innocent.

How does an inspector make a persuasive argument to demonstrate a licensee or registrant has violated one or more regulatory requirements? The inspector must identify and address, in detail, several essential elements.

1. What happened (describe the event)?
2. When did it happen (show exact date or dates)?
3. How or why it happened (equipment failure, human error)?
4. How many times it happened (were violations repetitive)?
5. How do we know it happened (e.g., inspector saw it happen, a licensee's or registrant's records documented the occurrence, the licensee or registrant told us what happened)? In other words, on what basis did we conclude a violation occurred?

It should not be necessary to remind an inspector to address each of these essential elements in a Draft Inspection Report Form. It should be understood that failure to obtain and record this information might jeopardize a proposed enforcement action against a licensee or registrant because the Department will not be able to substantiate a violation.

THE EVOLUTION OF A ROUTINE ENFORCEMENT ACTION

Let's analyze a violation from a hypothetical Notice of Violation issued to a hospital that conducts a conventional nuclear medicine program and see if it meets the above criteria.

In this example, the Notice of Violation stated a licensee was in violation of rules because it failed to survey packages of Iodine-131 at the time of receipt. Upon reading the inspector's report, only what is stated above was found. No additional facts relating to the citation were available. In the Notice of Violation, the licensee is told that it must describe any corrective action taken, when it was taken, and what will be done in the future to prevent a similar occurrence.

Since the licensee does not want to antagonize the regulatory Department or the inspector, it admits to the violation and states that in the future all shipments of Iodine-131 will be surveyed at the time of receipt. This is often a licensee's total response. Clearly, the questions set forth in the Notice of Violation have not been answered. Unfortunately, in many cases, regulatory agencies consider this an adequate response. The case is closed and the license file is returned to the file cabinet until the next inspection or until some unrelated administrative action, such as a license renewal or license amendment, is taken.

The first and obvious question should be: "Is the citation valid?" Note: the question is not, did the licensee do something wrong, instead, is the citation valid. The simple answer is "no!"

This might be confusing since many citations have been and are still being written this way. Before one can determine if something is wrong with the citation as stated, it is necessary to analyze the regulatory requirement and all facts the inspector obtained or failed to obtain relating to the "apparent violation."

First let's look at the rule and see what is the requirement. This rule has two parts:

The first part requires that a licensee or registrant monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form. This would seem to be the appropriate regulatory requirement to cite since hospitals routinely receive shipments of Iodine-131 and these shipments are not in the form of a gas or in special form. Perhaps this is what the inspector had in mind when the citation was written. However, the citation has serious flaws, which flaws make the citation invalid.

The second part requires that a licensee or registrant monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity. The Type A quantity for Iodine-131 (assuming it isn't special form) is 10 curies. Since a trained inspector would know that a hospital will never receive a shipment as large as 10 curies of Iodine-131 the rule will never apply to a nuclear medicine program.

If the inspection report is responding to the first part of the rule, the inspection report is flawed because it does not document when or if the licensee received a package containing Iodine-131. If such a package was never received, a survey would obviously not be required.

One could argue that if the licensee did not violate a regulatory requirement, it would not admit it had done something wrong and agree to take corrective action. However, there are a number of plausible reasons for the licensee's actions. Perhaps, at the conclusion of the inspection the inspector failed to explain the details of the violation during an exit meeting. As a result, the licensee may not have been told of the proposed violation or did not fully understand it. Many licensees have learned it was easier and safer to agree to fix a problem even though the licensee does not understand the problem.

The inspector may claim the licensee was fully informed of the details of the violation during an exit meeting. However, if the inspector were unable to document that the licensee ever received a shipment of Iodine-131, it would be impossible to support such a claim.

The inspection report used to document and support this violation must state that on a specific date or on several specific dates a licensee or registrant received packages containing a specific amount of Iodine-131 in a particular physical form. Moreover, the report must include statements made by licensee personnel that no surveys were made at the time the package(s) was received. These details *must* appear in the report if the violation is to be supported.

If information in the citation were complete, the licensee could check its records for the dates in question and substantiate whether it did or did not receive shipments of Iodine-131. It could then respond accurately and truthfully to the issues in the Notice of Violation. In this example, if the licensee had sufficient details to show the citation was in error, it should deny the citation and state why the Notice of Violation is invalid. However, taking into account the second portion of the rule, the failure to monitor the Iodine-131 shipments does not represent non-compliance. A citation should not have been issued.

In addition to an understanding of the applicable rules, there are essential elements that must be explored and documented in an inspection report before any enforcement action is attempted. The following discussion will address each of the elements and explain why each must be addressed completely.

1. What happened
2. When it happened
3. How or why it happened
4. How many times it happened
5. How we know it happened

What Happened

Perhaps the most important of the five elements is determining exactly what happened. This involves getting all the details from licensee management, from individuals who were involved, and if applicable any individuals who were or may have been exposed to radiation doses or radioactive contamination. The primary objective is not to see if a violation of regulatory requirements can be identified but, instead, to find out exactly what happened. Once the facts of an occurrence have been identified and documented, an inspector can objectively review the findings to see if there are any regulatory implications. An enforcement action should be proposed only if there are accurate documented inspection findings. An inspector should never propose an enforcement action based solely on speculation of what is the most likely cause of the violation. **IT IS THE INSPECTOR'S RESPONSIBILITY TO PROVE A VIOLATION OCCURRED.** In other words, the licensee is innocent until proven guilty.

Occasionally, a situation arises that motivates an inspector to initiate some type of enforcement action. For example, a licensee's personnel exposure report shows an individual's whole body dosimeter received a dose of 10 rem. This, if it is a valid record of a dose received by an individual is justification for taking a significant enforcement action. However, without knowing a great deal more about the reading, it is not appropriate to initiate any enforcement action at this point.

The inspector needs to do something; but what? First, facts must be gathered to determine if the dosimetry reading represents a valid dose to an individual or is only an exposure to the device itself. This can best be accomplished through a routine inspection, a special inspection, or an investigation. The exact techniques to be used for each of these actions are beyond the scope of this Manual. Asking the Radiation Control Supervisor or referring to the Inspection Procedures Manual (or training course material that is available to inspectors) can address such questions.

When It Happened

Assume that the personnel exposure records referred to above were an accurate representation of a dose actually received by a radiation worker. The inspector needs to know when the event occurred vs. when the inspector learned about it. Assume the individual who received a dose in excess of regulatory limits did so about a year ago but that it was first discovered while an inspector reviewed personnel monitoring records during a routine inspection a few days ago.

This somewhat complicates the enforcement picture. It started with a single violation for permitting an individual to receive a radiation dose in excess of regulatory limits. It has since been determined that the event occurred a year ago and that the licensee either was not aware of the event or was aware of the event and failed to report it to the Department. In either case, it appears another violation of a Department requirement, which is the failure to report the event, has been identified.

We must now return to the first essential element and find out what happened. The licensee was required to report this event to the Department but it did not. We must determine:

- (1) Did responsible licensee management fail to review personnel monitoring records,
- (2) Did licensee management know about the event but willfully failed to report it, or
- (3) Did responsible licensee management know about the apparent event and without any meaningful evaluation assumes the personnel monitoring record was in error.

Regardless of which situation applies, it is likely that we have identified another violation. There may be further violations if it is determined that not only did licensee management fail to perform routine reviews of its personnel monitoring records, as required, but also failed to report the event when it did discover the event.

How or Why It Happened

The how or why a violation occurred is extremely important because it enables the inspector to conclude whether licensee or registrant management acted responsibly in overseeing regulated activities. Some violations occur due to legitimate accidents that cannot be prevented; however, most violations result from deficiencies in the way that a licensee or registrant conducts its program. While gathering information about how or why a violation occurred, it should be possible to determine the following:

- (1) Were personnel who work in controlled areas properly trained?
- (2) Were these individuals provided with a safe working environment?
- (3) Did management make periodic surveys and evaluations of radiological personnel as well as facilities to ensure that radiological hazards were being adequately controlled?
- (4) Did radiation workers and management personnel properly document the various activities that were carried out under the provisions of its license or registration?

Negative findings in any of these areas could provide a basis for additional violations of regulatory requirements.

How Many Times Did It Happen

The number of times a violation or unsafe condition occurs is a good indicator of the quality of management. If the licensee's management identifies a violation immediately or shortly after it occurs, documents the violation, and initiates effective corrective action, it would get a positive rating from the Department and it is quite possible that some mitigation of the enforcement action may be appropriate. This would be especially true if the corrective action was so effective that the same or a similar violation did not recur. Conversely, if licensee management fails to identify (or ignores) a violation or unsafe condition when it should clearly have done so, it is quite likely the licensee would be found guilty of committing another violation. Likewise, if management identifies a violation or unsafe condition but takes no effective action to correct the situation, the licensee would be cited for another violation.

One of the most important factors the inspector must evaluate after a serious safety event or violation occurs is whether a licensee's or registrant's corrective action was effective in preventing a repeat of the same or similar violations.

How Do We Know It Happened

To ensure that information relating to a licensee's or registrant's activities can be correctly evaluated, an inspector must gather all information in a precise and objective manner. It is also very important to identify the source of all information contained in an inspection report. The amount of detail required is related to the significance of information that is being gathered.

Whenever there are apparent violations of regulatory requirements, information should be documented accurately so a competent person who has experience working with rules would arrive at the same conclusion as the inspector.

There are several ways one can obtain valid information regarding the conduct of a licensed program:

1. The inspector observes licensee or registrant personnel as they perform or fail to perform specific activities during an inspection. For example, during a radiography inspection, the inspector observes a radiographer making a series of radiographic exposures but notes that the radiographer failed to perform a direct reading radiation survey after each exposure.
2. The inspector reviews various records prepared by the licensee or registrant and observes that the activities have not been documented or that the licensee or registrant has conducted activities in ways that are not consistent with regulatory requirements. (This assumes that the inspector believes with reasonable certainty that the records being reviewed have not been falsified.) If the review of records identifies problems, the inspector should accurately document those issues. An even better method would be to obtain actual photocopies of the records, if the licensee or registrant is willing to provide copies of its records to the inspector.
3. While interviewing licensee or registrant employees, violations of regulatory requirements may be identified. In that case, the inspector should carefully document the problem and if necessary quote in the inspection notes exactly what the employee said. In some cases the individual interviewed may not be an employee of the licensee. However, if concerns are identified, it is appropriate to quote individuals who are not employees of the licensee or registrant.

ROUTINE ENFORCEMENT ACTIONS

Routine enforcement actions are taken whenever the violations identified are either Severity Level IV or V and, in some cases, Severity Level III. There is an exception to this principle: a significant number of Severity Level IV or V violations that collectively demonstrate a persistent breakdown in the licensee's management program, which has allowed the series of violations to occur.

ESCALATED ENFORCEMENT ACTIONS

The escalated enforcement process is more complicated because there are many more options available as well as many decisions that must be made before the process can begin. Before attempting to take an escalated enforcement action, it is essential that the inspection and enforcement staff have a clear understanding of each kind of escalated enforcement option and what factors should be considered before choosing the appropriate option. When escalated enforcement is involved, it is often beneficial to ask the question: "What is the action intended to correct?" The ultimate goal of any regulatory action should be to correct the root cause of the problems. It becomes even more essential in escalated enforcement situations.

It should also be noted that, in some cases, there might be more than one acceptable enforcement action. If the violations are particularly egregious, several escalated actions may be taken at the same time.

PART II - THE RADIOACTIVE MATERIALS GROUP'S ENFORCEMENT PROGRAM

The goal of this enforcement program is to promote and protect the environment, the health and safety of the public, and employees' health and safety, by:

- Ensuring compliance with Minnesota's rules and license conditions;
- Obtaining prompt correction of violations and adverse conditions that may affect safety;
- Deterring future violations and occurrences of conditions adverse to quality;
- Encouraging the prompt identification and reporting safety of problems
- Promoting improvement of regulated entity's performance and, by example, that of all industry.

Enforcement actions depend on the circumstances of each case and require discretion and careful consideration of enforcement policies and procedures. Regulated entities that do not achieve and maintain adequate levels of protection for the public and their employees will not be permitted to conduct regulated activities. (The term "regulated entity," as used in this Enforcement Program, includes facilities that license radioactive materials or registration of radiation machine facilities or tanning facilities.)

SEVERITY OF VIOLATIONS

Regulatory requirements have various degrees of safety or environmental significance. The relative importance of each violation must be evaluated as the first step in the enforcement process. A violation is normally categorized according to five levels of severity to show the relative importance. Severity Level I violations are the most significant and Severity Level V violations are the least significant.

Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public health and safety. Both Severity Level I and II violations should impose a non-forgivable civil penalty. Additionally, Severity Level I violations require notification of the media to avert serious health and safety consequences. Such notifications require coordination with the Division communications staff.

Severity Level III violations are cause for significant concern. Severity Level III violations may be considered for escalated enforcement but do not mandate such actions.

Severity Level IV violations are less serious but are of more than minor concerns; i.e., if left uncorrected, such violations could lead to a more serious concern.

Severity Level V violations are of minor safety or environmental concern. These violations are usually record keeping issues.

FACTORS USED IN THE CHARACTERIZATION OF VIOLATIONS

The Department reviews each case being considered for enforcement action on its own merits to ensure the severity of a violation is characterized at the level best suited to the significance of the particular violations.

- A. **Aggregation of Violations** - A group of Severity Level IV and Severity Level V violations may be evaluated in the aggregate and assigned a single higher severity level. It would then be classified as

a Severity Level III problem. Such actions are appropriate only if the violations have the same underlying cause or if the violations contributed to or were unavoidable consequences of the underlying problem.

Aggregating violations is done to focus the regulated entity's attention on the root causes for which enforcement action is being taken and to emphasize that several violations with a common cause are more significant.

Severity Level I and II violations are never aggregated.

B. Repetitive Violations - For a violation after the initial violation, in determining the amount of the penalty, the Division must consider the factors for an initial penalty above and also the:

- similarity of the most recent previous violation and the violation to be penalized;
- time elapsed since the last violation;
- number of previous violations; and
- response of the person to the most recent previous violation identified.

The Division uses a worksheet, called a penalty calculation worksheet, found in Appendix C of The Plan, to determine the penalty amount for repeat violations.

C. Willful Violations - Willful violations are of particular concern because the Department's program requires that regulated entities, their contractors, employees, and agents act with integrity and communicate with candor.

Willful violations cannot be tolerated by the Department. A regulated entity is expected to take significant and immediate remedial actions whenever a willful violation is identified. This will create a deterrent effect in the regulated entity's organization. Removal or termination of a person who commits a willful violation is not a requirement; however, significant corrective action by regulated entity management is expected.

The severity level of a violation may be increased if it involves careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness," as used in this Enforcement Program, includes a spectrum of violations ranging from deliberate intent to violate or falsify up to and including careless disregard for regulatory requirements. Willfulness does not include acts, which do not rise to the level of careless disregard, e.g., inadvertent clerical errors in a document submitted to the Department.

In determining the severity level of a specific violation involving willfulness, consideration will be given to such factors as:

- the position and responsibilities of the person involved in the violation (e.g., a regulated entity official versus a non-supervisory employee),
- the significance of any related violations,
- the violator's intent (careless disregard or deliberate act), and
- economic or other advantage gained as a result of committing the violation.

(The term "regulated entity official," as used in this Enforcement Program, means a first-line supervisor or above, a regulated individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on a license.)

Notwithstanding an individual's job title, severity level categorization for willful acts involving individuals who can be considered regulated entity officials will consider several factors including the position of the individual relative to the regulated entity's organizational structure and the individual's responsibilities relative to the oversight of regulated activities and to the use of licensed material.

The relative weight given to each factor when determining the appropriate severity level will depend on the circumstances of the violation. The severity level of a willful Severity Level V violation will be increased to at least Severity Level IV.

D. Violations of Reporting Requirements - The Department expect regulated entities to provide complete, accurate, and timely information and reports.

The severity level of a violation involving a failure to make a required report to the Department will be based upon the significance of and the circumstances surrounding the matter that should have been reported.

The severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances. A regulated entity will not normally be cited for a failure to report a condition or an event unless it was aware of the condition or event it failed to report. However, it will normally be cited for a failure to report a condition or event if it knew of the information to be reported, but did not recognize that it was required to make a report.

E. Inaccurate and Incomplete Information - A violation of the rules involving the submittal of incomplete and/or inaccurate information, whether or not considered a false statement, can result in the full range of enforcement sanctions. MDH recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, MDH must be able to rely on oral communications from licensee officials concerning significant information. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to factors such as:

- (1) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;
- (2) the opportunity and time available prior to the communication to assure the accuracy or completeness of the information;
- (3) the degree of intent or negligence, if any, involved;
- (4) the formality of the communication;
- (5) the reasonableness of MDH reliance on the information;
- (6) the importance of the information which was wrong or not provided; and
- (7) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official.

However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to MDH by a licensee or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee thereby permitting an opportunity to correct the oral information. For example: If a transcript of the communication or meeting summary containing the error was made available to the licensee and was not subsequently corrected in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue Notice of Violation or an Administrative Penalty Order for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including:

- ✓ the ease of detection of the error,
- ✓ the timeliness of the correction,
- ✓ whether the MDH or the licensee identified the problem with the communication, and
- ✓ whether the MDH relied on the information prior to the correction.

Generally, if the matter was promptly identified and corrected by the licensee prior to reliance by the MDH, or before the MDH raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified or after some question is raised regarding the accuracy of the information, some enforcement action normally will be taken even if it is corrected. However, if the initial submittal was accurate when made but later becomes erroneous because of newly discovered information, a citation normally would not be appropriate provided the initial submittal was corrected that when the new information became available.

In serious cases where the licensee's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, MDH may exercise its authority to issue orders modifying, suspending, or revoking the license. MDH recognizes that enforcement determinations must be made on a case-by-case basis, taking into consideration the issues described in this section.

ENFORCEMENT ACTIONS INVOLVING INDIVIDUALS

Enforcement actions involving an individual are significant personnel actions, which must be closely controlled and judiciously applied. An enforcement action involving an individual will normally be taken only when MDH is satisfied that the individual:

- fully understood, or should have understood, his or her responsibility;
- knew, or should have known, the required actions; and
- knowingly, or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance.

Most transgressions of individuals at the level of a Severity Level III, IV or V violation will be handled by citing only the facility licensee.

Serious violations (including those involving the integrity of an individual) will be considered for enforcement action against the individual as well as the licensee. However, action against the individual will not be taken if the improper action by the individual was caused by management failures. The following examples of situations illustrate this concept:

- Inadvertent mistakes resulting from inadequate training or guidance provided by the facility licensee.
- Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, which resulted in a violation, unless the individual did not express his or her concern or objection to the direction.
- Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.
- A violation resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Listed below are examples of situations that could result in enforcement actions involving individuals. If a person deliberately takes actions described in these examples, enforcement action may be taken directly against the individual. The situations include, but are not limited to, violations that involve:

- Willfully causing a licensee to be in violation of MDH requirements.
- Willfully taking action that would have caused a licensee to be in violation of MDH requirements but the action did not do so because it was detected and corrective action was taken.
- Recognizing a violation of procedural requirements and willfully not taking corrective action.
- Willfully defeating alarms, which have safety significance.
- Dereliction of duty.
- Falsifying records required by MDH rules or by the facility license.
- Willfully providing, or causing a licensee to provide, an MDH inspector or investigator with inaccurate or incomplete information on a matter material to the MDH.
- Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel in the licensee's organization.
- Willfully providing false data to a licensee by a contractor or other person who provides test or other services, when the data affects the licensee's compliance with regulatory requirement.
- Willfully providing false certification that components meet the requirements of their intended use.
- Willfully performing unauthorized bypassing of required facility safety systems.

Normally, some enforcement action is taken against a licensee for violations caused by significant acts of wrongdoing by its employees, contractors, or contractors' employees. In deciding whether to issue an enforcement action to an individual as well as to the licensee, MDH recognizes that judgments will have to be made on a case-by-case basis. In making these decisions, MDH will consider factors such as the following:

1. The level of the individual within the organization.

2. The individual's training and experience as well as knowledge of the potential consequences of the wrongdoing.
3. The safety consequences of the misconduct.
4. The benefit to the wrongdoer, e.g., personal or corporate gain.
5. The degree of supervision of the individual, i.e., how closely is the individual monitored or audited, and the likelihood of detection (such as a radiographer working independently in the field as contrasted with a team activity at a laboratory).
6. The employer's response, e.g., disciplinary action taken.
7. The attitude of the wrongdoer, e.g., admission of wrongdoing, acceptance of responsibility.
8. The degree of management responsibility or culpability.
9. Who identified the misconduct.

The particular sanction should be determined on a case-by-case basis. Notices of Violation and Orders are examples of enforcement actions that may be appropriate against individuals. In addition, the MDH may issue Demands for Information to gather information that will enable it to determine whether an order or other enforcement action should be issued.

Orders issued by the Department may involve suspension for a specified period, modification, or revocation of individual privileges. Orders to other individuals might include provisions that would:

- Prohibit involvement in MDH licensed activities for a specified period of time (normally the period of suspension would not exceed five years) or until certain conditions are satisfied, e.g., completing specified training or meeting certain qualifications.
- Require notification to the MDH before resuming work in licensed activities.
- Require the person to tell a prospective employer or customer engaged in MDH licensed activities that the person has been subject to an MDH order.

In addition, MDH may take enforcement action against a licensee if the conduct of the individual has jeopardized the reasonable assurance that licensed activities will be conducted properly. That action may also effect the individual. Finally, for initial applications, the MDH may take enforcement action for reasons that would warrant refusal to issue a license.

Individuals who can directly be effected by MDH enforcement actions include:

- Radiation Safety Officers
- industrial radiography trainers
- industrial radiographers and radiographer trainees
- authorized users listed on specific licenses
- individuals with permit to practice

In the case of a person that is not specifically authorized, certified or permitted by the Department, an order modifying the facility license may be issued to require:

- (1) the removal of the person from all licensed activities for a specified period of time or indefinitely,
- (2) prior notice to the MDH before using the person in licensed activities, or
- (3) the licensee to provide notice of the issuance of such an order to other persons involved in licensed activities making reference inquiries.

In addition, orders to employers might require retraining, additional oversight, or independent verification of activities performed by the person, if the person is to be involved in licensed activities.

ESCALATED ENFORCEMENT OPTIONS

- A. **Administrative Penalty Order (APO)** - The law grants the commissioner authority to issue Administrative Penalty Orders requiring that violations be corrected and allows for the assessment of a monetary penalty. The Administrative Penalty Order identifies violations discovered, requires that the violations be corrected, and imposes a penalty that may or may not be forgiven by the Director depending on the seriousness or repetitiveness of the violation and the violator's response to the order.

The statute provides criteria to be considered in determining the amount of any penalty. The maximum penalty is \$10,000 for each violator for all violations by that violator identified in an inspection or review of compliance. The order must include a statement of fact supporting the claim that violations have occurred, a reference to the rule, law or order violated, the amount of the penalty and the factors on which it is based, and a statement of the person's right to review the order.

For Severity Level V and IV violations, the Division may issue an Administrative Penalty Order if the licensee fails to accomplish one of the following:

- Demonstrate, in writing to the Director, before the 31st day after receiving a Notice of Violation, that the violation has been corrected; or
- Develop a corrective plan acceptable to the Director before the 31st day after receiving a Notice of Violation.

Severity Level III violations may or may not be forgivable. In determining whether a civil penalty should be forgiven or not, the inspector should consider the following factors:

- (a) **Identification**- The purpose of this factor is to encourage regulated entities to monitor, supervise, and audit activities to ensure safety and compliance. A forgivable civil penalty may be warranted when a regulated entity identifies a violation resulting from a self-disclosing event where the regulated entity demonstrates initiative and takes corrective action when it identifies the root cause of the violation. (The term "self-disclosing event," as used in this Enforcement Program, means an event that is readily obvious by human observation or mechanical instrumentation such as a spill of liquid, an open door that is required to be closed, an overexposure documented in a dosimetry report, or an radiation monitor alarm.)

The forgivable civil penalty may also be warranted if a regulated entity identifies a violation as a result of its review of a generic notification such as a manufacturer's bulletin or an Information Notice issued by the Department. While mitigation under this factor is appropriate for a violation identified by the regulated entity that was not reported to the

Department, a separate enforcement action will normally be issued for the failure to make the required report.

(b) Corrective Action - The purpose of this factor is to encourage regulated entities to:

- (1) immediately take actions upon discovering a violation to restore safety and compliance with the license, with rules, or with other requirements; and
- (2) develop and implement in a timely manner actions that will prevent recurrence of the violation at issue, and will be sufficiently comprehensive to prevent an occurrence of similar violations.

Forgivable civil penalties may be mitigated depending on the promptness and extensiveness of the regulated entity's corrective action. In evaluating this factor, consideration will be given to:

- the timeliness of the corrective action (including the promptness in developing the schedule for long term corrective action),
- the degree of the regulated entity initiative (i.e., whether Department involvement was required before acceptable action was taken),
- the adequacy of the regulated entity's root cause analysis for the violation, and
- whether the action is focused narrowly on the specific violation or broadly in the general area of concern.

If action was not taken immediately to restore safety and compliance once the violation was identified, mitigation of the civil penalty based on this factor will not normally be considered.

(c) Licensee Performance - The purpose of this factor is to recognize and encourage good or improving performance and to recognize and deter poor or declining performance.

A forgivable civil penalty may be appropriate if the current violation is an isolated failure that is not consistent with outstanding prior performance or if poor prior performance clearly appears to be improving.

Prior performance normally refers to a regulated entity's performance within the period covered by the last two inspections. When assessing prior performance, consideration will be given to the effectiveness of previous corrective actions for similar problems, overall performance, and the prior enforcement history in the area of concern. Mitigation based on this factor is not normally warranted if the current violation reflects a substantial decline in performance since the last Department inspection.

This factor should not be applied in cases where the regulated entity has not been in existence long enough to establish an inspection history. Similarly, mitigation based on this factor is not normally appropriate where the area of concern has not been previously inspected, unless overall performance is good.

(d) Prior Opportunity to Identify - The purpose of this factor is to encourage regulated entities to take effective action in response to opportunities to identify or prevent problems or violations. A non-forgivable civil penalty may be appropriate if the regulated entity should have identified the violation sooner because of prior opportunities such as:

- (1) through normal surveillance, audits, or quality assurance (QA) activities;
- (2) through prior notice i.e., specific Department or industry notification; or
- (3) through any other indication of a potential problem or violation.

Prior notification may include findings of the Department or the regulated entity that were made at other facilities operated by the regulated entity and where it is reasonable to expect the regulated entity to take needed action to identify or prevent similar problems at the facility being considered.

In evaluating this factor, consideration will be given to, among other things:

- the opportunities available to discover the violation,
- the ease of discovery,
- the similarity between the violation and the notification,
- the time between the occurrence of the violation and issuance of the notification,
- the action taken (or planned) by the regulated entity in response to the notification, and
- the level of management review that the notification received or should have received.

A non-forgivable civil penalty based solely on prior notification is normally not warranted if the regulated entity reviewed the notification as it applied to its activities and reasonable action was taken or planned to be taken within a reasonable time.

(e) Multiple Occurrences - The purpose of this factor is to reflect the added significance resulting from multiple occurrences of a violation. The civil penalty may be appropriate if multiple examples of a particular violation are identified during the inspection period.

A non-forgivable civil penalty based on this factor will normally be considered only if there are multiple examples of Severity Level I, II, or III violations with the same root causes.

(f) Duration- The purpose of this factor is to recognize the added significance of violations that remain uncorrected for more an extended period. If a licensee is aware or clearly should have been aware of a violation, the non-forgivable civil penalty may be appropriate to reflect the added technical and/or regulatory significance that results from the violation remaining uncorrected for longer than would reasonably be expected. This factor should normally be applied in cases involving major safety violations or where a significant message is warranted.

- B. **Orders** - In addition to the Orders authorized in The Plan, the Radioactive Materials Group may issue an Order, which may be a written directive to modify or revoke a license, permit, or registration. An Order may also be written to take such other action as may be proper. Orders may be issued in lieu of or in addition to civil penalties, as appropriate for Severity Level I, Severity Level II, or Severity Level III violations.

There are several Orders that may be issued. These include:

1. License Modification Orders - may be issued when a change in a regulated entity's equipment, procedures, personnel, or management controls is necessary.
2. Revocation Orders - may be issued:
 - (a) When a regulated entity is unable or unwilling to comply with Department requirements;
 - (b) When a regulated entity refuses to correct a violation;
 - (c) When a regulated entity does not respond to a Administrative Penalty Order when a response is required;
 - (d) When a regulated entity refuses to pay an applicable fee under the Department's rules;
 - (e) For any other reason for which revocation is legally authorized (e.g., any condition which would warrant refusal of a license or a registration on an original application).
3. Orders to Unlicensed Persons - including vendors and contractors, and their employees, are issued when the Department has identified:
 - deliberate misconduct that may cause a regulated entity to be in violation of an Department requirement, or
 - where incomplete or inaccurate information is deliberately submitted, or
 - where the Department loses its reasonable assurance that the regulated entity will meet Department requirements if the unlicensed person continues to be involved in activities covered by a license, registration, or permit.

- C. **Impoundment** - The Department may impound or order the impounding of radioactive material in the possession of a person who fails to observe the provisions of any rules, license or registration conditions, or orders issued by this Department. If the action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If action is not necessary to protect the public health and safety, the Department will give written notice to the owner and/or possessor of the source of radiation of the intention to impound the source of radiation.
- The owner or possessor shall have 20 days from the date of personal service or certified mailing to request a Department hearing, except in the case where the regulated entity has consented in writing to the impoundment.
 - If a hearing is requested, the Department will issue an order designating the time and place of hearing.

At the Department's discretion, the impounded sources of radiation may be disposed of by:

- Returning the source of radiation to a properly licensed or registered owner who did not cause the emergency (provided proof of ownership is obtained);
- Returning the source of radiation to a licensee or registrant after the emergency is over and after settlement of any compliance action; or
- Sale, destruction, or other disposition within the Department's discretion.

ENFORCEMENT CONFERENCES

Whenever the Department learns of an apparent violation for which escalated enforcement action may be warranted, it may provide the regulated entity or other person an opportunity for an enforcement conference before proposing enforcement action.

Enforcement conferences are not normally held for Severity Level IV and/or Severity Level V violations; however, they may be scheduled if management attention is inadequate or corrective action is ineffective (e.g., if violations are repetitive).

Enforcement conferences are held to:

- (1) discuss the significance of the violations, the reason(s) for their occurrence, apparent root causes, and the regulated entity's corrective actions,
- (2) determine whether there were aggravating or mitigating circumstances, and
- (3) obtain other information that will help the Department determine the appropriate enforcement action.

During an enforcement conference, the regulated entity or other person will be given an opportunity to provide information consistent with the purpose of the conference. This will include an explanation of immediate corrective actions, if any, that were taken after identifying an apparent violation and any long-term action(s) that will be taken to prevent recurrence. Regulated entities or other persons will always be told when a meeting is an enforcement conference. Because enforcement conferences occur during the investigative phase of an inspection, they are not normally open to the public.

If needed to protect the public health and safety, emergency escalated enforcement action such as issuance of an immediately effective order modifying or suspending a license, permit, or registration may be taken before holding an enforcement conference. In such cases, an enforcement conference may be held after emergency enforcement action has been taken. Additional enforcement sanctions such as civil penalties may then be proposed.

REOPENING CLOSED ENFORCEMENT ACTIONS

If significant new information is received or obtained by MDH which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely.

PART III - ESCALATED ENFORCEMENT PROCESS – THE PLAN

The following are relevant portions of the Division of Environmental Health's *Plan for the Use of Administrative Penalty and Cease and Desist Authority* (The Plan). A complete copy of the plan can be accessed at the following web site:

<http://mdh-fyi.health.state.mn.us/eh/policy/enforcement/apoplan.pdf>

JURISDICTION

The 1993 Minnesota Legislature granted the authority to use these enforcement tools in the "Health Enforcement Consolidation Act of 1993." (Laws of Minnesota 1993, Chapter 206, sections 7 to 11.) This law, codified as Minnesota Statutes, sections 144.989 to 144.993, was effective August 1, 1993. The Minnesota Legislature subsequently amended Minnesota Statutes, sections 144.989 to 144.993 in:

Laws of Minnesota 1994, Chapter 465, Article 1, sections 18 and 19.
Laws of Minnesota 1995, Chapter 165, sections 5 to 10.
Laws of Minnesota 1997, Chapter 205, sections 29 and 30
Laws of Minnesota 1998, Chapter 261, section 2
Laws of Minnesota 1998, Chapter 407, Article 2, section 80
Laws of Minnesota 1999, Chapter 245, Article 2, sections 28 and 29
Laws of Minnesota 2002, to be codified.

The department prompted the original legislation in an effort to develop a statewide enforcement system that promotes compliance and deterrence. Additional objectives include streamlined procedures, improved consistency and fairness for the regulated community, and increased Division efficiency. The Health Enforcement Consolidation Act:

- Consolidates the enforcement provisions for the Minnesota Department of Health, Environmental Health Division's regulatory programs; and
- Provides Administrative Penalty Order and cease and desist order authority for all Environmental Health Division regulatory programs.

The Administrative Penalty Order authority (APO) gives the Division of Environmental Health an administrative remedy to gain compliance with programs administered by the Division. The purpose of the cease and desist order authority is to stop an activity covered by Minnesota Statutes, section 144.99, subdivision 1, if continuation of the activity would result in an immediate risk to public health.

CIVIL PENALTY

In any administrative enforcement action, the department determines if a civil penalty for the violations involved is appropriate and, if so, what those penalties should be based on applying statutory criteria. An established set of factors is used to calculate civil penalties, ensuring that each proposed penalty is reasonable, fair and defensible and that penalties are consistent within each Division. For more information, see *The Plan for the Use of Administrative Penalty and Cease and Desist Authority* including the penalty calculation worksheet included in The Plan.

The calculation for civil penalties using the penalty calculation worksheet includes two components:

- imposition of a gravity-based component with consideration for adjustments

- recovery of the economic benefit the company realized through noncompliance

Gravity - The gravity-based component is a dollar figure intended to reflect the seriousness of the violations. The purpose of the gravity-based component is to ensure that the violator is economically worse off than if the violator had obeyed the law. The gravity-based component gives the violation a value. If the Department recovered only the economic benefit the violator gained, the violator would be no worse off than if the violator had maintained compliance. The following factors are used to assess a gravity-based penalty:

Severity -

- Extent of deviation from the regulatory or statutory requirement
- Duration of noncompliance
- Number of violations

Impact -

- Harm or potential harm to public health
- Harm or potential harm to animals, air, water, land or other natural resources of the state
- Extent of irreparable harm caused by the violation(s)

The rule of thumb is this:

The more serious the violation, the greater the potential for harm; the larger the number of violations, the higher the gravity-based component.

After establishing the base gravity penalty, the department's penalty policy allows for adjustments, either up or down, to the gravity-based component. It may be adjusted either up or down, based on "Adjustment Factors" which include at least the following:

Willfulness - Under Minnesota law, regulated parties are liable even if they were unaware of the law or that they were in violation. This is known as strict liability. Nonetheless, the extent to which a regulated party's behavior was informed or deliberate may be a factor in calculating the penalty. A willful violation should result in the penalty being adjusted upward.

History - A regulated party's compliance history can be used to adjust a penalty up or down. Factors to consider are: past violations, good/bad faith, unjustified delay in responding to violations, failure to provide timely and full information, and compliance with prior enforcement actions.

Other factors as justice may require - There may be other factors and issues that would cause the penalty to be adjusted. Because these factors have infinite variety, they cannot all be listed here. Some examples are: bankruptcy, labor disputes which effect operations, conducted public health audit, and weather. In cases where unique factors are used to adjust a penalty, you are required to explain the factor and your reasoning for the adjustment.

Economic Benefit - In order for a penalty to be an effective deterrent, the penalty amount must address the economic benefit the regulated party derived from the violation. Therefore, calculating the economic benefits associated with a violation as accurately as possible and using all of the information is important. Economic benefit generally falls into two categories:

- 1) delayed or avoided (unincurred) costs; and
- 2) violation-related profits.

A regulated party realizes delayed or avoided cost savings when they fail to invest in equipment or personnel or fail to take other actions that would have kept them in compliance. Consider, for example, an asbestos contractor that has improperly disposed of asbestos wastes. The generator benefited economically by avoiding the costs of proper disposal. In a case like this, the department calculates the economic benefit by first determining the cost of proper disposal for how much waste was disposed of improperly.

Regulated parties realize violation-related profits when they take unauthorized or illegal measures that result in increased level of service or production of a product. This increase results in increased profits.

Ability to pay - Although not included on the penalty calculation worksheet, the financial status of a regulated party can come under consideration when determining a civil penalty. Sometimes, payments can be extended over time. In rare cases, inability to pay may reduce a penalty. The burden is on the regulated party to prove that a penalty will have a dire financial impact. This factor will not, however, excuse the regulated party from complying with the law

In an effort to recognize and encourage good performance, deter poor performance, and emphasize violations of particular regulatory concern, the Department reviews each proposed civil penalty on its own merits. After considering all relevant information, it may adjust the base civil penalty.

While management involvement, direct or indirect, in a violation may lead to an increase in a civil penalty, a lack of management involvement may not be used to mitigate a civil penalty. Allowing mitigation in such a case could encourage lack of management control or involvement in regulated activities and could result in a significant decrease in protection of the public health and safety.

FORGIVABLE ADMINISTRATIVE PENALTY ORDERS

1. Violation is not serious or repeated

Except for repeated or serious violations, the Director must forgive the penalty assessed, if:

- the regulated party demonstrates, in writing to the Director before the 31st day after receiving the order, that the violation has been corrected; or
- before the 31st day after receiving the order, the regulated party has developed a corrective plan acceptable to the Director.

2. Compliance determination; forgiveness of penalty

The Director will determine whether a violation has been corrected. The regulated party will be notified of the determination. Except in the case of a serious or repeated violation, if the Director determines that the violation has been corrected or the Director has approved a corrective plan, the penalty must be forgiven.

NON-FORGIVABLE ADMINISTRATIVE PENALTY ORDERS

The Director is authorized to assess an administrative penalty that is non-forgivable for repeated or serious violations. Unlike the forgivable Administrative Penalty Order, the regulated party regardless of whether the corrective action is performed must pay a non-forgivable Administrative Penalty Order.

Under Minnesota Statutes, section 144.991, subdivision 4, a penalty issued pursuant to a non-forgivable Administrative Penalty Order is due 31 days after the regulated party received the order unless that party requests an administrative hearing as provided for in Minnesota Statutes, section 144.991, subdivision 4, paragraph (a).

Because of the seriousness and finality of a non-forgivable Administrative Penalty Order, the Division will provide notice of the alleged violation and an opportunity for response before issuing the non-forgivable order. Without a prior meeting or other communication related to the violation, the Division will provide a letter, called a "ten-day letter," to the regulated party clearly explaining the violations and underlying facts. The letter contains a request that the regulated party provide, within ten calendar days, any information that may impact the Director's determination. In addition, Division staff may contact the regulated party by telephone to explain the violations and ask about factual issues.

- In situations where a ten-day response time is not appropriate because of potential immediate public health risk or environmental concerns, the Division will attempt to contact the regulated party by telephone to discuss the violations and request any response concerning the facts of the case.
- The regulated party's response, if any, will be considered before issuing a non-forgivable Administrative Penalty Order.

CEASE AND DESIST ORDERS

The Department may issue a cease and desist order to stop an activity if continuation of the activity would result in an immediate risk to public health. Generally, a cease and desist order may be appropriate if an individual or group is in danger of specific harmful consequences in the immediate future if an action or activity goes unchecked.

In addition to the general statutory test of "posing an immediate risk to public health," each environmental health regulatory program has provided program specific additional examples that would warrant issuance of a cease and desist order. The list of program specific examples of violations that would warrant cease and desist action is not exclusive. It is expected that you may determine additional cease and desist violations using the statutory criteria.

Procedures for Issuance - To issue a cease and desist order, a determination that failure to issue the order would result in an immediate risk to public health must be made. Such an order may be issued on-site after prior approval by the Director. A sign or notice indicating a cease and desist order has been issued and specifying the duration of the order may also be posted. This sign is only to be removed after authorization by the Commissioner or the Director. A cease and desist order must be issued in writing except in cases of extreme emergency. If a cease and desist order is issued on-site, a formal written confirmation must be issued to the regulated party within 24 hours. Written confirmation of a cease and desist order must include:

- a concise statement of the fact alleged to constitute a violation;
- a reference to the section of the statute, rule, regulation, order, or term or condition of a permit violated; and
- a statement requiring that the violations cited be corrected or ceased immediately.
- The Director will provide a copy to the commissioner of all cease and desist orders upon issuance. A copy will also be provided to the assistant attorney general representing the regulatory program issuing the order in case further action becomes necessary.

- **Compliance Verification.** Once a regulated party has resolved a violation, you must verify compliance.
- The inspector will review and evaluate all information related to the issuance of a cease and desist order to determine if violations have been corrected and there is no longer an immediate risk to public health.
- The inspector may make compliance verification by site visit, re-inspection, examination of documentation, or other means as may be reasonable under the facts of the case.
- The inspector will determine whether a violation has been corrected, confer with the Director, and notify the regulated party of the determination.
- The inspector must document compliance verification. The program has established record keeping procedures as necessary to enable the status of cease and desist orders to be followed and reporting made to the commissioner.

Further Action – The Division, in addition to any other remedy, may take further actions such as injunctive relief to restrain activities for a period beyond 72 hours or referral for criminal prosecution.

PART IV – SEVERITY CATEGORIES

HEALTH PHYSICS

A. Severity Level I - Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 25 rems total effective dose equivalent, 75 rems to the lens of the eye, or 250 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 2.5 rems total effective dose equivalent;
3. A radiation exposure during any year of a minor in excess of 2.5 rems total effective dose equivalent, 7.5 rems to the lens of the eye, or 25 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. An annual exposure of a member of the public in excess of 1.0 rem total effective dose equivalent;
5. A release of radioactive material to an unrestricted area at concentrations in excess of 50 times the limits for members of the public; or
6. Disposal of licensed material in quantities or concentrations in excess of 10 times the limits.

B. Severity Level II - Violations involving for example;

1. A radiation exposure during any year of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye, or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue
2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 1.0 rem total effective dose equivalent;
3. A radiation exposure during any year of a minor in excess of 1.0 rem total effective dose equivalent; 3.0 rems to the lens of the eye, or 10 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. An annual exposure of a member of the public in excess of 500 millirems total effective dose equivalent;
5. A release of radioactive material to an unrestricted area at concentrations in excess of 10 times the limits for members of the public (except when operation up to 500 millirems a year has been approved by the Department);
6. Disposal of licensed material in quantities or concentrations in excess of 5 times the limits; or
7. A failure to make an immediate notification, as required.

C. Severity Level III - Violations involving for example:

1. A radiation exposure during any year of a worker in excess of 5 rems total effective dose equivalent, 15 rems to the lens of the eye, or 50 rems to the skin of the whole body or to the feet, ankles, hands or forearms, or to any other organ or tissue;

2. A radiation exposure over the gestation period of the embryo/fetus of a declared pregnant woman in excess of 500 millirems total effective dose equivalent (except when doses are in accordance with the planned special exposures);
3. A radiation exposure during any year of a minor in excess of 500 millirems total effective dose equivalent; 1.5 rems to the lens of the eye, or 5 rems to the skin of the whole body, or to the feet, ankles, hands or forearms, or to any other organ or tissue;
4. A worker exposure above regulatory limits when such exposure reflects a programmatic (rather than an isolated) weakness in the radiation control program;
5. An annual exposure of a member of the public in excess of 100 millirems total effective dose equivalent (except when operation up to 0.5 rem a year has been approved by the Department);
6. A release of radioactive material to an unrestricted area at concentrations in excess of 2 times the effluent concentration limits (except when operation up to 0.5 rem a year has been approved by the Department);
7. A failure to make a 24-hour notification or an immediate notification, as required;
8. A substantial potential for exposures or releases in excess of the applicable limits whether or not an exposure or release occurs;
9. Disposal of licensed material not covered in Severity Levels I or II;
10. A release for unrestricted use of contaminated or radioactive material or equipment that poses a realistic potential for exposure of the public to levels or doses exceeding the annual dose limits for members of the public, or that reflects a programmatic (rather than an isolated) weakness in the radiation control program;
11. Conduct of regulated entity activities by a technically unqualified person;
12. A significant failure to control licensed material; or
13. A breakdown in the radiation safety program involving a number of violations that are related (or, if isolated, that are recurring) that collectively represent a potentially significant lack of attention or carelessness toward regulated responsibilities.

D. Severity Level IV - Violations involving for example:

1. Exposures in excess of the limits not constituting Severity Level I, II, or III violations;
2. A release of radioactive material to an unrestricted area at concentrations in excess of the limits for members of the public (except when operation up to 500 millirems per year has been approved by the Department);
3. A radiation dose rate in an unrestricted area in excess of 2.0 millirems in any one hour or 50 millirems in a year;
4. Failure to maintain and implement radiation programs to keep radiation exposures as low as is reasonably achievable;
5. Doses to members of the public in excess of any EPA applicable environmental radiation standard, such as 40 CFR part 190;

6. A failure to make a 30-day notification, as required;
 7. A failure to make a timely written report, as required;
 8. Any other matter that has more than a minor safety, health, or environmental significance.
- E. **Severity Level V** - Violations that are of a minor safety, health, or environmental significance.

TRANSPORTATION OF RADIOACTIVE MATERIALS

A. Severity Level I - Violations involving for example:

1. A failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that the material caused a radiation exposure to a member of the public and there was clear potential for the public to receive more than 100 millirems to the whole body;
2. Surface contamination in excess of 50 times the Department limit; or
3. External radiation levels in excess of 10 times the Department limit.

B. Severity Level II - Violations involving for example:

1. A failure to meet transportation requirements that resulted in loss of control of radioactive material with a breach in package integrity such that there was a clear potential for a member of the public to receive more than 100 millirems to the whole body;
2. Surface contamination in excess of 10 but not more than 50 times the Department limit;
3. External radiation levels in excess of five, but not more than 10 times the Department limit; or
4. A failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity Level III - Violations involving for example:

1. Surface contamination in excess of five but not more than 10 times the Department limit;
2. External radiation in excess of one but not more than five times the Department limit;
3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:
 - (a) A significant failure to identify the type, quantity, or form of material;
 - (b) A failure of the carrier or recipient to exercise adequate controls; or
 - (c) A substantial potential for either personnel exposure or contamination above regulatory limits or improper transfer of material;
4. A failure to make required initial notification associated with Severity Level III violations; or
5. A breakdown in the licensee's program for the transportation of licensed material involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV - Violations involving for example:

1. A breach of package integrity without external radiation levels exceeding the Department limit or without contamination levels exceeding five times the Department limit;
2. Surface contamination in excess of but not more than five times the Department limit;
3. A failure to register as an authorized user of an Department Certified Transport package;
4. A noncompliance with shipping papers, marking, labeling, placarding, packaging, or loading not amounting to a Severity Level I, II, or III violation;
5. A failure to demonstrate that packages for special form radioactive material meets applicable regulatory requirements;
6. A failure to demonstrate that packages meet DOT specifications for 7A Type A packages; or
7. Other violations that have more than minor safety or environmental significance.

E. Severity Level V - Violations that have minor safety or environmental significance.

CERTAIN USES OF RADIOACTIVE MATERIAL

A. Severity Level I - Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the registration or license;
2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

B. Severity Level II - Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the registration or license;
2. A system designed to prevent or mitigate a serious safety event being inoperable.

C. Severity Level III - Violations involving for example:

1. A failure to control access to licensed materials for radiation purposes as specified by Department requirements;
2. Possession or use of unauthorized equipment or materials in the conduct of registrant or licensee activities, which degrades safety;
3. Use of radioactive material on humans where such use is not authorized;
4. Conduct of registered or licensed activities by a technically unqualified person;
5. Radiation levels, contamination levels, or releases that exceed the limits specified in the registration or license;

6. A substantial failure to implement the quality management program; failure to follow the procedures of the quality management program that results in a misadministration or a failure to report a misadministration.
7. A breakdown in the control of licensed activities involving a number of violations that are related (or, if isolated, that are recurring violations) that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.
8. A failure, during radiographic operations, to have present or to use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required;
9. A failure by a person to notify the Department at least three working days before bringing a radiation machine or radioactive material into the state, as required.
10. A failure to receive required Department approval prior to the implementation of a change in licensed activities that has radiological or programmatic significance, such as, a change in ownership; lack of a radiation safety officer (RSO) or replacement of an RSO with an unqualified individual; a change in the location where licensed activities are being conducted, or where licensed material is being stored where the new facilities do not meet safety guidelines; or a change in the quantity or type of radioactive material being processed or used that has radiological significance.

D. Severity Level IV - Violations involving for example:

1. A failure to maintain patients hospitalized who have Cobalt-60, Cesium-137, Radium-226, or Iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment; other violations that have more than minor safety or environmental significance.
2. A failure to follow the procedures of the quality management program, or failure to conduct the annual review, or failure to take corrective actions as required by the quality management program.
3. A failure to keep the records required by the quality management program.

E. Severity Level V - Violations that have minor safety or environmental significance.

MISCELLANEOUS MATTERS

A. Severity Level I - Violations involving for example:

1. Inaccurate or incomplete information that is provided to the Department:
 - (a) deliberately with the knowledge of a regulated entity official that the information is incomplete or inaccurate, or
 - (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations;
2. Incomplete or inaccurate information that the Department requires be kept by a regulated entity that is:

- (a) incomplete or inaccurate because of falsification by or with the knowledge of a regulated entity official, or
 - (b) if the information, had it been complete and accurate when reviewed by the Department likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations;
3. Information that the regulated entity has identified as having significant implications for public health and safety or the common defense and security ("significant information identified by a regulated entity") and is deliberately withheld from the Department;
 4. An action by senior corporate management, in violation of rules, against an employee;
 5. A knowing and intentional failure to provide the notice required by these rules; or

B. Severity Level II - Violations involving for example:

1. Inaccurate or incomplete information, which is provided to the Department:
 - (a) by a regulated entity official because of careless disregard for the completeness or accuracy of the information, or
 - (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
2. Incomplete or inaccurate information that the Department requires be kept by a regulated entity which is:
 - (a) incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a regulated entity official, or
 - (b) if the information, had it been complete and accurate when reviewed by the Department likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
3. "Significant information identified by a regulated entity" and not provided to the Department because of careless disregard on the part of a regulated entity official;
4. An action by plant management above first-line supervision, in violation of rules, against an employee;

C. Severity Level III - Violations involving for example:

1. Incomplete or inaccurate information that is provided to the Department
 - (a) because of inadequate actions on the part of regulated entity officials but not amounting to a Severity Level I or II violation, or
 - (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
2. Incomplete or inaccurate information that the Department requires be kept by a regulated entity that is

- (a) incomplete or inaccurate because of inadequate actions on the part of regulated entity officials but not amounting to a Severity Level I or II violation, or
 - (b) if the information, had it been complete and accurate when reviewed by the Department, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
3. A failure to provide "significant information identified by a regulated entity" to the Department and not amounting to a Severity Level I or II violation;
 4. An action by first-line supervision, in violation of rules, against an employee;
 5. An inadequate review or failure to review such that, if an appropriate review had been made as required, a report would have been made.

D. Severity Level IV - Violations involving for example:

1. Incomplete or inaccurate information of more than minor significance that is provided to the Department but not amounting to a Severity Level I, II, or III violation;
2. Information that the Department requires be kept by a regulated entity and which is incomplete or inaccurate and of more than minor significance but not amounting to a Severity level I, II, or III violation; or
3. An inadequate review, failure to review, or other procedural violations associated with reporting requirements with more than minor safety significance.

E. Severity Level V - Violations involving for example:

1. Incomplete or inaccurate information that is provided to the Department and the incompleteness or inaccuracy is of minor significance;
2. Information that the Department requires be kept by a regulated entity that is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance; or
3. Minor procedural requirements.



Protecting, maintaining and improving the health of all Minnesotans

License Number:

Dear :

Subject: Violation of Minnesota Rules, Chapter 4731 at located at in ,
Minnesota

On , Timothy Donakowski of the Minnesota Department of Health (MDH) conducted a radiological safety inspection of equipment operations at the location cited above. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with your organization's staff. A report listing violations identified during this inspection is attached.

Please review for accuracy the description of the conditions observed. If you believe the information on the violations specified in the Notice of Violation is incorrect, you must respond in writing within ten days of receipt of this letter with an explanation of what you believe is incorrect.

If the violations cited in the Notice of Violation are correct, you must respond to the MDH in writing within 30 days of receipt of this letter. Your response must include the action(s) taken to correct each of the deficiencies cited and the required documentation of these corrective actions. Failure to respond in a timely manner could result in an enforcement action of up to \$10,000 as specified by the statute.

All correspondence should be directed to:

Radiation Control Unit
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

State rules relating to radioactive materials can be found at www.leg.state.mn.us. Go to Rules, Chapter 4731. For information regarding factors considered in levying penalties and your appeal rights see the above legislative site under Minnesota Statutes 144.989-144.993. You will also find useful information on our web site at www.health.state.mn.us/divs/eh/radiation.

Please contact Timothy Donakowski or me at (651) 642-0492 if you have questions regarding this matter.

Sincerely,

George F. Johns, Jr., Supervisor
Radiation Control Unit
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Enclosure: Notice of Violation

NOTICE OF VIOLATION

License Number:

During an inspection conducted by the Minnesota Department of Health, violations of the Radioactive Materials Rules, Chapter 4731, were identified. The violations are listed below.

You are required to submit a written explanation or statement. Your reply should include the documentation, films and other items as specified at the end of the deficiencies. Where there are no stated requirements, an explanation of the corrective action(s) taken for each violation is necessary. The corrective action(s) should include: (1) the corrective steps that have been or will be taken, (2) the date when full compliance will be achieved, and (3) the actions that have been or will be taken to prevent recurrence. Consideration may be given to extending the response time for good cause shown.

With respect to the correction orders, you have the rights specified in Minnesota Statutes section 144.989 - 144.993 and are subject to enforcement actions specified by the statute. Minnesota Rules, Chapter 4731, Radioactive Materials, can be obtained on the internet at www.leg.state.mn.us or on the MDH Radiation Control website at www.health.state.mn.us/divs/eh/radiation.

4.5.2

Escalated Enforcement Procedures

4.5.2

ESCALATED ENFORCEMENT PROCEDURES

Minnesota's procedures for escalating enforcement actions are included in the *Plan for Use of Administrative Penalty and Cease and Desist Authority*. These address the notification of the licensee of proposed escalated enforcement actions. These notifications are written using standard wording and format when practical and are coordinated with legal counsel. Also included in this section are a *Sample APO Cover Letter* and *Sample APO*.

SUMMARY

The escalated enforcement action process is more complicated because there are many more options available as well as many decisions that must be made before the process can begin. The ultimate goal of any regulatory action should be to correct the root cause of the problems. This becomes even more essential in escalated enforcement situation. In escalated enforcement there might be more than one acceptable action. If the violations are particularly egregious several escalated actions may be taken at the same time.

Severity level III violations are the threshold of the escalated enforcement program. Escalated enforcement is the sanction of choice for less than one percent of all inspections in which violations have been identified. For Severity Level III violations, the Radioactive Materials Unit staff must review the inspection report to determine if the penalty should be forgivable or non-forgivable in accordance with the Administrative Penalty Plan.

Non-forgivable enforcement action should be taken whenever the identified violations are of Severity Level II or I.

The principal criteria for determining whether routine enforcement or escalated enforcement is appropriate is to determine the Severity Level of each violation identified during an inspection. It is essential that the inspector refer to the Minnesota Enforcement Applications Manual to aid them in making this determination.

The list of the severity of violations and factors to be used in the characterization of violations are found in the Minnesota Enforcement Applications Manual, Part II.

The list of options for escalated enforcement is also included in Part II. This list includes an Administrative Penalty Order (APO). This order identifies violations discovered, requires that the violations be corrected, and imposes a penalty that may or may not be forgiven by the Director depending on the seriousness or repetitiveness of the violation and the violator's response to the order. The maximum penalty is \$10,000 for each violator for all violations by that violator identified in an inspection or review of compliance.



Protecting, maintaining and improving the health of all Minnesotans

License Number:
Certified Mail

Dear _____ :

Subject: Violation of Minnesota Rules, Chapter 4731 at _____ located at _____ in _____, Minnesota

On _____, Timothy Donakowski of the Minnesota Department of Health (MDH) conducted a radiological safety inspection of equipment operations at the location indicated above. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with your organization's staff.

During the inspection, violations of Minnesota Department of Health Radioactive Materials Rules were identified. A report listing these violations is enclosed. As specified in Minnesota Statutes section 144.989 – 144.993, you are subject to enforcement actions. Due to the serious nature of the violations, you have been assessed an Administrative Penalty Order, which you will find enclosed. This Order carries with it a monetary penalty in the amount of \$ _____ .00. Should you complete the identified corrective action(s) or develop a plan for correction and provide the Department with supporting documentation within 30 days of receipt of this Order, the penalty will be reduced to \$ _____ .00.

As provided by law and noted within the Order, you have the right to appeal this Order by requesting a hearing. However, if an administrative law judge finds that the hearing was requested solely for the purposes of delay or that the request was frivolous, the Commissioner of Health may add to the amount of the penalty the costs charged to the Department by the Office of Administrative Hearings for the hearing.

All correspondence should be directed to:

Radiation Control Unit
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

State rules relating to Radiation can be found at www.leg.state.mn.us. Go to Rules, Chapter 4731. For information regarding factors considered in levying penalties and your appeal rights see the above legislative site under Minnesota Statutes 144.989-144.993. You will also find useful information on our web site at www.health.state.mn.us/divs/eh/radiation.

Please contact Timothy Donakowski or George F. Johns, Jr. at (651) 642-0492 if you have questions regarding this matter.

Sincerely,

Linda B. Bruemmer, Manager
Asbestos, Indoor Air, Lead & Radiation
Environmental Health Division
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Enclosure: Administrative Penalty Order
Notice of Violation



ADMINISTRATIVE PENALTY ORDER

Registration Number:

I. AUTHORITY

- A. The Minnesota Department of Health (MDH) has statutory authority to order corrections and assess administrative penalties for violations of law under Minnesota Statutes, sections 144.989 to 144.993.
- B. Minnesota Statutes, section 144.121, subdivision 2, provides the periodic inspection of sources of ionizing radiation shall be made by the commissioner; Minnesota Statutes, section 144.12, subdivision 1, clause (15) and section 144.121, provides that the commissioner may control, by rule, sources of ionizing radiation.
- C. Minnesota Statutes, section 144.99 authorizes the commissioner of health to assess a non-forgivable administrative penalty in an amount up to \$10,000 for serious or repeated violations of Minnesota Statutes, section 144.12, subdivision 1, clause (15) and Minnesota Rules, Chapter 4731.

II. FINDINGS OF FACT

On _____, Timothy Donakowski of the Minnesota Department of Health (MDH) conducted an inspection at _____ located at _____ in _____, Minnesota and observed the deficiencies noted in the enclosed Notice of Violation.

III. CORRECTIVE ORDER

IT IS HEREBY ORDERED THAT _____ must demonstrate, **IN WRITING**, to the satisfaction of the director of the Environmental Health Division within 30 days of receipt of this Order, that the violations have been corrected or that appropriate steps toward correcting the violations, which may include the development of a plan for correction, have been taken.

Failure to demonstrate to the satisfaction of the director that the violations have been corrected or that appropriate steps have been taken toward correcting the violations, within the 30-day period,

shall be cause for subsequent enforcement action. A plan to correct the violations may be developed within the 30-day period for corrective action. The director must approve the plan. Failure to comply with the approved plan shall be cause for subsequent enforcement action.

If the director determines that your corrective action is unsatisfactory, you have the right to a review of the director's determination by requesting a hearing within 20 days of receipt of the director's determination. To request a hearing, you must file a written hearing request with the Environmental Health Division. The hearing request must specifically state your reasons for appealing this Order. Pursuant to Minnesota Statutes, section 144.991, subdivision 5, an expedited hearing, conducted by the Office of Administrative Hearings, will then be scheduled. Your review rights are more thoroughly described in Minnesota Statutes, section 144.991, subdivision 5.

IV. PENALTY

NON-FORGIVABLE PENALTY ASSESSMENT

You have been assessed a non-forgivable administrative penalty of \$.00, for the violations specified in the enclosed Notice of Violation. Based on the repeat nature of the violations, the commissioner has determined that the penalty is non-forgivable. The penalty must be paid by certified check or money order, payable to the Minnesota Department of Health. The payment must be submitted to the MDH, within 30 days of the date of receipt of this Order.

In determining the amount of the penalty, the director has considered the extent of deviation from compliance; whether the violations were willful; the gravity of the violations; the number of violations; whether there is a history of past violations; whether you gained economic benefit in not complying with the requirements, and other factors as justice may require.

FORGIVABLE PENALTY ASSESSED

You have also been assessed a forgivable administrative penalty of \$.00, for the violations specified in the enclosed Notice of Violation. If you demonstrate, **IN WRITING**, to the satisfaction of the director of the Environmental Health Division within 30 days of receipt of this Order, that the violations have been corrected or that appropriate steps have been taken, which may include the development of a plan for correction, this penalty will be **FORGIVEN**.

If you fail to demonstrate to the director that the violations have been corrected or that appropriate steps toward correcting the violations have been taken, the assessed penalty becomes **DUE AND PAYABLE** on the 31st day after this Order was received. A plan to correct the violations may be developed within the 30-day period for corrective action. The director must approve the plan. Failure to comply with the approved plan shall be cause for subsequent enforcement action.

V. FAILURE TO COMPLY

This Order will become final after 30 days unless you request a hearing as provided below or, following a hearing, when the time for filing an appeal with the Court of Appeals has expired. If you fail to comply with the final Order, the MDH may file the final Order in district court where it will become a court judgment against you without further notice or additional proceedings. The MDH may then proceed to enforce the Order, including collecting the penalty, attorney fees, interest, and other costs.

VI. RIGHT TO APPEAL

You have the right to appeal this Order by requesting a hearing within 30 days of receipt of this Order. To request a hearing a written hearing request must be received by the Environmental Health Division within 30 days of receipt of this Order. The hearing request must specifically state that you are requesting a hearing and state your reasons for appealing this Order. Pursuant to Minnesota Statutes, section 144.991, subdivision 5, an expedited hearing conducted by the Office of Administrative Hearings will then be scheduled. Your appeal rights are more thoroughly described in Minnesota Statutes, section 144.991, subdivision 5.

Direct all correspondence to:

Minnesota Department of Health
Radiation Control Unit
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

SO ORDERED this _____ day of _____, 20_____.

Linda B. Bruemmer, Manager
Asbestos, Indoor Air, Lead and Radiation
Environmental Health Division
P.O. Box 64975
St. Paul, Minnesota 55164-0975

NOTICE OF VIOLATION

License Number:

During an inspection conducted by the Minnesota Department of Health, violations of the Radioactive Materials Rules, Chapter 4731, were identified. The violations are listed below.

You are required to submit a written explanation or statement. Your reply should include the documentation, films and other items as specified at the end of the deficiencies. Where there are no stated requirements, an explanation of the corrective action(s) taken for each violation is necessary. The corrective action(s) should include: (1) the corrective steps that have been or will be taken, (2) the date when full compliance will be achieved, and (3) the actions that have been or will be taken to prevent recurrence. Consideration may be given to extending the response time for good cause shown.

With respect to the correction orders, you have the rights specified in Minnesota Statutes section 144.989 - 144.993 and are subject to enforcement actions specified by the statute. Minnesota Rules, Chapter 4731, Radioactive Materials, can be obtained on the internet at www.leg.state.mn.us or on the MDH Radiation Control website at www.health.state.mn.us/divs/eh/radiation.



Plan for the Use of Administrative Penalty and Cease and Desist Authority

and Other Division-Wide Enforcement Tools

Prepared for



**Minnesota Department of Health
Division of Environmental Health**

by the

Policy Analysis Unit

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I. Introduction

The Environmental Health Division of the Minnesota Department of Health has developed a plan for the use of administrative penalty and cease and desist orders. The 1993 Minnesota Legislature granted the authority to use these enforcement tools in the "Health Enforcement Consolidation Act of 1993." (Laws of Minnesota 1993, Chapter 206, sections 7 to 11.) This law, codified as Minnesota Statutes, sections 144.989 to 144.993, was effective August 1, 1993. The Minnesota Legislature subsequently amended Minnesota Statutes, sections 144.989 to 144.993 in:

Laws of Minnesota 1994, Chapter 465, Article 1, sections 18 and 19.
Laws of Minnesota 1995, Chapter 165, sections 5 to 10.
Laws of Minnesota 1997, Chapter 205, sections 29 and 30.

The department prompted the legislation in an effort to develop a statewide enforcement system that promotes compliance and deterrence. Streamlined procedures, improved consistency and fairness for the regulated community, and increased division efficiency were also objectives.

The Health Enforcement Consolidation Act:

- consolidates the enforcement provisions for the Minnesota Department of Health, Environmental Health Division's regulatory programs; and
- provides administrative penalty order and cease and desist order authority for all Environmental Health Division regulatory programs.

The administrative penalty order authority (APO) gives the Environmental Health Division an administrative remedy to gain compliance with programs administered by the division. The purpose of the cease and desist order authority is to stop an activity covered by Minnesota Statutes, section 144.99, subdivision 1, if the continuation of the activity would result in an immediate risk to public health.

A. Definitions

For purposes of this plan the following terms have the meaning given them.

Commissioner means the commissioner of the Minnesota Department of Health or the commissioner's designee.

Department means the Minnesota Department of Health.

Director means the director of the Environmental Health Division of the Minnesota Department of Health or the director's designee.

Division means the Environmental Health Division of the Minnesota Department of Health.

B. Programs to Which the Law Applies

The programs specified in Minnesota Statutes, section 144.99, subdivision 1 to which the law applies are as follows:

<u>Minnesota Statutes</u>	<u>Regulatory area</u>
Sections 103I.001 to 103I.715	Wells and borings
Sections 115.71 to 115.77	Water treatment operators
Section 144.12, subdivision 1, paragraph (1) paragraph (2) paragraph (5)	Food sanitation Sewage Sewage and drinking water, water haulers and marine toilets

paragraph (6)	Sanitary conditions for food, plumbing, water, lodging and public pools
paragraph (10)	Filthy conditions, marine toilets
paragraph (12)	Sanitation in camps
paragraph (13)	Sanitation in tourist camps, hotels, resorts, sewage, garbage, public pools
paragraph (14)	Clean indoor air, indoor sports arenas
paragraph (15)	Sources of ionizing radiation
Section 144.121	X-ray machines and operators
Section 144.1222	Public pools; Enclosed sports arenas
Section 144.35	Sewage
Sections 144.381 to 144.385	Public water supplies
Sections 144.411 to 144.417	Clean indoor air – smoking
Section 144.491	Lead absorption
Sections 144.71 to 144.74	Children’s camps
Sections 144.9501 to 144.9509	Lead abatement
Sections 157.011 to 157.22	Food, beverage and lodging establishments; Board and lodging houses; Hotels, motels and resorts
Sections 326.37 to 326.45	Plumbing
Sections 326.57 to 326.65	Water conditioning

Sections 326.70 to 326.785	Asbestos
Sections 327.10 to 327.20	Hotels, motels, resorts and manufactured homes

C. Enforcement Consistency

The Consolidated Health Enforcement Act creates a uniform set of enforcement tools for the division regulatory programs specified in the preceding box. Minnesota established these programs over many years in separate legislative initiatives. One consequence of this is that each program had a unique set of enforcement authorities and procedures.

Before 1993, the division had 7 different procedures for administrative action, such as the suspension or denial of a license; 6 different corrective order provisions; 5 different permit revocation procedures; 4 different cease and desist order procedures; and 11 misdemeanor provisions. The division also had a variety of access and injunctive relief statutes.

Consolidation of the enforcement provisions means greater predictability for regulated parties and better protection of due process rights.

D. Improved Efficiency

An objective for state agencies is to find ways to do more with less. Streamlining enforcement procedures provides the opportunity to computerize common enforcement documents, monitor and pinpoint activities routinely violated or inconsistently enforced, and move regulatory programs to improved service delivery. A single inspection of a resort, for example, may involve a lodging license, a food service license, public pool regulations, plumbing regulations, and public water supply and sewage standards.

E. Compliance

The emphasis of the act is on compliance rather than punishment. While it provides ample procedural safeguards to regulated parties, including the right to an expedited hearing before an administrative law judge, the

emphasis of the act is on administrative action and compliance rather than litigation. Given the limited resources available to regulators, the enforcement process should return a violation to compliance as quickly and efficiently as possible. Effective enforcement serves to clearly inform the regulated industry of the requirements and consequences of violations and, as a result, provides a deterrence to future noncompliance.

F. The Enforcement Process

The enforcement process begins when staff in the division determine that a violation has or may have occurred. The division may discover violations through an inspection, submission of compliance data, through a complaint from citizens, district offices or other governmental agencies, or from the regulated community. Violations noted on inspection reports or complaints may trigger enforcement action. The division determines appropriate enforcement action in consultation with the Office of the Attorney General. The division supports this determination through facts established during an investigation and documentation process. Once staff determines that a violation has occurred, they decide the gravity of the violation and recommend an appropriate enforcement response. Division staff performs the primary enforcement role; legal counsel may advise in the investigation process and often review proposed enforcement action.

G. Range of Enforcement Tools

The administrative penalty order is one administrative remedy available to the division in a continuum of tools provided by the Health Enforcement Consolidation Act. The remedies available are not exclusive and the division may employ them in sequence or with one another as circumstances and law indicate. The tools include access to information and property, correction orders without a penalty, administrative penalty orders which include forgivable and nonforgivable penalties, cease and desist orders, injunctive relief, denial or refusal to reissue, or suspension or revocation of licenses, registrations, certificates, or permits, and misdemeanor penalties. Beyond the enforcement tools codified in statute, the commissioner may also attempt to resolve violations through means such as a stipulation agreement or settlement.

For a violation that is neither serious nor a repeated violation, the division may issue a forgivable administrative penalty order. The director will forgive a forgivable penalty if the violation is corrected within a specified time. For a serious or a repeated violation, the division may issue a nonforgivable administrative penalty. The director will not forgive a nonforgivable penalty, even if the violation is corrected within a specified

Plan for the Use of Administrative Penalty and Cease and Desist Authority

time. If the violation is not corrected, the division may issue an additional penalty order or take other enforcement action. Other factors in a given situation may call for other or additional remedies. The general criteria for use of remedies other than, or remedies in addition to, an administrative penalty order are indicated in statute.

If the continuation of an activity would result in an immediate risk to public health, the division may issue a cease and desist order to cease the activity. A cease and desist order issued under the statute is effective for a maximum of 72 hours. The commissioner must seek an injunction or take other authorized action to restrain activities for a period beyond 72 hours.

Beyond any other remedy, the commissioner may bring an action for injunctive relief (stop or prohibit an activity) in the district court in Ramsey County or, at the commissioner's discretion, in the county in which the violation occurred.

If a case appears to the division to warrant criminal prosecution, the division may refer the case to the appropriate city or county attorney.

If the division determines that they must gather that information decided what action or actions are appropriate with respect to a possible violation, they may gather the information informally or formally by inspection. The statute provides for access to information and property for the purposes of taking steps to remedy violations, or conducting surveys or investigations. To evaluate what remedies to pursue, the division may meet with regulated persons.

The division may issue correction orders to require a regulated party to correct a violation. The correction order must state the violation, cite the statute or rule or other action, and the time for correction. Pursuant to written delegation maintained in the director's office, appropriate division personnel may issue a correction order. If a regulated party subject to the correction order believes the information in the order is in error, the regulated party may, in writing delivered to the commissioner by certified mail within seven days after receipt of the order, request the commissioner to reconsider a part of the order alleged to be in error. The commissioner must respond within 15 calendar days after receiving a request and her/his disposition of the request is final. The correction order assesses no penalty. However, as set forth in section III below, it will be considered a violation and used for purposes of determining subsequent enforcement action including administrative penalty orders.

Division enforcement tools remain in other statutes. Some programs have authority to take action against a bond or impound equipment. Other

programs have authority to issue civil penalties and pursue criminal action through district court. However, according to Minnesota Statutes, section 144.991, subdivision 9, the state may not seek civil penalties under any other provision of law for violations covered by an administrative penalty order.

H. Licensure and Permit Actions

I. Denial or Refusal to Reissue

As stated in Minnesota Statutes, section 144.99, subdivision 8, the commissioner may deny or refuse to renew an application for a permit, license, registration, or certificate, if the applicant:

- does not meet or fails to maintain the minimum qualifications for holding a permit, license, registration, or certificate;
- has any unresolved violations related to the activity for which the permit, license, registration, or certificate was issued;
- has a persistent pattern of violations related to the permit, license, registration, or certificate; or
- submitted false material information to the division or department in connection with the application.

The commissioner may condition the grant or renewal of a permit, license, registration, or certificate on a demonstration by the applicant that actions needed to ensure compliance with the requirements of the statute have been taken, or may place conditions on or issue a limited permit, license, registration, or certificate because of previous violations by the applicant.

2. Suspension, Conditions, and Revocation

As stated in Minnesota Statutes, section 144.99, subdivision 9, the commissioner may suspend, place conditions on, or revoke a permit, license, registration, or certificate for:

- serious or repeated violations related to the permit, license, registration, or certificate;
- submitting false material information in connection with the activities for which the permit, license, registration or certificate is issued;
- allowing the alteration or use of one's own permit, license, registration or certificate by another; or

- within the previous five years, conviction of a crime in connection with activities for which the permit, license, registration, or certificate was issued.

I. Reporting, Monitoring, and Documentation

An effective reporting and monitoring system, including adequate documentation of violations, is essential to ensure compliance with law and regulations. This system should also ensure that the division takes proper enforcement action, and that the division maintains a record of the outcome of enforcement actions.

Where the division cites violations, they may assess and note the following to the extent known or available:

- the cause of the violation,
- frequency of the violation,
- magnitude and duration of the violation;
- whether the violation presents an actual or imminent risk to public health, animals, air, water, land or other natural resources of the state;
- past violations of the regulated party; and
- past and present corrective action efforts by the regulated party.

The director's office has established record keeping procedures and a reporting system to monitor the status of enforcement actions and compliance, and developed regular reports on enforcement activities.

All information in the department and division's files on enforcement matters, except data classified as confidential, private, or nonpublic under state or federal law, is open and readily accessible and the public.

J. General Information about the Administrative Penalty and the Cease and Desist Order Authority

The law grants the commissioner authority to issue administrative penalty orders requiring that violations be corrected and allows for the assessment of a monetary penalty. The administrative penalty order identifies violations discovered, requires that the violations be corrected, and imposes a penalty that may or may not be forgiven by the director depending on the seriousness or repetitiveness of the violation and the violator's response to the order.

The maximum penalty is \$10,000.

The statute provides criteria to be considered in determining the amount of any penalty. The maximum penalty is \$10,000 for each violator for all violations by that violator identified in an inspection or review of compliance. Willfulness, gravity, history, number of violations, economic benefit and other factors specifically identified in the order may be considered. For repeat violations, the commissioner must also consider similarity to previous violations, time elapsed, the number of previous violations, and the response of the party to the most recent previous violation. The order must include a statement of fact supporting the claim that violations have occurred, a reference to the rule, law or order violated, the amount of the penalty and the factors on which it is based, and a statement of the person's right to review the order. The act provides an expedited hearing process in case of appeal.

A cease and desist order is only effective for 72 hours.

The act also granted authority to issue cease and desist orders in cases where the violation poses an "immediate risk to public health." The cease and desist order is effective for 72 hours. In conjunction with the issuing a cease and desist order, division staff may post a sign to cease an activity until the cease and desist order is lifted. Only division staff are to remove the sign.

K. Procedures Used to Develop the Plan for Use of Administrative Penalty Order and Cease and Desist Order Authority

See Appendix B for the procedures used to review and modify the plan.

Minnesota Statutes, section 144.99, subdivision 7, provides that the commissioner of health prepare a plan for the use of the administrative penalty and cease and desist authority; that the commissioner provide a 30-day period for public comment on the plan; and that the initial plan be finalized by December 1, 1993. The division followed the procedures for plan development delineated in statutes and augmented them with further opportunity for public review and comment. Copies of the procedures used to solicit comment, notices issued requesting comment, and public comment received on development and revision of the plan, remain on file with the division. The commissioner approved the initial plan on November 8, 1993 with provisions for review and modification. The division revised the plan in 1995 and 1997. Attached to this plan as Appendix B is a copy of the procedures the division will use to review and modify an existing plan.

II. Use of the Administrative Penalty Order Authority

A. General

1. Use

Administrative penalty orders may be used as a remedy for violations of the statutes set forth in Minnesota Statutes, section 144.99, subdivision 1 and for violations of the statutes, rules, orders, stipulation agreements, settlements, compliance agreements, licenses, registrations, certificates, and permits adopted or issued by the division or under any other law now in force or later enacted for the preservation of public health.

2. Issuance

Pursuant to written delegation maintained in the director's office, the director may authorize designated division staff to issue administrative penalty orders.

3. Content

An administrative penalty order assessing either a forgivable penalty or a penalty that is not forgivable must include:

- a concise statement of the facts alleged to constitute a violation;
- a reference to the section of the statute, rule, variance, order, stipulation agreement, or term or condition of a permit violated;
- a statement of the monetary amount of the administrative penalty to be imposed and the factors on which the penalty is based; and
- a statement of the party's right to review of the order.

4. Report of issuance of penalty orders and other enforcement actions

The director will provide fiscal year reports to the commissioner of the issuance of administrative penalty orders and other enforcement actions.

5. Amount of penalty

The director may issue an administrative penalty order of up to \$10,000 for each violator for all the violations by that violator identified in an inspection or review of compliance.

In determining the amount of an administrative penalty for an initial violation, the division may consider:

- the willfulness of the violation;
- the gravity of the violation, including damage to humans, animals, air, water, land, or other natural resources of the state;
- the history of past violations;
- the number of violations;
- the economic benefit gained by the party by allowing or committing the violation; and
- other factors as justice may require, if the additional factors are specifically identified in the administrative penalty order.

See Appendix C for a copy of the penalty calculation worksheet.

In determining the gravity of the violation, the division will consider both the extent of the potential for harm from the violation and the deviation from compliance with the rule or statute violated by a regulated party. To determine a penalty, the division uses a worksheet, called a penalty calculation worksheet, found in Appendix C.

6. Repeat violations

For a violation after the initial violation, in determining the amount of the penalty, the division must consider the factors for an initial penalty above and also the:

- similarity of the most recent previous violation and the violation to be penalized;
- time elapsed since the last violation;
- number of previous violations; and
- response of the person to the most recent previous violation identified.

The division uses a worksheet, called a penalty calculation worksheet, found in Appendix C, to determine the penalty amount for repeat violations.

7. Compliance verification

Once a regulated party has resolved a violation, the division must verify compliance.

- The director will review and evaluate all information related to the issuance of an administrative penalty order to determine if the violation has been corrected.

- The director may direct compliance verification by site visit, reinspection, examination of documentation, or other means as may be reasonable under the facts of the case.
- The director must document compliance verification. Division program's have established record keeping procedures as necessary to enable the status of the administrative penalty orders to be followed and reporting made to the commissioner.

B. Forgivable Administrative Penalty Orders

I. Violation is not serious or repeated

Except for repeated or serious violations, the director must forgive the penalty assessed, if:

- the regulated party demonstrates, in writing to the director before the 31st day after receiving the order, that the violation has been corrected; or
- before the 31st day after receiving the order, the regulated party has developed a corrective plan acceptable to the director.

2. Compliance determination; forgiveness of penalty

The director will determine whether a violation has been corrected and notify the regulated party of the determination. Except in the case of a serious or repeated violation, if the director determines that the violation has been corrected or the director has approved a corrective plan, the penalty must be forgiven.

- Within 31 days the regulated party must provide information to the director demonstrating that the violation has been corrected or that a regulated party has taken appropriate steps to correct the violation. The director will find a corrective plan acceptable only if the violation cannot be corrected within the time period, not to exceed 30 days, specified by the director. A corrective plan must be in writing.
- The director will obtain, review and evaluate all information provided by the regulated party subject to a forgivable penalty order. The director will determine whether the violation has been corrected or an acceptable corrective plan developed.
- Ordinarily, the division will mail written notice of the director's determination of compliance to the regulated party within ten working days after receipt of the information; or within ten

working days after the 31st day after the division issued the penalty order, whichever is later.

- The director will not approve a corrective plan unless the regulated party acknowledges that forgiveness of the penalty is contingent on a timely completion of the corrective action contained in the plan. The director will not forgive the penalty if the corrective action is not completed in a specified time period.

3. Failure to comply; penalty due

a. Forgivable penalties

Unless the regulated party requests an expedited administrative hearing on a forgivable penalty assessed in an administrative penalty order as discussed in section III below, the forgivable penalty is due and payable to the department the 31st day after the regulated party received the order if:

- the regulated party fails to provide information demonstrating to the division that the violation has been corrected; or
- the regulated party has not taken appropriate steps toward correcting the violation.

If the regulated party has submitted information to the division that the director determines is not sufficient to show that the violation has been corrected or that appropriate steps have been taken toward correcting the violation, the forgivable penalty is due on the 20th day after the regulated party receives this determination.

b. Interest

Interest, at the rate established by the state court administrator pursuant to Minnesota Statutes, section 549.09, begins to accrue on forgivable penalties on the 31st day after the regulated party received the administrative penalty order. However, if the director cannot reach a determination of compliance within ten working days after the expiration of the 31-day period, interest will be abated until the division has notified the regulated party of the director's decision.

*See MN
Statutes, section
549.09 for
information on
interest rates.*

C. Nonforgivable Administrative Penalty Orders

The director is authorized to assess an administrative penalty that is nonforgivable for repeated or serious violations. Unlike the forgivable administrative penalty order, a nonforgivable administrative penalty order

must be paid by the regulated party regardless of whether the corrective action is performed. Under Minnesota Statutes, section 144.991, subdivision 4, a penalty issued pursuant to a nonforgivable administrative penalty order is due 31 days after the regulated party received the order unless that party requests an administrative hearing as provided for in Minnesota Statutes, section 144.991, subdivision 4, paragraph (a).

Because of the seriousness and finality of a nonforgivable administrative penalty order, the division will provide notice of the alleged violation and an opportunity for response before issuing the nonforgivable order. Without a prior meeting or other communication related to the violation, the division will provide a letter, called a "ten-day letter," to the regulated party clearly explaining the violations and underlying facts. The letter contains a request that the regulated party provide, within ten calendar days, any information that may impact the director's determination. In addition, division staff may contact the regulated party by telephone to explain the violations and ask about factual issues.

- In situations where a ten-day response time is not appropriate because of potential immediate public health risk or environmental concerns, the division will attempt to contact the regulated party by telephone to discuss the violations and request any response concerning the facts of the case.
- The regulated party's response, if any, will be considered before issuing a nonforgivable administrative penalty order.

I. Serious violations

Serious violations include conduct showing disregard of requirements or standards, or violations that present an actual or potential danger to public health or natural resources. Division regulatory programs are likely to consider the following types of violations as serious:

List of serious violations.

- operation or performance of work for which a license, certificate, registration or permit is required without the required license, certificate, registration or permit;
- employing a person who does not have the appropriate license, certification, registration or permit;

List of serious violations, continued.

- failure to call for an inspection, failure to provide notice, plans, reports or other information required to be submitted to the division or department under statute or rule, failure to secure plan approval prior to commencement of an activity;
- failure to comply with a cease and desist order issued pursuant to Minnesota Statutes, section 144.199, subdivision 6 including removal of a sign;
- failure to provide the division or department with access to information or property as provided under Minnesota Statutes, section 144.199, subdivision 2 and adopted rules;
- knowingly providing inaccurate or fraudulent information to the division or department, failure to comply with a reasonable request for information; and
- failure to comply with an order, agreement or corrective plan.

See Appendix A for program specific serious violations.

In addition to the division-wide serious violations described above, the regulatory programs specified under Minnesota Statutes, section 144.99, subdivision 1 have provided additional examples in Appendix A of violations considered serious and subject to a nonforgivable administrative penalty order. The list of program specific examples of serious violations is not exclusive. It is expected that each program may determine additional violations using the statutory criteria for penalty assessment specified in the consolidated enforcement act.

Violations that warrant a cease and desist order are also presumed to be serious violations and may also warrant a penalty assessment.

2. Repeat violations

The division may issue an administrative penalty order for a repeat violation of statutes, rules or other actions listed in Minnesota Statutes, section 144.99, subdivision 1.

To be considered a repeat violation, the subsequent violation must be of a similar type as the prior violation, although it need not be based on identical facts. For example, the division may cite a restaurant for a repeat

violation of the rule requiring food to be kept at specific temperatures if the first violation related to food in a salad bar and the second violation was for failure to cook hamburger at the required temperature. Similarly, a well contractor is subject to a repeat violation if the first violation related to placing a well too close to an agricultural chemical storage site and the second violation was for placing a well too close to a sanitary landfill, dump or waste stabilization pond. Both violations relate to the failure to locate a well the appropriate distance from a contamination source, and are the same type.

A repeat violation may be based on a variety of prior enforcement actions. The division may determine a repeat violation if a similar violation occurs after any of the following actions:

*Repeat
violations
criteria.*

- a correction order, whether corrected or not;
- a forgivable administrative penalty order where a correction was made;
- a forgivable administrative penalty order where a correction was not made and a penalty was assessed;
- a nonforgivable administrative penalty order;
- failure to comply with a commissioner's order, agreement, corrective plan or other action contained in Minnesota Statutes, section 144.99, subdivision 1;
- any other violation for which notice has been given to the regulated party for a violation of Minnesota Statutes, section 144.99, subdivision 1.

A repeat violation may be based on the same conduct that led to the initial violation. For example, if a regulated party fails to correct a violation after a correction order and the division subsequently inspects and finds the violation, it is considered a repeat violation and may be subject to a nonforgivable penalty assessment. The fact that a party appeals a prior penalty amount will not prejudice the determination of a current penalty amount.

3. Correction of violation

The director is authorized to include in an order assessing a nonforgivable administrative penalty a requirement that the violations cited in the order be corrected within 30 days from the date the regulated party receives the order.

- A regulated party which receives such an order must correct the violation within 30 days, unless the director issues a written extension of the deadline.

- The regulated party must promptly provide to the director evidence that the violations have been corrected, including any evidence which is reasonably requested by the director.
- Correction of violations does not relieve the regulated party of the duty to pay the nonforgivable penalty.
- Failure to correct violations may be grounds for an additional administrative penalty order or other enforcement action.

4. Penalty due; interest

Unless the regulated party requests review of the administrative penalty order in an expedited administrative hearing as discussed in section III below, the nonforgivable penalty is due and payable to the Minnesota Department of Health on the 31st day after the order was received regardless of whether the regulated party has performed the corrective action required in the order. Interest at the rate established by the state court administrator pursuant to Minnesota Statutes, section 549.09 begins to accrue on the nonforgivable penalty on the 31st day after the regulated party received the order.

*See MN Statutes,
section 549.09
for information
on interest rates.*

D. Combination Violations

The division issues a combination administrative penalty order when the case represents forgivable and nonforgivable violations. In determining which violations are forgivable and which violations are not forgivable, and in determining the penalty amounts, the factors will be considered as described in sections A, B and C above.

As in the case of a nonforgivable administrative penalty order, division staff will issue a ten-day letter before issuing a combination administrative penalty order and request any information relating to the violation unless a meeting or other communication has occurred relating to the violation.

The forgivable penalty is due and interest owed for the forgivable portion of the combination administrative penalty as described in section B for forgivable penalties. The nonforgivable penalty portion of the combination administrative penalty is due and interest owed as described in section C for nonforgivable penalties.

E. Cross Program Administrative Penalty Orders

Administrative penalty orders issued by the division may cite violations of more than one regulatory program. When the staff of one program discovers violations of another program, they must contact the supervisor of that program immediately. In general, the program that cites the most serious violations will take the lead in the case once violations have been identified. Communication among all staff involved in an enforcement action is critical.

F. Referral for Collection of Penalty

All penalties, interest, costs, attorney fees and litigation expenses collected under an administrative penalty order or the enforcement of an administrative penalty order must be paid by the regulated party within a specified time by certified or cashier's check made payable to the Minnesota Department of Health.

For more information on collections, see the Revenue Recapture Act, MN Statutes, sections 270A.01 to 270A.12.

- Any penalty, interest, costs, attorney fees and litigation expenses not timely remitted to the division may be collected by using such lawful means as determined will be efficient and cost effective, including those specified in the Minnesota Revenue Recapture Act, Minnesota Statutes, sections 270A.01 to 270A.12.
- In addition, or alternatively, the division may, within 30 days of the regulated party's failure to make timely remittance, refer the matter for collection to the Office of the Attorney General.

III. Hearing Requests

A. Expedited hearing

The recipient of an administrative penalty order has the right to challenge the order by requesting an expedited administrative hearing. Deadlines for requesting a hearing are described in Minnesota Statutes, section 144.991, subdivision 5. Deadlines for requesting a hearing depend on whether the penalty is forgivable, nonforgivable, or a combination of both are discussed below.

I. Forgivable administrative penalty orders

The recipient of a forgivable administrative penalty order has two alternative deadlines for requesting a hearing.

- The recipient of a forgivable administrative penalty order who fails to provide information showing the violation has been corrected or fails to submit a corrective plan, has 30 days from receipt of the administrative penalty order to request an expedited administrative hearing.
- Alternatively, if a recipient of a forgivable administrative penalty order provides information showing the violation has been corrected or submits a corrective plan, and if the recipient receives notice that the director has determined that a violation has not been corrected or an appropriate plan has not been approved, then the recipient has 20 days after receipt of the director's notice to request a hearing on the director's determination of the inadequacy of the corrective action or plan.

Regardless of which deadline the recipient of a forgivable administrative penalty order meets, the recipient may challenge the penalty, the corrective action required, or both.

2. Nonforgivable administrative penalty orders

If the recipient of a nonforgivable administrative penalty order wants to challenge the penalty, the recipient has 30 days from receipt of the nonforgivable administrative penalty order to request an expedited administrative hearing on the penalty. If the recipient of a nonforgivable administrative penalty order wants to challenge the corrective action required in the administrative penalty order, then the recipient has two deadlines for requesting a hearing on the corrective action.

- A recipient of a nonforgivable administrative penalty order who fails to provide information showing the violation has been corrected and fails to submit a corrective plan has 30 days from receipt of the administrative penalty order to request an expedited administrative hearing on the corrective action.
- Alternatively, if a recipient of a nonforgivable administrative penalty order provides information showing the violation has been corrected or submits a corrective plan, and if the recipient receives notice that the director has determined that a violation has not been corrected or a submitted plan has not been approved, then the recipient has 20 days after receipt of the notice to request a hearing on the corrective action.

3. Combination nonforgivable and forgivable administrative penalty orders

If the recipient of a combination administrative penalty order wants to challenge the nonforgivable penalty, the recipient has 30 days from receipt of the combination administrative penalty order to request an expedited administrative hearing. If the recipient of a combination administrative penalty order wants to challenge the forgivable penalty, or the corrective action required in the order, or both, then the recipient has two alternative deadlines for requesting a hearing.

- A recipient of a combination administrative penalty order who fails to provide information showing the violation has been corrected and fails to submit a corrective plan has 30 days from receipt of the administrative penalty order to request an expedited administrative hearing.
- Alternatively, if a recipient of a combination administrative penalty order provides information showing the violation has been corrected or submits a corrective plan, and if the recipient receives notice that the director has determined that a violation has not been corrected or a submitted plan has not been approved, then the recipient has 20 days after receipt of the notice to request a hearing on the corrective action, the forgivable penalty, or both.

In any hearing request, the recipient of the administrative penalty order must specifically state the reasons for requesting the hearing. If the recipient does not respond to the administrative penalty order, agency staff may contact the recipient before the end of the 30-day compliance period to determine the recipient's intentions.

Procedural time lines for the hearing process are set out in Minnesota Statutes, section 144.991, subdivision 5. The hearing must be held within 30 days after the recipient of an administrative penalty order files a hearing request with the commissioner, unless all parties agree to a later date. The commissioner must notify the recipient of the time and place of the hearing at least 15 days before the hearing.

*Hearing
procedures are
in
MN Rules,
parts
1400.8510 to
1400.8612.*

An administrative law judge from the Office of Administrative Hearings will conduct the hearing. The procedures for the conduct of the hearing are set out in Minnesota Rules, parts 1400.8510 to 1400.8612, as modified by Minnesota Statutes, section 144.991.

At the hearing, both parties will have an opportunity to present evidence. Any party wishing to submit written arguments to the administrative law

judge must do so within ten days after the end of the hearing. The administrative law judge must issue a report making recommendations to the commissioner within 30 days after the close of the hearing record. After the commissioner receives the administrative law judge's report, the recipient of the administrative penalty order has five days in which to submit comments for consideration by the commissioner before the commissioner issues a final administrative penalty order. If the administrative law judge makes a finding that the hearing was requested solely for purposes of delay or that the hearing request was frivolous, the commissioner may add to the amount of the penalty the costs charged to the agency by the Office of Administrative Hearings for the hearing.

The recipient of the final administrative penalty order may appeal it to the Minnesota Court of Appeals. If the recipient does not appeal a final administrative penalty order to the Minnesota Court of Appeals, or the order is reviewed and upheld by the court, then the recipient must pay the amount of the penalty plus interest accruing from 31 days after the recipient received the original administrative penalty order.

4. Independence of the commissioner

*Enforcement
Teams and
Advising Teams.*

To provide for the issuance of an unbiased final administrative penalty order, the division has a procedure for separating persons involved in the issuance of the administrative penalty order from persons involved in consideration of an appeal through the expedited hearing process. Persons involved in the issuance of the administrative penalty order are the "enforcement team"; persons involved in advising the commissioner are the "advisory team."

When an administrative penalty order is anticipated, division staff identifies members of the enforcement team and the advisory team. The staff member set forth the membership of these groups. In a case involving more than one regulatory program, the enforcement team and advisory team will each contain representatives of all programs that have cited violations in the administrative penalty order.

The enforcement team consists of division staff and attorney general staff involved in the process of issuing the administrative penalty order. The enforcement team defends the division and department if there are any challenges to the administrative penalty order and conducts any meetings with the regulated party.

The advisory team consists of the deputy commissioner of health, an attorney from the Attorney General's Office and one or more division staff who has had no involvement with the decision-making process of issuing

the administrative penalty order. To maintain the commissioner's independence, the advisory team has no involvement with the administrative penalty order until the administrative law judge's order is issued.

The only contact the enforcement team will have with the commissioner, until the commissioner's decision is issued and the appeal process has concluded or the time for appeal has expired, will be through the adversarial process in conjunction with the contested case proceedings with contemporaneous notice to the administrative penalty order recipient.

To preserve its independence, the advisory team must have no ex parte discussions with members of the enforcement team, other program staff or attorney's representing the enforcement team (discussions without the APO recipient or representatives of the administrative penalty order recipient present) of the case until the appeal process has concluded or the time for appeal has expired.

5. Mediation; Collection; District court petition

In addition to review of a penalty assessment by the Office of Administrative Hearings on these proceedings, the commissioner may enter into mediation.

The attorney general may enforce penalties that are due and payable in any manner provided by law for the collection of debts and may bring a civil action in district court seeking payment of the penalties, injunctive or other appropriate relief including monetary damages, attorney fees, costs and interest.

The attorney general may petition the district court to file the administrative penalty order as an order of the court. At any court hearing the only issues a party may contest are procedural and notice issues. Once entered, the administrative penalty order may be enforced in the same manner as a final judgment of the district court. In any judicial action brought by the attorney general, if the state finally prevails and if the proven violation was willful, the state may be allowed an amount determined by the court to be the reasonable value of all or part of the litigation expenses incurred by the state. In determining the amount, the court will give consideration, in addition to other penalties, to the economic circumstances of the defendant.

B. Hearings related to denial, refusal to renew, suspension, or revocation of a permit, license, registration, or certificate

As stated in Minnesota Statutes, section 144.99, subdivision 10, if the division proposes to deny, refuses to renew, suspends, or revokes a permit, license, registration, or certificate for any of the reasons described in section II, item H of this plan, the commissioner must first notify, in writing, the person against whom the action is proposed to be taken. The division must give the person an opportunity to request a hearing under the contested case provisions of Minnesota Statutes, Chapter 14. If the person does not request a hearing by notifying the commissioner within 20 days after receipt of the notice of proposed action, the commissioner may proceed with the action without a hearing.

This does not apply to:

- the denial of or refusal to renew a permit, license, registration, or certificate based on the applicant's failure to meet or maintain the minimum qualifications for holding the permit, license, registration, or certificate;
- the denial of or refusal to renew a permit, license, registration, or certificate based on the applicant's failure to submit a complete application, including any application fee;
- the denial of, refusal to renew, suspension of, or revocation of a permit, license, registration, or certificate if the person against whom the action is proposed to be taken has been granted a hearing described above within the previous 12 months;
- the denial of, refusal to renew, suspension of, or revocation of a permit, license, registration, or certificate, due, for example, to an outstanding tax liability or child support payments, under the authority of another government agency.

IV. Use of Cease and Desist Order Authority

A. General; Immediate Risk to Public Health

The director may issue a cease and desist order to stop an activity covered by Minnesota Statutes, section 144.99, subdivision 1, if continuation of the activity would result in an immediate risk to public health.

Generally, a cease and desist order may be appropriate if an individual or group is in danger of specific harmful consequences in the immediate future if an action or activity goes unchecked.

Some programs of the division had similar authority in the past and those programs suggest the kinds of violations which may call for the use of a cease and desist order.

In addition to the general statutory test of "posing an immediate risk to public health," each regulatory program specified under Minnesota Statutes, section 144.99, subdivision 1, has provided program specific additional examples in Appendix A of violations which would warrant issuance of a cease and desist order. The list of program specific examples of violations which would warrant cease and desist action is not exclusive. It is expected that each program may determine additional cease and desist violations using the statutory criteria.

B. Procedures for Issuance

To issue a cease and desist order, the division must make a prior determination that failure to issue the order would result in an immediate risk to public health.

- A cease and desist order may be issued on-site by division staff after prior approval by the director. A sign or notice indicating a cease and desist order has been issued and specifying the duration of the order may be posted and may be removed only on authorization by the commissioner or the director.
- A cease and desist order must be issued in writing except in cases of extreme emergency.
- If a cease and desist order is issued on-site, formal written confirmation to the regulated party from the director must follow within 24 hours. Written confirmation of a cease and desist order must include:
 - a concise statement of the fact alleged to constitute a violation;
 - a reference to the section of the statute, rule, variance, order, or term or condition of a permit violated; and
 - a statement requiring that the violations cited be corrected or ceased immediately.
- The director will provide a copy to the commissioner of all cease and desist orders upon issuance. A copy will also be provided to the assistant attorney general representing the regulatory program issuing the order in case further action becomes necessary.

C. Compliance Verification

Once a regulated party has resolved a violation, compliance must be verified.

- The director will review and evaluate all information related to the issuance of a cease and desist order to determine if violations have been corrected and there is no longer an immediate risk to public health.
- The director may make compliance verification by site visit, re-inspection, examination of documentation, or other means as may be reasonable under the facts of the case.
- The director will determine whether a violation has been corrected and notify the regulated party of the determination.
- The director must document compliance verification. Division program's have established record keeping procedures as necessary to enable the status of cease and desist orders to be followed and reporting made to the commissioner.

D. Further Action

The commissioner, in addition to any other remedy, may take further actions such as injunctive relief to restrain activities for a period beyond 72 hours or referral for criminal prosecution.

V. Plan Revision

The division will evaluate this plan as necessary and at least every five years according to the process delineated in Appendix B. If revisions are necessary, public notice that the plan has been modified will be made.

VI. Adoption of Revised Plan

Pursuant to authority granted under the Health Enforcement Consolidation Act, Minnesota Statutes, sections 144.989 to 144.993, and pursuant to the procedures specified in section V above, I approve and adopt this revised plan for the use of administrative penalty and cease and desist orders.

SO APPROVED AND ADOPTED this ____ day of _____,
19____.

Anne M. Barry, Commissioner of Health

Appendix A Specific Program Information

Use of Appendix A

In addition to the general criteria for the assessment of administrative penalties described in section II and the general criteria for the use of cease and desist orders described in section IV, each regulatory program specified under Minnesota Statutes, section 144.99, subdivision 1, has provided examples of violations which the program considers serious and subject to a nonforgivable administrative penalty order or a violation warranting a cease and desist order. The program specific examples are not exclusive.

These examples are in addition to the common elements of division wide serious violations described in section II, item C (see pages 15 and 16 of this plan) and the common element of "*posing an immediate risk to public health*" for the issuance of a cease and desist order (see page 24 of this plan).

Violations that warrant a cease and desist order are presumed to be serious violations and may also warrant an administrative penalty assessment. Each program may determine additional violations using the statutory criteria specified in the consolidated enforcement act. When new or modified rules or laws are adopted or changes in public health hazard are determined by the agency, Appendix A will be updated to reflect these changes.

Indoor Air Quality

Serious violations

1. **Minnesota Rules, part 4620.4600, subpart 3:** An enclosed sports arena which exceeds one-hour average air concentration of 125 parts per million of carbon monoxide or 2.0 parts per million of nitrogen dioxide and the facility fails to shut down operation immediately and evacuate the arena.
2. **Minnesota Rules, part 4620.4500:** Failure of an enclosed sports arena to measure carbon monoxide levels or nitrogen dioxide levels at least once every week when internal combustion engines are operated.
3. **Minnesota Rules, part 4620.4600, subpart 2:** Failure by an enclosed sports arena to notify the department of one-hour average of carbon monoxide which exceeds 30 parts per million or nitrogen dioxide which exceeds 0.5 parts per million within five working days.
4. **Minnesota Rules, part 4620.4500, subpart 1:** Failure of an enclosed sports arena to submit air quality testing logs as requested by the department.
5. **Minnesota Statutes, section 144.416 and Minnesota Rules, part 4620.0700:** Failure of the proprietor or other person in charge of a public place to provide an acceptable nonsmoking area.
6. **Minnesota Statutes, sections 144.414, subdivision 2 and 144.416:** Failure by the proprietor or person in charge to prohibit smoking in a child care center or family child care home during the hours of operation.
7. **Minnesota Statutes, sections 144.414, subdivision 3 and 144.416:** Failure by the proprietor or person in charge to prohibit smoking in a health care facility or clinic.
8. **Minnesota Statutes, sections 144.4165 and 144.416:** Failure to prohibit smoking in a public school.

Cease and desist

1. **Minnesota Rules, part 4620.4600, subpart 3:** An enclosed sports arena which exceeds 125 parts per million of carbon monoxide or 2.0 parts per million of nitrogen dioxide and the facility fails to shut down operation immediately, evacuate the arena, and notify the department within five working days.
2. **Minnesota Rules, part 4620.4600, subpart 2:** Failure to notify the department within five working days when there is a violation of Minnesota Rules, part 4620.4600, subpart 3.

Food, Beverage And Lodging Establishments Manufacture Home Parks Recreational Camping Areas Children's Camps

Serious violations

1. **Minnesota Rules, parts 4625.1300; 4625.3901, subpart 1; 4630.0600; 4630.3100; chapter 4720; and Code of Federal Regulations, title 40, part 141.63:** Failure to take appropriate corrective action (disinfect) for coliform maximum contaminant level.
2. **Minnesota Rules, parts 4625.1300; 4625.3901, subpart 1; 4630.0600; 4630.3100; chapter 4720; and Code of Federal Regulations, title 40, part 141.32:** Failure to provide public notice for acute maximum contaminant level violations (coliform and nitrates).
3. **Minnesota Rules, parts 4625.1300; 4625.3901, subpart 1; 4630.0600; 4630.3100; chapter 4720; and Code of Federal Regulations, title 40, part 141.73:** Failure to continuously provide required treatment at surface water systems.
4. **Minnesota Statutes, section 327.20, subdivision 1, clauses (6) and (7):** Failure to provide a municipally-approved shelter or evacuation plan for a manufactured home park after notification by the department.

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5. **Minnesota Rules, part 4625.1700:** Failure to comply with an order for a lodging establishment to hire a pest control operator licensed by the state to exterminate pests.
6. For food establishments, failure to provide convenient hand washing facilities.
7. For food establishments, failure to wash hands.
8. For food establishments, potentially hazardous food found to be at improper temperatures on two or more consecutive occasions.
9. For food establishments, possession or service of food obtained from an unapproved source.
10. For food establishments, no certified food service operator as required by law and rule.
11. For permanent food service establishments, lack of hot and cold water under pressure.
12. For permanent food service establishments, lack of approved utilities so hand washing, warewashing, and food preparation equipment are operable.
13. For food establishments, removing embargoed or condemnation signs.
14. For food establishments, rodent, cockroach or fly infestation.
15. In a lodging facility, hot water that exceeds 130 degrees Fahrenheit at hand washing sinks, showers or bathtubs.
16. Failure to comply with a commissioner's order relating to food, waterborne outbreaks, flooding, sewage backup that endangers water or food sources, sources of contamination, ill employees, service or possession of embargoed or condemned food, or use of condemned equipment.
17. For food establishments, lack of approved functional toilet facilities.

18. For a food establishment, an inspection rating score falling in the marginal category of 60 to 69 percent on two or more consecutive inspections.
19. Failure to correct a failing on-site sewage treatment system.
20. Failure to correct the same or similar serious violations on two or more consecutive inspections.

Cease and desist

1. **Minnesota Rules, part 4717.3800:** Operation of a public pool after notification to close.
2. **Minnesota Rules, part 4625.2601, subparts 2 and 3 and part 4625.3601, subpart 2:** Failure to comply with a commissioner's order dealing with food or waterborne outbreaks, flooding, or sewage backup which endangers water or food sources, sources of contamination, ill employees, serving of embargoed or condemned food, or use of condemned equipment.
3. **Minnesota Rules, parts 4625.1300; 4625.3901, subpart 1; 4630.0600; 4630.3100; chapter 4720; and Code of Federal Regulations, title 40, parts 141.32 and 141.63:** Failure to take appropriate corrective action (disinfect) and provide public notice for coliform maximum contaminant level violation.
4. Lack of approved ware washing facilities, convenient hand washing facilities, adequate food preparation and storage equipment, or functional toilet facilities.
5. The licensed food establishment scores below 60 on two consecutive inspections on a rated inspection as measured by the rating system approved by the Minnesota Department of Health.
6. The licensed lodging establishment scores below 60 on two consecutive inspections on a rated inspection as measured by the rating system approved by the Minnesota Department of Health.

Public Water Supplies

Regulated under Minnesota Statutes, sections 144.381 to 144.385
Minnesota Rules, chapter 4720 incorporates federal code by reference.

Serious violations

1. **Code of Federal Regulation, title 40, section 141.63:** Failure to take appropriate corrective action (disinfect) for coliform maximum contaminant level.
2. **Code of Federal Regulation, title 40, section 141.32:** Failure to provide public notice for acute maximum contaminant level violations (coliform and nitrates).
3. **Code of Federal Regulation, title 40, section 141.73:** Failure to continuously provide required treatment at surface water systems.

Cease and desist

1. **Code of Federal Regulation, title 40, sections 141.63 and 141.32:** Failure to take appropriate corrective action (disinfect) and provide public notice for coliform maximum contaminant level violation.

Public Pools

Regulated under Minnesota Statutes, section 144.12, subdivision 1,
paragraph (6).

Serious Violations

In addition to those violations described in section II, item C of this plan,
any violation cited for pool closure in Minnesota Rules, part 4717.3970.

Cease and desist

Any violation cited for pool closure in Minnesota Rules, part 4717.3970.

Plumbing And Water Conditioning

Serious violations

See those violations which are described in section II, item C of this plan.

Cease and desist

1. Working without a required current license or registration.
2. Working without approved plans.

Wells And Borings

Serious violations

1. **Minnesota Rules, part 4725.2020: Interconnection of Aquifers**
2. **Minnesota Rules, part 4725.2050: Disposal of Contaminants in Wells**
3. **Minnesota Rules, parts 4725.2250, 4725.2350, 4725.2450, 4725.2550, and 4725.2650: Certain Casing Requirements**

Termination of casing below grade.

Use of non-watertight casing.

Use of previously rejected casing.

Telescoped casing.

Failure to properly join casing.

Screwing plastic casing together.

Drilling inside plastic casing.

Use of plastic in limestone or dolomite.

Driving plastic casing.

4. **Minnesota Rules, part 4725.2850: Gravel Pack**

Extending gravel pack >10 feet above static or top or bottom of screen.

5. **Minnesota Rules, part 4725.2950: Drilling Fluids**

Use of non-potable water for drilling.

6. **Minnesota Rules, part 4725.3050: Grouting**
 - Failure to grout where grouting is required.
 - Use of bentonite where cement is required.
 - Use of unapproved grout materials.
 - Failure to extend tremie line to bottom of space to be grouted.
 - Dump grouting through more than 10 feet.
 - Failure to use drive shoe.
 - Improper bore hole size.
 - Gross violation of above ground, below ground casing connection requirements.
 - Interconnecting wells without proper connection.
 - No back flow prevention device for chemigation systems.

7. **Minnesota Rules, part 4725.4450: Flowing Wells or Borings**
 - Failure to control the flow on a flowing well.
 - Failure to grout.
 - Failure to use neat cement grout.

8. **Minnesota Rules, part 4725.3650: Special Well Construction Areas**
 - Failure to have plan review prior to construction.
 - Failure to comply with special construction area requirements.

9. **Minnesota Rules, part 4725.3850: Well Sealing**
 - Failure to fill well with proper grout.
 - Use of improper grout material.
 - Dump grouting.
 - Failure to submerge tremie pipe during grouting.
 - Failure to remove obstructions and debris prior to sealing.
 - Failure to remove or perforate casing where required.

10. **Minnesota Rules, part 4725.4450: Isolation Distances**
 - Gross violation of isolation distance requirements.

11. **Minnesota Rules, part 4550: Minimum Protective Depth**
 - Failure to construct with at least 15 feet of casing.

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12. **Minnesota Rules, part 4725.5150: Buried Suction Line**
Installation of buried suction line without proper protection.
13. **Minnesota Rules, part 4725.5550: Disinfection**
Failure to disinfect.
14. **Minnesota Rules, part 4725.6150: Dewatering Wells**
See grouting and sealing violations.
15. **Minnesota Rules, part 4725.6450: Monitoring Wells**
See grouting and sealing violations.
16. **Minnesota Rules, part 4725.6850: At-Grade Monitoring Wells**
Flagrant at-grade violations.
At-grade without permit.
17. **Minnesota Rules, part 4725.7050: Vertical Heat Exchangers**
Improper heat transfer fluid.
Improper piping.
Grouting violations.
18. **Minnesota Rules, part 4725.7250: Elevator Shafts**
Improper grouting.
Improper sealing.
19. **Minnesota Rules, part 4725.7450: Environmental Bore Holes**
See grouting and sealing violations.
See casing and construction violations.
20. **Willful or Flagrant Disregard of Construction or Sealing Requirements: Failure to obtain a Maintenance Permit after Third Notice**

Cease and desist

1. **Minnesota Statutes, section 103I.205: Location of a Source of Contamination**

Placement of contaminant source too close to existing well.
2. **Construction in well advisory area without plan review.**
3. **Minnesota Rules, part 4725.2050: Injection of Contaminants into Groundwater**
4. **Improper construction, repair or sealing that poses an imminent threat to health or groundwater.**

Asbestos

Serious violations

1. **Minnesota Statutes, section 326.74, Minnesota Rules, part 4620.3410, Minnesota Rules, part 4620.3420: Failure to provide advance notification and reporting of asbestos-related work.**
2. **Minnesota Statutes, section 326.73; Minnesota Rules, parts 4620.3300, subpart 1; 4620.3310, subpart 1; 4620.3330, subpart 1; 4620.3340, subpart 1; and 4620.3350, subpart 1: Failure to obtain certification prior to performing asbestos-related work or asbestos management activity.**
3. **Minnesota Statutes, section 326.72, subdivision 1 and Minnesota Rules, part 4620.3200, subpart 9: Failure to be licensed to perform asbestos-related work.**
4. **Minnesota Rules, part 4620.3250, items A and C: Failure to employ only persons certified to do asbestos-related work and failure to ensure that certified asbestos site supervisor is present at the work site at all times when asbestos-related work is performed.**
5. **Violations of Minnesota Statutes, section 326.76 and Minnesota Rules, part 4620.3450, item B relating to the Duties of Contracting Entities.**

6. **Violations of Minnesota Rules, part 4620.3460 relating to Inspection and Assessment of Asbestos-containing Materials.**
7. **Violations of Minnesota Rules, part 4620.3559 relating to Applicable Work Practices for Abatement.**
8. **Minnesota Rules, part 4620.3566, Cleaning Containment Area before Abatement; Minnesota Rules, part 4620.3567, Installation of Critical Barriers; Minnesota Rules, part 4620.3568, Containment; Minnesota Rules, part 4620.3569, Decontamination Units; Minnesota Rules, part 4620.3570, HEPA-filtered Negative Pressure; Minnesota Rules, part 4620.3571, Removal of Asbestos-containing Material; Minnesota Rules, part 4620.3572, Encapsulation of Asbestos-containing Material; Minnesota Rules, part 4620.3573, Permanent Enclosure of Asbestos-containing Material; Minnesota Rules, part 4620.3575, Completion of Abatement; Minnesota Rules, part 4620.3580, Glove Bag Procedures; Minnesota Rules, part 4620.3581, Mini-containment Procedures; Minnesota Rules, part 4620.3582, Removal of Entire Facility Components with Intact Asbestos-containing Material; Minnesota Rules, part 4620.3585, Abatement for Demolition by Destruction to the Ground; Minnesota Rules, part 4620.3592, Indoor Air Monitoring; Minnesota Rules, part 4620.3594, Clearance Air Sampling; Minnesota Rules, part 4620.3596, General Requirements for Air Monitoring Sample Collection; Minnesota Rules, part 4620.3597, Phase Contrast Microscopy; and Minnesota Rules, part 4620.3598, Transmission Electron Microscopy: Violations of minimum standards for the safe abatement of asbestos-containing material and air monitoring associated with safe abatement of asbestos-containing materials.**

Cease and desist

1. **Absence or severe impairment of one or more of the protective measures that potentially allows asbestos fibers to escape into the surrounding space if not corrected immediately. This situation could involve one or more violations of Minnesota Rules, part 4620.3559, Applicable Work Practices for Abatement; Minnesota Rules, part 4620.3566, Cleaning Containment Area before Abatement; Minnesota Rules, part 4620.3567, Installation of Critical Barriers; Minnesota Rules, part 4620.3568, Containment; Minnesota Rules, part 4620.3569,**

Decontamination Units; Minnesota Rules, part 4620.3570, HEPA-filtered Negative Pressure; Minnesota Rules, part 4620.3571, Removal of Asbestos-containing Material; Minnesota Rules, part 4620.3572, Encapsulation of Asbestos-containing Material; Minnesota Rules, part 4620.3573, Permanent Enclosure of Asbestos-containing Material; Minnesota Rules, part 4620.3575, Completion of Abatement; Minnesota Rules, part 4620.3580, Glove Bag Procedures; Minnesota Rules, part 4620.3581, Mini-containment Procedures; Minnesota Rules, part 4620.3582, Removal of Entire Facility Components with Intact Asbestos-containing Material; Minnesota Rules, part 4620.3585, Abatement for Demolition by Destruction to the Ground; Minnesota Rules, part 4620.3592, Indoor Air Monitoring; Minnesota Rules, part 4620.3594, Clearance Air Sampling; Minnesota Rules, part 4620.3596, General Requirements for Air Monitoring Sample Collection; Minnesota Rules, part 4620.3597, Phase Contrast Microscopy; and Minnesota Rules, part 4620.3598, Transmission Electron Microscopy.

2. **Minnesota Rules, part 4620.3571, subparts 1 and 2: Abatement of asbestos-containing material without adequate water.**
3. **Minnesota Rules 4620.3592, subparts 2 and 5: Absence of indoor air monitoring for greater than one work shift during asbestos-containing material disturbance.**
4. **Minnesota Rules, part 4620.3575, subpart 5: Removal of critical barriers and the decontamination unit prior to clearance air monitoring and sample analysis.**
5. **Minnesota Rules, part 4620.3594, subpart 1: Failure to conduct clearance air monitoring.**

Lead

Serious violations

1. **Minnesota Rules, part 4761.0500, subpart 2: Failure to contain a work site as required.**
2. **Minnesota Rules, part 4761.0500, subpart 4: Use of prohibited abatement methods.**

3. **Minnesota Rules, part 4761.0700:** Failure to use personal protective equipment, including respirators, as required.
4. **Minnesota Statutes, sections 144.9504, subdivision 8 and 144.9505, subdivision 4:** Failure to provide advance notice and reporting of lead abatement work.
5. **Minnesota Rules, part 4761.0700, subpart 1:** Failure of lead abatement workers or supervisors to properly use personal protection equipment.
6. **Minnesota Statutes, section 144.9504, subdivision 8:** Failure to complete an ordered lead hazard reduction with the required time frame.

Cease and desist

1. **Minnesota Rules, part 4761.0500:** Improper containment that allows abatement waste to escape into the surrounding area.
2. **Minnesota Statutes, section 144.9505, subdivision 1 and Minnesota Rules, part 4761.0700, subpart 3:** Use of personnel for lead abatement who are not certified as lead abatement workers.
3. **Minnesota Rules, part 4761.0500, subpart 6:** Failure to clean up site daily.

Radiation Control

Serious violations

1. **Minnesota Rules, parts 4730.1510, subpart 6, items A, D and F and 4730.2050, subpart 3, item B:** Staff, ancillary personnel or other individuals in the x-ray room when not required for the radiographic procedure.
2. **Minnesota Rules, part 4730.0380:** Dose level in unrestricted area exceeded.
3. **Minnesota Rules, part 4730.1510, subpart 6, items B, C, D, E, and F and subpart 7:** Personnel shielding not used.

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4. **Minnesota Statutes, section 144.121, subdivision 4 and Minnesota Rules part 4730.1510, subpart 11:** Required personnel monitoring devices not worn.
5. **Minnesota Rules, part 4730.1950, subpart 4, item A:** Intraoral film holders and bite blocks not used.
6. **Minnesota Rules, parts 4730.1510, subpart 8, items A and D and 4730.2050, subpart 2, item D:** Mechanical cassette holders not used.
7. **Minnesota Rules, part 4730.0360:** Minors occupationally exposed.
8. **Minnesota Rules, parts 4730.1510, subpart 6, items B, C, D, E and F; 4730.2050, subpart 3, item C; and 4730.2150, subpart 11, item B, subitem (1), items C and D:** Improper shielding of non-patients.
9. **Minnesota Rules, part 4730.1655:** No quality assurance program in place.
10. **Minnesota Rules, part 4730.1850, subpart 9:** Minimum source-to-skin distance not maintained on any portable x-ray unit.
11. **Minnesota Rules, part 4730.2150, subpart 9:** Source-to-skin restrictions less than the minimum specified on fluoroscopic equipment.
12. **Minnesota Rules part 4730.2150, subpart 11:** Scatter radiation levels exceeded when any fluoroscopic equipment is used.
13. **Minnesota Rules part 4730.0300, subparts 7 and 8:** Failure to calibrate radiation survey instruments and alarming ratemeters at intervals required.
14. **Minnesota Rules, part 4730.2510, subpart 3; part 4730.2710, subpart 2; and 4730.2750, subpart 3:** Failure to provide the registrant's employees with written operating and emergency procedures.

15. **Minnesota Rules, part 4730.2510, subpart 11; and 4730.2710, subpart 9:** Failure to properly secure an operable industrial ionizing radiation producing equipment, nonmedical accelerator or active NARM source that is left unattended.
16. **Minnesota Rules, part 4730.2510, subpart 13:** Failure of the registrant to provide at a permanent or temporary jobsite the personnel monitoring and radiation survey requirements for class A, class B or class E industrial radiographic equipment
17. **Minnesota Rules, part 4730.2580, subpart 4, items A to G; part 4730.2710, subpart 10:** Failure of the registrant to perform leak tests on sealed NARM sources that are in use at the proper intervals as required.

Cease and desist

1. **Minnesota Rules, part 4730.0310, subpart 2, items A or C and part 4730.2450, subpart 2:** Dose levels in restricted areas exceeded.
2. **Minnesota Rules, part 4730.0380:** Dose level in unrestricted area exceeded.
3. **Minnesota Rules, part 4730.1210:** Any prohibited use of ionizing radiation.
4. **Minnesota Rules, part 4730.1450:** Opportunity to inspect not afforded.
5. **Minnesota Rules, part 4730.1750, subpart 11:** Timer not functioning properly.
6. **Minnesota Rules, part 4730.1750, subpart 13, item A:** X-ray exposure control dead-man switch not functioning properly.
7. **Minnesota Rules, part 4730.1750, subpart 15, item E:** Certified x-ray equipment not meeting the compliance standards.
8. **Minnesota Rules, parts 4730.1691, subpart 4, item B; 4730.1850, subpart 6, item B; and 4730.2050, item A:** X-ray length field alignment exceeded five percent of total SID.

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9. **Minnesota Rules, parts 4730.1850, subparts 4, 5, 6, item A; 4730.2050, subpart 2, item C; and 4730.2150, subpart 2, item A:** Field size exceeds receptor size by 5 percent.
10. **Minnesota Rules, part 4730.2150, subpart 4:** Fluoroscopic exposure control dead-man feature not operational. Ability to get a fluoroscopic exposure while unit is in the parked position.
11. **Minnesota Rules, part 4730.2150, subpart 5, items A, B, C and E:** Fluoroscopic entrance exposure limits exceeded.
12. **Minnesota Statutes, section 144.121 and Minnesota Rules part 4730.5000:** Operator of equipment not qualified by having passed the x-ray operator examination or equivalent.
13. **Minnesota Statutes, section 144.121 and Minnesota Rules part 4730.5000:** Registrant allowing x-ray equipment to be operated by individual who was not qualified by passing the x-ray operator examination or equivalent.
14. **Minnesota Rules, part 4730.1310:** Healing arts screening conducted without the commissioner's approval.
15. **Minnesota Rules, part 4730.0300, subpart 5:** Failure to install or use warning devices.
16. **Minnesota Rules, part 4730.0300, subpart 6:** Failure to properly warn and use control devices at entrances to areas of high and very high radiation.
17. **Minnesota Rules, parts 4730.2510, subpart 4; 4730.2710, subpart 4; and 4730.2750, subpart 4:** Failure of the registrant to properly train and ensure that an employee is trained to use the industrial radiation producing equipment or nonmedical accelerator equipment and maintains this training.
18. **Minnesota Rules, part 4730.2550, subpart 13:** Failure to provide proper shielding of components for class D industrial equipment.
19. **Minnesota Rules, part 4730.2560, subpart 2:** Failure of the registrant to provide the necessary safety interlock system, separate circuits and manual resetting capability.

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20. **Minnesota Rules, part 4730.2580, subpart 4, item H:** Failure of registrant to immediately withdraw from service any sealed NARM source that reveals the presence of 0.005 microcurie or more of removable contamination.
21. **Minnesota Rules, part 4730.2750, subpart 6:** Failure of the registrant to remove a sealed source that has become lodge, damaged, or rupture in a well, boring, or drilled hole.
22. **Minnesota Rules, part 4730.2750, subpart 7:** Failure of a registrant to receive a variance before using a sealed source in a well or boring without casing.

Appendix B

Plan Review and Modification

Procedure to Review and Modify Plan for Use of Administrative Penalty and Cease and Desist Authority

1. Publish in the *State Register* a notice soliciting comment on existing plan. Request comment relating to existing plan and any modifications the division or department may be considering.
 - (a) A copy of the notice will be sent to all persons on the agency certified list and to persons representing Environmental Health Division regulated parties.
 - (b) Comment shall be requested for 30 calendar days.
2. Staff of the Environmental Health Division, along with representatives of the Office of the Attorney General, Health Division, will consider revisions to the plan and appendixes. After the close of the comment period, these persons will review external comment and recommend modifications.
3. Modifications to the existing plan shall be presented to representatives of regulated programs and any other interested parties at an informational meeting. Comment within 30 days on the modifications shall be requested.
4. Notice shall be published in the *State Register* that modifications have been proposed to the existing plan. A copy of the revised plan shall be made available. The public shall be afforded at least 30 days to comment.
 - (a) A copy of the notice shall be sent to all persons on the agency certified list for rulemaking and to a list of representatives of Environmental Health Division regulatory programs.
 - (b) Comment will be requested for at least 30 days.
5. At the close of the comment period, division staff, in consultation with representatives of the Office of the Attorney General, Health Division, will review comment and make a final recommendation to the commissioner for modifications to the existing plan.
6. Revision of the plan may occur when a new or modified rule or law are adopted or changes related to public health hazards are determined by the agency. To update the plan when a new or revised rule is adopted, notice of the changes to the plan will be published in the *State Register* when notice of the adoption of rules are published or through separate notice. Changes to the plan will be effective with the new or revised rules or as specified in the notice.
7. Revisions to the existing plan must be adopted by the commissioner of health and are effective on adoption.

Appendix C

Penalty Calculation Worksheet

Appendix C is a template of the worksheet used by division staff to calculate administrative penalties.

S U M M A R Y

General Information

Regulated Party Name:

Registration Number:

Address:

Inspector:

Date of Inspection:

EH Program:

Radiation Control

Site Name and Address:

	Present Violations Cite rules	Serious?	Repeat?	Forgivable (F) or Non-Forgivable (N)
1.	List Serious and Repeat Violations	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> F <input type="checkbox"/> N
2.	List Serious Violations	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> F <input checked="" type="checkbox"/> N
3.	List Repeat Violations	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> F <input type="checkbox"/> N

Forum Information

Date of Penalty Calculation Forum:

Forum Participants:

Inspector

Reviewer

Supervisor

Step 1: Determine if the penalty is forgivable or non-forgivable

A: Determine if the violation is Serious.

Are any of the violations serious?

Yes

No

Why?

B: Determine if the violation is a repeat

Are any of the violations repeat violations?

Yes

No

Why?

C: Determine if the penalty is forgivable?

Is a portion of the penalty forgivable?

Yes

No

Why?

Step 2: Calculate the base penalty.

Violation #1:

Potential for harm is: Minor

Why?

The deviation from compliance is: Minor

Why?

Base Penalty Amount: \$

Violation #2:

Potential for harm is:

Why?

The deviation from compliance is:

Why?

Base Penalty Amount: \$

Violation #3:

Potential for harm is: Minor

Why?

The deviation from compliance is: Minor

Why?

Base Penalty Amount: \$

Total Base Penalty

Forgivable	Non-Forgivable	Total
\$	\$	\$

Step 3: Determine any adjustments to base penalty
A. For repeat violations only.

	Forgivable	Non-forgivable	Total
(1) Similarity to previous violations			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			
(2) Time elapsed since last inspection			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			
(3) Number of previous violations			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			
(4) Response to most recent violation			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			

Step 3: Determine any adjustments to the base penalty.**B. For all violations:**

	Forgivable	Non-forgivable	Total
(1) The willfulness of the violation:			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			
(2) History of past violations:			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			
(3) The number of current violations:			
Adjustment percent	0%	0%	0%
Adjustment amount	\$0.00	\$0.00	\$0.00
Reason for adjustment:			
(4) Economic Benefit. (See attachment A.)			
Adjustment amount	\$0.00	\$	\$
Explanation of economic benefit gained: See Attachment A			
(5) Other factors justice may require:			
Amount of adjustment for other factors	\$0.00	\$0.00	\$0.00
Identify factors considered in this section:			
Reason for adjustment based on these factors:			

Step 4: For combination APOs only, calculate the forgivable and non-forgivable portions of the penalties

A. Determine forgivable and non-forgivable violations:	See steps 1 & 2
B. Total base penalty for all forgivable violations:	\$
C. Total base penalty for all non-forgivable violations:	\$
D. Total base penalty for all violations:	\$
E. Total percent ratio of non-forgivable base to total base:	%
F. Adjustments to non-forgivable, repeat violations:	\$0.00
G. Adjustment based on other factors:	\$0.00
H. Total economic benefit:	\$

Step 5: Reduce the penalty, only if greater than \$10,000.

	Forgivable	Non-forgivable	Total
Total initial penalty	\$0.00	\$0.00	\$0.00
Amount of reduction To meet \$10,000	\$0.00	\$0.00	\$0.00
Net penalty	\$0.00	\$0.00	\$0.00

Total Assessed Penalty

Forgivable	Non-forgivable	Total
\$	\$	\$

ATTACHMENT A

ECONOMIC BENEFIT WORKSHEET				
	COST PER UNIT	NUMBER OF UNITS	NUMBER OF YEARS	TOTAL
INTRA ORAL CALIBRATIONS	\$75			
PANORAMIC CALIBRATIONS	\$240			
MEDICAL CALIBRATIONS	\$300			
SENSITOMETER CALIBRATIONS	\$170			
DENSITOMETER CALIBRATIONS	\$120			
CASSETTE TESTS	\$10			
APRON TESTS	\$10			
OTHER				
TOTAL				
Additional Comments:				

		DEVIATION FROM COMPLIANCE		
POTENTIAL FOR HARM		MINOR	MODERATE	SEVERE
	MINOR	\$0 to \$500	\$200 to \$1,000	\$500 to \$2,000
	MODERATE	\$500 to \$2,000	\$1,000 to \$3,500	\$2,000 to \$5,000
	SEVERE	\$2,000 to \$5,000	\$3,500 to \$8,000	\$5,000 to \$10,000

4.6.1

Technical Staff
Organization

4.6.1

TECHNICAL STAFF ORGANIZATION

Minnesota's program staffing plan is included in the *Organizational Charts*, *Staff Needs Analysis*, and *Staff Balance Sheet*. These documents show the number of staff members assigned to the specific responsibilities and estimates the workload for the licensees that will transfer.

To develop and maintain an understanding of the content and implementation of various radiological programs, all staff are expected participate to some degree in inspections and licensing. Using the old system of 1.5 to 2.0 inspectors per 100 licenses, there appears to be sufficient workforce to support both efforts. However, after completing the *Staff Needs Analysis*, *Staff Resource Analysis*, and *Staff Balance Analysis*, it became obvious that MDH lacked sufficient depth to ensure program continuity. For that reason, MDH plans to hire and train an additional individual.

To develop and maintain an understanding of the content and implementation of various radiological programs, all staff are expected participate to some degree in inspections and licensing. Specific assignments within the Radioactive Materials Group are summarized in the table entitled *Professional Staff Assignments*.

PROFESSIONAL STAFF ASSIGNMENTS

STAFF MEMBER	PRIMARY ASSIGNMENT	SECONDARY ASSIGNMENT
Susan McClanahan Radiation Specialist 3	<ul style="list-style-type: none"> • Radiological Response Program Coordinator 	<ul style="list-style-type: none"> • Incident and Allegation Coordinator • Rules Coordinator • Radiological Training Coordinator • Positron Emission Tomography (PET) License Inspection • License Reviewer
Timothy Donakowski Health Physicist	<ul style="list-style-type: none"> • License Reviewer 	<ul style="list-style-type: none"> • License Inspector • Emerging Technologies Specialist • Environmental Issues Specialist
John Goepferd Radiation Specialist 2	<ul style="list-style-type: none"> • License Inspector 	<ul style="list-style-type: none"> • License Reviewer
Craig Verke Radiation Specialist 2	<ul style="list-style-type: none"> • License Inspector 	<ul style="list-style-type: none"> • License Reviewer
Katherine Johnson Radiation Specialist 1	<ul style="list-style-type: none"> • License Reviewer 	<ul style="list-style-type: none"> • License Inspector • Technical Documents Administrator • Radiological Trainer

**Linda Bruemmer, Manager
Asbestos, Indoor Air, Lead, & Radiation Section**

**George Johns
Environmental Health Supervisor**

Radioactive Materials Group

**Susan McClanahan
Radiation Specialist 3**

**Timothy Donakowski
Health Physicist 1**

**John Goepferd
Radiation Specialist 2**

**Craig Verke
Radiation Specialist 2**

**Katherine Johnson
Radiation Specialist 1**

Support Staff

**Tina Leland
Office Administrative Specialist
Intermediate**

**Lisa Schuck
Office Administrative Specialist**

STAFF NEEDS ANALYSIS

LICENSE CATEGORY	NUMBER OF LICENSES	LICENSING ACTIONS PER YEAR	STAFF DAYS PER ACTION	LICENSING STAFF DAYS	INSPECTIONS PER YEAR	STAFF DAYS PER INSPECTION	INSPECTION STAFF DAYS
Nuclear Medicine -- Diagnostic	12	4	3	12	4	3	12
Nuclear Medicine -- Therapy	27	8	4	32	10	4	40
HDR	7	3	4	12	7	3	21
Gamma Knife	1	1	4	4	1	3	3
Mobile Nuclear Van	3	1	5	5	2	4	8
Medical -- Broad Scope	4	1	15	15	4	20	80
Nuclear Pharmacy	2	1	7	7	2	4	8
Fixed Gauge	27	8	2	16	6	2	12
Portable Gauge	18	5	2	10	5	2	10
Industrial -- Other	46	12	2	24	10	2	20
Broad Scope -- Industrial	6	2	10	20	6	20	120
Industrial Radiography	6	2	5	10	6	5	30
PET	1	1	5	5	1	4	4

STAFF RESOURCE ANALYSIS¹

LICENSE CATEGORY	TIM DONAKOWSKI		CRAIG VERKE		JOHN GOEPFERD		TOTAL	
	LIC	INSP	LIC	INSP	LIC	INSP	LIC	INSP
Nuclear Medicine – Diagnostic	14			7		6	14	13
Nuclear Medicine – Therapy	38			22		22	38	44
HDR	14			12		11	14	23
Gamma Knife	5			2		1	5	3
Mobile Nuclear Van	6			5		4	6	9
Medical – Broad Scope	9	10		39	9	39	18	88
Nuclear Pharmacy	7			5		4	7	9
Fixed Gauge	19			7		6	19	13
Portable Gauge	12			5		6	12	11
Industrial – Other	19		5	11	5	11	29	22
Broad Scope – Industrial	12	15	12	58		59	24	132
Industrial Radiography	12			17		16	12	33
PET	6			3		2	6	5

¹ Assumes 0.8 FTE for each employee dedicated to the Agreement State Program. Other duties include Radiological Response, instructional opportunities, and training.

STAFF BALANCE ANALYSIS

LICENSE CATEGORY	LICENSING STAFF DAYS		INSPECTION STAFF DAYS	
	NEEDED	AVAILABLE	NEEDED	AVAILABLE
Nuclear Medicine – Diagnostic	12	14	12	13
Nuclear Medicine – Therapy	32	38	40	44
HDR	12	14	21	23
Gamma Knife	4	5	3	3
Mobile Nuclear Van	5	6	8	9
Medical – Broad Scope	15	18	80	88
Nuclear Pharmacy	7	7	8	9
Fixed Gauge	16	19	12	13
Portable Gauge	10	12	10	11
Industrial – Other	24	29	20	22
Broad Scope – Industrial	20	24	120	132
Industrial Radiography	10	12	30	33
PET	5	6	4	5

4.6.2 Formal Qualification Plan

4.6.2

FORMAL QUALIFICATION PLAN

Position descriptions and plans for the formal qualification of technical staff members can be found in the *Licensing and Inspections Qualification Journal* under the section, "Academic Qualifications." Also addressed in the *Licensing and Inspections Qualification Journal* are program qualification plans. These plans address job-specific training and experience, along with qualification procedures and times for completing requirements. Currently, there are no specific time frames for qualification deadlines. All training and qualification requirements meet the NRC/OAS working group recommendations. The *Position Descriptions* included in this section further detail the qualifications of the Radioactive Materials Group staff.

The following has been excerpted from the *Licensing and Inspections Qualification Journal*:

ACADEMIC QUALIFICATIONS:

The usual criteria for evaluating technical personnel are academic qualifications. Most assume that more degrees equal greater ability to perform complex technical tasks. Unfortunately, most resumes and job interviewers focus almost entirely on academic qualifications. Little effort is made to evaluate the other areas listed above. This does not imply academic excellence is not important, it obviously is. However, academic excellence without collateral skills (those listed above) will not result in a competent and effective radioactive materials license reviewer or inspector. The qualification objectives¹ for entry-level license reviewers and inspectors are:

- Graduation from an accredited college or university with major coursework in a natural science; or
- An equivalent combination of the required education and experience, substituting one year of full-time professional experience in a radiation or environmental control program for thirty semester hours of education; or
- An equivalent combination of education and full-time experience in radiological technology, nuclear medicine technology or radiation therapy, substituting thirty semester hours or equivalent or one year of full-time experience for one year or thirty semester hours of the required education or experience.

¹ The specific education and experience requirements for employees are included in the position descriptions.

STATE OF MINNESOTA		EMPLOYEE'S NAME	
POSITION DESCRIPTION A		Trainee	
AGENCY/DIVISION		ACTIVITY	
Health/Environmental Health		Radiation Control Unit	
CLASSIFICATION TITLE		WORKING TITLE (IF DIFFERENT) RAM LICENSER AND INSPECTOR	POSITION CONTROL #
Radiation Specialist 1			
PREPARED BY:		PREVIOUS INCUMBENT	APPRAISAL PERIOD
George F. Johns, Jr.		None	
EMPLOYEE'S SIGNATURE (THIS POSITION DESCRIPTION ACCURATELY REFLECTS MY CURRENT JOB)		DATE	SUPERVISOR'S SIGNATURE (THIS POSITION DESCRIPTION REFLECTS THIS EMPLOYEE'S CURRENT JOB)
POSITION PURPOSE	This position exists to ensure that the public does not receive unnecessary ionizing radiation.		
REPORTABILITY			
REPORTS TO:	Radiation Unit Supervisor		
SUPERVISES:	None		
DIMENSIONS			
BUDGET:	Travel and Expenses \$25,000		
CLIENTELE:	<ul style="list-style-type: none"> • Owners and users of radioactive materials (167 specific licensees and approximately 250 general licenses). • Members of the general public who are exposed to ionizing radiation. • Nuclear Power Plant Response Operations. 		

POSITION DESCRIPTION B	EMPLOYEE'S NAME	POSITION CONTROL NUMBER
	Trainee	00022950

RESP. NO.	PRINCIPAL RESPONSIBILITIES, TASKS AND PERFORMANCE INDICATORS	PRIORITY	% OF TIME	DISCRETION
1.	<p>Training for agreement state inspector position.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Training for NRC agreement state status for the inspection portion as available. • Perform assigned collateral duties. • Attend relevant agreement state meetings. • Work on form development for radioactive material program • Review NRC licenses and licensing guidance documents. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete training for NRC agreement state inspection and licensing portion. • Complete requirements of extra duties for the unit, section, and division. • Written reports of external meetings attended are to be provided to the unit supervisor within one week of the meeting. 	B	30	B
2.	<p>To determine compliance with state regulations by performing routine and special radiation safety inspections of radiation sources.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Schedule and conduct radiation safety inspections in areas assigned by the radiation unit supervisor. • Respond to questions regarding ionizing radiation sources. • Work to locate unregistered sources of ionizing radiation. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Perform radiation safety inspections at a rate to accomplish the team's goal of no significant overdue inspections. • Reviews appropriate material to identify unlicensed sources of ionizing radiation. • Maintains equipment in calibrated and good operating condition. • Wear appropriate dosimetry and PPE. 	A	15	B

POSITION DESCRIPTION B	EMPLOYEE'S NAME Trainee	POSITION CONTROL NUMBER 00022950
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3.	<p>To prepare written reports on inspections conducted.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Complete reports of inspections. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete reports of inspections and submit for peer review and issuance within 30 days. • Adequately address all comments made by reviewer. • Provided support staff with the documentation necessary to generate a formal report. 	A	15	B
4.	<p>To assist compliance reviewer on follow up of deficiencies found during inspections to ensure compliance with Minnesota Rules, Chapter 4731 or applicable agency regulations.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Advise supervisor of inspections needing further follow up. • Provide information for the enforcement process. • Prepare Administrative Penalty Orders and present Penalty calculation forms. • Participate in enforcement forums. • Deliver enforcement forms. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Facilitates issuance of Ten-day letters, APOs, and other enforcement documents. • Ensures that all enforcement documents are issued within ten days of the respective due dates. • Reviews deficiency response letters for compliance. • Performs follow up inspections for compliance as directed. 	A	10	C
5.	<p>To prepare license documents.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review applications for new licenses, license amendments, and license renewals. • Complete deficiency letters as appropriate. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete deficiency letters for new license, license renewal, 	A	10	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Trainee	POSITION CONTROL NUMBER 00022950
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	<p>or amendment.</p> <ul style="list-style-type: none"> • Complete licenses and submit for peer review within 30 days of licensee's response, if appropriate. • Adequately address all comments made by reviewers. • Provided support staff with the documentation necessary to generate a formal license. 			
6.	<p>To participate as a member of the Radiation Emergency Response Team to assist in preventing unnecessary radiation exposure to the public.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review notification and response procedures and guidelines in the emergency plan. • Maintain a capability for using and reading the appropriate equipment and instruments. • Assist with assessing radiation dose information. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Participate in Nuclear Power Plant Drills and Exercises as scheduled. • Attend seminars, meetings, and training on emergency response at least annually. • Attend, if assigned, team briefing and debriefing meetings associated with drills, two to four times a year. • Review Radiation dose and preventive action information monthly. • Respond to radiation emergencies when notified. 	C	5	B
7.	<p>To perform other work related to the Agreement State Program.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Work on rule and guidance documents. • Assist in rule enforcement meetings <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Participate as a team member in development of new rules and policy. • Identify those rules and policies that need revision or rescission. 	A	5	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Trainee	POSITION CONTROL NUMBER 00022950
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8.	<p>To participate in training as assigned.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Train registrants as necessary to facilitate compliance with MDH rules. • Make presentations to the public, the regulated community, and MDH staff as assigned. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Minimizes requests for clarification from the inspected facilities. 	C	5	A
9.	Perform other duties as assigned.	C	5	B
10.	<p>Treat all MDH staff members and clients with respect, patience, and courtesy so that effective and cooperative working relationships with others are established and maintained.</p> <p><u>Tasks</u></p> <ul style="list-style-type: none"> • Interaction with staff members, vendors, and the public is conducted in a professional and responsive manner. • Identify conflicts and develop constructive solutions through discussion, flexibility, and compromise. • Promote and support team building. <p><u>Indicators</u></p> <ul style="list-style-type: none"> • Concerns are taken seriously and issues are resolved. Telephone calls, e-mails, and correspondence are returned within a reasonable time period and requested help, information or appropriate referral is provided courteously. • Conflicts are handled in a constructive manner. • Team commitment is demonstrated on a daily basis. Team members share a mutual respect. • Acquired knowledge is shared. 	C	--	B

POSITION DESCRIPTION C	EMPLOYEE'S NAME Trainee	POSITION CONTROL NUMBER 0026130
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

RELATIONSHIPS:

This position interacts with the regulated community to provide technical assistance conduct inspections; to enforce compliance with rules; to educate staff, licensees, the general public. This position reports to the unit supervisor. Relationships are also maintained with staff of the section, staff of other departmental programs and other state agencies, as well as the general public.

KNOWLEDGE, SKILLS, AND ABILITIES:

The following knowledge and skills is essential:

- Knowledge of the basic health physics as well as basic physics and biological science
- Familiarity with the instrumentation and it's use
- The ability to present information
- Communication and human relation skills
- Organizational and prioritizing skills
- Self motivation skills
- A knowledge of the English language, including composition, spelling, grammar and punctuation
- An understanding of the department's and division's administrative rules, policies, and procedures

The following abilities are necessary:

- To interact cooperatively with coworkers, division and department employees and customers/clients
- To receive and react to changes in priorities and be able to implement these changes into the daily schedule
- To exercise good judgment, especially as it relates to matters of confidentiality
- To organize work and meet deadlines
- To use a personal computer utilizing various software programs

PROBLEM SOLVING:

The problems confronted by this position are mostly technical in nature. These problems relate to the application of radiation protection principles in inspecting sources of ionizing radiation.

FREEDOM TO ACT:

This position has the freedom to act only on those matters outlined previously under the heading of principal responsibilities. Any actions taken will conform the Minnesota Department of Health Rules relating to Radioactive Materials, Chapter 4731. Any actions that would involve determination of policy or would concern other state departments, sections, or federal agencies must be brought to the attention of the unit supervisor. Reporting to the unit supervisor is done routinely through the completed inspection reports and other reports that are submitted.

STATE OF MINNESOTA		EMPLOYEE'S NAME	
POSITION DESCRIPTION A		Inspector	
AGENCY/DIVISION		ACTIVITY	
Health/Environmental Health		Radiation Unit	
CLASSIFICATION TITLE		WORKING TITLE (IF DIFFERENT)	POSITION CONTROL #
Radiation Specialist 2		None	00329640
PREPARED BY:		PREVIOUS INCUMBENT	APPRAISAL PERIOD
G. F. Johns		None	FROM 01/05 TO 01/06
EMPLOYEE'S SIGNATURE (THIS POSITION DESCRIPTION ACCURATELY REFLECTS MY CURRENT JOB)		DATE	SUPERVISOR'S SIGNATURE (THIS POSITION DESCRIPTION REFLECTS THIS EMPLOYEE'S CURRENT JOB)
POSITION PURPOSE		This position exists to ensure that the public does not receive unnecessary ionizing radiation.	
REPORTABILITY		Radiation Unit Supervisor	
REPORTS TO:		Radiation Unit Supervisor	
SUPERVISES:		None	
DIMENSIONS		BUDGET: Travel and Expenses \$15,000 CLIENTELE: <ul style="list-style-type: none"> • Owners and users of radioactive materials (167 specific licensees and approximately 250 general licenses). • Members of the general public who are exposed to ionizing radiation. • Nuclear Power Plant Response Operations. 	

POSITION DESCRIPTION B	EMPLOYEE'S NAME Inspector	POSITION CONTROL NUMBER 00329640
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RESP. NO.	PRINCIPAL RESPONSIBILITIES, TASKS AND PERFORMANCE INDICATORS	PRIORITY	% OF TIME	DISCRETION
1.	<p>Training for agreement state inspector position.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Training for NRC agreement state status for the inspection portion as available. • Perform assigned collateral duties. • Attend relevant agreement state meetings. • Work on form development for radioactive material program • Review NRC licenses and licensing guidance documents. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete training for NRC agreement state inspection and licensing portion. • Complete requirements of extra duties for the unit, section, and division. • Written reports of external meetings attended are to be provided to the unit supervisor within one week of the meeting. 	B	10	B
2.	<p>To determine compliance with state regulations by independently performing routine and special safety inspections of radiological programs and x-ray equipment.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Independently schedule and conduct radiation safety inspections in areas assigned by the radiation unit supervisor. • Respond to questions regarding ionizing radiation sources. • Work independently to locate unregistered sources of ionizing radiation. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Perform radiation safety inspections at a rate to accomplish the team's goal of no significant overdue inspections. • Reviews appropriate material to identify unlicensed sources of ionizing radiation. • Maintains equipment in calibrated and good operating condition. • Wear appropriate dosimetry and PPE. 	A	30	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Inspector	POSITION CONTROL NUMBER 00329640
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3.	<p>To independently prepare written reports on inspections.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Complete reports of inspections. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete reports of inspections and submit for peer review and issuance within 30 days. • Adequately address all comments made by reviewer. • Provided support staff with the documentation necessary to generate a formal report. 	A	20	A
4.	<p>To independently monitor deficiencies found during inspections to ensure compliance with Minnesota Rules, Chapter 4731 or applicable agency regulations.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Advise supervisor of inspections needing further follow up. • Provide information for the enforcement process. • Prepare Administrative Penalty Orders and present Penalty calculation forms. • Participate in enforcement forums. • Deliver enforcement forms. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Facilitates issuance of Ten-day letters, APOs, and other enforcement documents. • Ensures that all enforcement documents are issued within ten days of the respective due dates. • Reviews deficiency response letters for compliance. • Performs follow up inspections for compliance as directed. 	A	10	A
5.	<p>To independently prepare license documents.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review applications for new licenses, license amendments, and license renewals. • Complete deficiency letters as appropriate. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete deficiency letters for new license, license renewal, 	A	10	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Inspector	POSITION CONTROL NUMBER 00329640
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	<p>or amendment.</p> <ul style="list-style-type: none"> • Complete licenses and submit for peer review within 30 days of licensee's response, if appropriate. • Adequately address all comments made by reviewers. • Provided support staff with the documentation necessary to generate a formal license. 			
6.	<p>To participate as a member of the MDH Radiological Emergency Program (REP) and non-power plant emergency response team to assist in preventing unnecessary radiation exposure to the public.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review notification and response procedures and guidelines in the emergency plan. • Maintain a capability for using and reading the appropriate equipment and instruments. • Maintain the capability for interpreting environmental data to determine abnormal data and unusually high readings. • Assist with assessing radiation dose information. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Attend seminars and meetings on emergency response at least annually. • Attend, if assigned, team briefing and debriefing meetings associated with drills, two or four times a year. • Review radiation dose and preventive action information monthly. • Respond to radiation emergencies when notified. 	C	5	B
7.	<p>To perform other work related to the Agreement State Program.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Work on rule and guidance documents. • Assist in rule enforcement meetings <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Participate as a team member in development of new rules and policy. • Identify those rules and policies that need revision or rescission. 	A	5	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Inspector	POSITION CONTROL NUMBER 00329640
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8.	<p>To participate in training as assigned.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Assist in training new staff. • Train registrants as necessary to facilitate compliance with MDH rules. • Make presentations to the public, the regulated community, and MDH staff as assigned. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Provides training to qualify inspection staff to function independently. • Minimizes requests for clarification from the inspected facilities. 	C	5	A
9.	Perform other duties as assigned.	C	5	B
10.	<p>Treat all MDH staff members and clients with respect, patience, and courtesy so that effective and cooperative working relationships with others are established and maintained.</p> <p><u>Tasks</u></p> <ul style="list-style-type: none"> • Interaction with staff members, vendors, and the public is conducted in a professional and responsive manner. • Identify conflicts and develop constructive solutions through discussion, flexibility, and compromise. • Promote and support team building. <p><u>Indicators</u></p> <ul style="list-style-type: none"> • Concerns are taken seriously and issues are resolved. Telephone calls, e-mails, and correspondence are returned within a reasonable time period and requested help, information or appropriate referral is provided courteously. • Conflicts are handled in a constructive manner. • Team commitment is demonstrated on a daily basis. Team members share a mutual respect. • Acquired knowledge is shared. 	C	--	B

POSITION DESCRIPTION C	EMPLOYEE'S NAME Inspector	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

RELATIONSHIPS:

This position interacts with the regulated community to conduct specialty inspections; to enforce compliance with the radiation rules; to educate staff, licensees (general and specific), and the general public. The assigned individual also provides technical research and assistance when needed. This position reports to the unit supervisor. Relationships are maintained with staff of the section, staff of other departmental programs, other state and federal agencies, licensing boards, as well as the general public.

KNOWLEDGE, SKILLS, AND ABILITIES:

The following knowledge and skills is essential:

- To be knowledgeable in the basic health physics as well as basic physics and biological science
- Familiarity with the instrumentation and it's use
- The ability to present information and train other people
- Communication and human relation skills
- Organizational and prioritizing skills
- Self motivation skills
- A broad knowledge of the English language, including composition, spelling, grammar and punctuation
- A broad understanding of the department's and division's administrative rules, policies, and procedures

The following abilities are necessary:

- To interact cooperatively and professionally with coworkers, division and department employees and customers/clients
- To receive and react to changes in priorities and be able to implement these changes into the daily schedule
- To exercise good judgment, especially as it relates to matters of confidentiality
- To organize work and meet deadlines
- To use a personal computer utilizing various software programs
- To work independently

PROBLEM SOLVING:

The problems confronted by this position are more than technical in nature. These problems, in addition to the application of radiation protection principles in inspecting ionizing radiation will include identifying and researching regulatory issues.

FREEDOM TO ACT:

This position has the freedom to act only on these matters outlined previously under the heading principal responsibilities. Any actions taken will conform the Minnesota Department of Health, Rules relating to Radioactive Materials, Chapter 4731. Any actions that would involve determination of policy or would concern other state departments, sections, or federal agencies must be brought to the attention of the unit supervisor.

POSITION DESCRIPTION C	EMPLOYEE'S NAME Inspector	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

Reporting to the unit supervisor is done routinely through the completed inspection reports and other reports that are submitted.

STATE OF MINNESOTA		EMPLOYEE'S NAME	
POSITION DESCRIPTION A		License Reviewer	
AGENCY/DIVISION		ACTIVITY	
Health/Environmental Health		Radiation Unit	
CLASSIFICATION TITLE		WORKING TITLE (IF DIFFERENT)	POSITION CONTROL #
Radiation Specialist 2		None	00329640
PREPARED BY:		PREVIOUS INCUMBENT	APPRAISAL PERIOD
G. F. Johns		None	FROM 01/05 TO 01/06
EMPLOYEE'S SIGNATURE (THIS POSITION DESCRIPTION ACCURATELY REFLECTS MY CURRENT JOB)		DATE	SUPERVISOR'S SIGNATURE (THIS POSITION DESCRIPTION REFLECTS THIS EMPLOYEE'S CURRENT JOB)
DATE		DATE	
POSITION PURPOSE	This position exists to ensure that the public does not receive unnecessary ionizing radiation.		
REPORTABILITY	Radiation Unit Supervisor		
REPORTS TO:	Radiation Unit Supervisor		
SUPERVISES:	None		
DIMENSIONS	Travel and Expenses \$15,000		
BUDGET:			
CLIENTELE:	<ul style="list-style-type: none"> • Owners and users of radioactive materials (167 specific licensees and approximately 250 general licenses). • Members of the general public who are exposed to ionizing radiation. • Nuclear Power Plant Response Operations. 		

POSITION DESCRIPTION B	EMPLOYEE'S NAME	POSITION CONTROL NUMBER
	License Reviewer	00329640

RESP. NO.	PRINCIPAL RESPONSIBILITIES, TASKS AND PERFORMANCE INDICATORS	PRIORITY	% OF TIME	DISCRETION
1.	<p>Training for agreement state inspector position.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Training for NRC agreement state status for the inspection portion as available. • Perform assigned collateral duties. • Attend relevant agreement state meetings. • Work on form development for radioactive material program • Review NRC licenses and licensing guidance documents. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete training for NRC agreement state inspection and licensing portion. • Complete requirements of extra duties for the unit, section, and division. • Written reports of external meetings attended are to be provided to the unit supervisor within one week of the meeting. 	B	10	B
2.	<p>To independently prepare license documents.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review applications for new licenses, license amendments, and license renewals. • Complete deficiency letters as appropriate. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete deficiency letters for new license, license renewal, or amendment. • Adequately address all comments made by reviewer. • Complete licenses and submit for peer review within 30 days of licensee's response, if appropriate. • Adequately address all comments made by reviewer. • Provided support staff with the documentation necessary to generate a formal license. 	A	30	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME License Reviewer	POSITION CONTROL NUMBER 00329640
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3.	<p>To determine compliance with state regulations by independently performing routine and special safety inspections of radiological programs and x-ray equipment.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Independently schedule and conduct radiation safety inspections in areas assigned by the radiation unit supervisor. Respond to questions regarding ionizing radiation sources. Work independently to locate unregistered sources of ionizing radiation. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> Perform radiation safety inspections at a rate to accomplish the team's goal of no significant overdue inspections. Reviews appropriate material to identify unlicensed sources of ionizing radiation. Maintains equipment in calibrated and good operating condition. Wear appropriate dosimetry and PPE. 	A	20	A
4.	<p>To independently prepare written reports on inspections.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Complete reports of inspections. Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> Complete reports of inspections and submit for peer review and issuance within 30 days. Adequately address all comments made by reviewer. Provided support staff with the documentation necessary to generate a formal report. 	A	10	A
5.	<p>To independently monitor deficiencies found during inspections to ensure compliance with Minnesota Rules, Chapter 4731 or applicable agency regulations.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Advise supervisor of inspections needing further follow up. Provide information for the enforcement process. Prepare Administrative Penalty Orders and present Penalty calculation forms. 	A	10	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME License Reviewer	POSITION CONTROL NUMBER 00329640
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	<ul style="list-style-type: none"> • Participate in enforcement forums. • Deliver enforcement forms. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Facilitates issuance of Ten-day letters, APOs, and other enforcement documents. • Ensures that all enforcement documents are issued within ten days of the respective due dates. • Reviews deficiency response letters for compliance. • Performs follow up inspections for compliance as directed. 			
6.	<p>To participate as a member of the MDH Radiological Emergency Program (REP) and non-power plant emergency response team to assist in preventing unnecessary radiation exposure to the public.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review notification and response procedures and guidelines in the emergency plan. • Maintain a capability for using and reading the appropriate equipment and instruments. • Maintain the capability for interpreting environmental data to determine abnormal data and unusually high readings. • Assist with assessing radiation dose information. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Attend seminars and meetings on emergency response at least annually. • Attend, if assigned, team briefing and debriefing meetings associated with drills, two or four times a year. • Review radiation dose and preventive action information monthly. • Respond to radiation emergencies when notified. 	C	5	B
7.	<p>To perform other work related to the Agreement State Program.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Work on rule and guidance documents. • Assist in rule enforcement meetings <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Participate as a team member in development of new rules and policy. 	A	5	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME License Reviewer	POSITION CONTROL NUMBER 00329640
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	<ul style="list-style-type: none">Identify those rules and policies that need revision or rescission.			
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POSITION DESCRIPTION B	EMPLOYEE'S NAME	POSITION CONTROL NUMBER
	License Reviewer	00329640

8.	<p>To participate in training as assigned.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Assist in training new staff. • Train registrants as necessary to facilitate compliance with MDH rules. • Make presentations to the public, the regulated community, and MDH staff as assigned. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Provides training to qualify inspection staff to function independently. • Minimizes requests for clarification from the inspected facilities. 	C	5	A
9.	<p>Perform other duties as assigned.</p>	C	5	B
10.	<p>Treat all MDH staff members and clients with respect, patience, and courtesy so that effective and cooperative working relationships with others are established and maintained.</p> <p><u>Tasks</u></p> <ul style="list-style-type: none"> • Interaction with staff members, vendors, and the public is conducted in a professional and responsive manner. • Identify conflicts and develop constructive solutions through discussion, flexibility, and compromise. • Promote and support team building. <p><u>Indicators</u></p> <ul style="list-style-type: none"> • Concerns are taken seriously and issues are resolved. Telephone calls, e-mails, and correspondence are returned within a reasonable time period and requested help, information or appropriate referral is provided courteously. • Conflicts are handled in a constructive manner. • Team commitment is demonstrated on a daily basis. Team members share a mutual respect. • Acquired knowledge is shared. 	C	--	B

POSITION DESCRIPTION C	EMPLOYEE'S NAME License Reviewer	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

RELATIONSHIPS:

This position interacts with the regulated community to conduct specialty inspections; to enforce compliance with the radiation rules; to educate staff, licensees (general and specific), and the general public. The assigned individual also provides technical research and assistance when needed. This position reports to the unit supervisor. Relationships are maintained with staff of the section, staff of other departmental programs, other state and federal agencies, licensing boards, as well as the general public.

KNOWLEDGE, SKILLS, AND ABILITIES:

The following knowledge and skills is essential:

- To be knowledgeable in the basic health physics as well as basic physics and biological science
- Familiarity with the instrumentation and it's use
- The ability to present information and train other people
- Communication and human relation skills
- Organizational and prioritizing skills
- Self motivation skills
- A broad knowledge of the English language, including composition, spelling, grammar and punctuation
- A broad understanding of the department's and division's administrative rules, policies, and procedures

The following abilities are necessary:

- To interact cooperatively and professionally with coworkers, division and department employees and customers/clients
- To receive and react to changes in priorities and be able to implement these changes into the daily schedule
- To exercise good judgment, especially as it relates to matters of confidentiality
- To organize work and meet deadlines
- To use a personal computer utilizing various software programs
- To work independently

PROBLEM SOLVING:

The problems confronted by this position are more than technical in nature. These problems, in addition to the application of radiation protection principles in inspecting ionizing radiation will include identifying and researching regulatory issues.

FREEDOM TO ACT:

This position has the freedom to act only on these matters outlined previously under the heading principal responsibilities. Any actions taken will conform the Minnesota Department of Health, Rules relating to Radioactive Materials, Chapter 4731. Any actions that would involve determination of policy or would concern

POSITION DESCRIPTION C	EMPLOYEE'S NAME License Reviewer	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

other state departments, sections, or federal agencies must be brought to the attention of the unit supervisor. Reporting to the unit supervisor is done routinely through the completed inspection reports and other reports that are submitted.

STATE OF MINNESOTA		EMPLOYEE'S NAME	
POSITION DESCRIPTION A		Radioactive Materials Lead	
AGENCY/DIVISION		ACTIVITY	
Health/Environmental Health		Radiation Unit	
CLASSIFICATION TITLE		WORKING TITLE (IF DIFFERENT)	POSITION CONTROL #
Radiation Specialist 3		None	00329640
PREPARED BY:		PREVIOUS INCUMBENT	APPRAISAL PERIOD
George F. Johns, Jr.		None	FROM 01/05 TO 01/06
EMPLOYEE'S SIGNATURE (THIS POSITION DESCRIPTION ACCURATELY REFLECTS MY CURRENT JOB)	DATE	SUPERVISOR'S SIGNATURE (THIS POSITION DESCRIPTION REFLECTS THIS EMPLOYEE'S CURRENT JOB)	DATE
POSITION PURPOSE	This position exists to ensure that the public does not receive unnecessary ionizing radiation.		
REPORTABILITY			
REPORTS TO:	Radiation Unit Supervisor		
SUPERVISES:	None		
DIMENSIONS			
BUDGET:	Travel and Expenses \$15,000		
CLIENTELE:	<ul style="list-style-type: none"> • Owners and users of radioactive materials (167 specific licensees and approximately 250 general licenses). • Members of the general public who are exposed to ionizing radiation. • Nuclear Power Plant Response Operations. 		

POSITION DESCRIPTION B	EMPLOYEE'S NAME	POSITION CONTROL NUMBER
	Radioactive Materials Lead	00329640

RESP. NO.	PRINCIPAL RESPONSIBILITIES, TASKS AND PERFORMANCE INDICATORS	PRIORITY	% OF TIME	DISCRETION
1.	<p>Training for agreement state inspector position.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Training for NRC agreement state status for the inspection portion as available. • Perform assigned collateral duties. • Attend relevant agreement state meetings. • Work on form development for radioactive material program • Review NRC licenses and licensing guidance documents. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete training for NRC agreement state inspection and licensing portion. • Complete requirements of extra duties for the unit, section, and division. • Written reports of external meetings attended are to be provided to the unit supervisor within one week of the meeting. 	B	10	B
2.	<p>To independently prepare license documents.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review applications for new licenses, license amendments, and license renewals. • Complete deficiency letters as appropriate. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete deficiency letters for new license, license renewal, or amendment. • Adequately address all comments made by reviewer. • Complete licenses and submit for peer review within 30 days of licensee's response, if appropriate. • Adequately address all comments made by reviewer. • Provided support staff with the documentation necessary to generate a formal license. 	A	15	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Radioactive Materials Lead	POSITION CONTROL NUMBER 00329640
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3.	<p>To determine compliance with state regulations by independently performing routine and special safety inspections of radiological programs and x-ray equipment.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Independently schedule and conduct radiation safety inspections in areas assigned by the radiation unit supervisor. Respond to questions regarding ionizing radiation sources. Work independently to locate unregistered sources of ionizing radiation. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> Perform radiation safety inspections at a rate to accomplish the team's goal of no significant overdue inspections. Reviews appropriate material to identify unlicensed sources of ionizing radiation. Maintains equipment in calibrated and good operating condition. Wear appropriate dosimetry and PPE. 	A	15	A
4.	<p>To independently prepare written reports on inspections.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Complete reports of inspections. Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> Complete reports of inspections and submit for peer review and issuance within 30 days. Adequately address all comments made by reviewer. Provided support staff with the documentation necessary to generate a formal report. 	A	10	A
5.	<p>To independently monitor deficiencies found during inspections to ensure compliance with Minnesota Rules, Chapter 4731 or applicable agency regulations.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Advise supervisor of inspections needing further follow up. Provide information for the enforcement process. Prepare Administrative Penalty Orders and present Penalty calculation forms. 	A	10	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Radioactive Materials Lead	POSITION CONTROL NUMBER 00329640
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	<ul style="list-style-type: none"> • Participate in enforcement forums. • Deliver enforcement forms. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Facilitates issuance of Ten-day letters, APOs, and other enforcement documents. • Ensures that all enforcement documents are issued within ten days of the respective due dates. • Reviews deficiency response letters for compliance. • Performs follow up inspections for compliance as directed. 			
6.	<p>To participate as a member of the MDH Radiological Emergency Program (REP) and non-power plant emergency response team to assist in preventing unnecessary radiation exposure to the public.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review notification and response procedures and guidelines in the emergency plan. • Maintain a capability for using and reading the appropriate equipment and instruments. • Maintain the capability for interpreting environmental data to determine abnormal data and unusually high readings. • Assist with assessing radiation dose information. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Attend seminars and meetings on emergency response at least annually. • Attend, if assigned, team briefing and debriefing meetings associated with drills, two or four times a year. • Review radiation dose and preventive action information monthly. • Respond to radiation emergencies when notified. 	C	10	B
7.	<p>To perform other work related to the Agreement State Program.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Work on rule and guidance documents. • Assist in rule enforcement meetings <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Participate as a team member in development of new rules and policy. 	A	10	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Radioactive Materials Lead	POSITION CONTROL NUMBER 00329640
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	<ul style="list-style-type: none">Identify those rules and policies that need revision or rescission.			
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POSITION DESCRIPTION B	EMPLOYEE'S NAME Radioactive Materials Lead	POSITION CONTROL NUMBER 00329640
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8.	<p>To participate in training as assigned.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Assist in training new staff. • Train registrants as necessary to facilitate compliance with MDH rules. • Make presentations to the public, the regulated community, and MDH staff as assigned. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Provides training to qualify inspection staff to function independently. • Minimizes requests for clarification from the inspected facilities. 	C	10	A
9.	Perform other duties as assigned.	C	10	B
10.	<p>Treat all MDH staff members and clients with respect, patience, and courtesy so that effective and cooperative working relationships with others are established and maintained.</p> <p><u>Tasks</u></p> <ul style="list-style-type: none"> • Interaction with staff members, vendors, and the public is conducted in a professional and responsive manner. • Identify conflicts and develop constructive solutions through discussion, flexibility, and compromise. • Promote and support team building. <p><u>Indicators</u></p> <ul style="list-style-type: none"> • Concerns are taken seriously and issues are resolved. Telephone calls, e-mails, and correspondence are returned within a reasonable time period and requested help, information or appropriate referral is provided courteously. • Conflicts are handled in a constructive manner. • Team commitment is demonstrated on a daily basis. Team members share a mutual respect. • Acquired knowledge is shared. 	C	--	B

POSITION DESCRIPTION C	EMPLOYEE'S NAME	POSITION CONTROL NUMBER
	Radioactive Materials Lead	00329640

NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

RELATIONSHIPS:

This position interacts with the regulated community to conduct specialty inspections; to enforce compliance with the radiation rules; to educate staff, licensees (general and specific), and the general public. The assigned individual also provides technical research and assistance when needed. This position reports to the unit supervisor. Relationships are maintained with staff of the section, staff of other departmental programs, other state and federal agencies, licensing boards, as well as the general public.

KNOWLEDGE, SKILLS, AND ABILITIES:

The following knowledge and skills is essential:

- To be knowledgeable in the basic health physics as well as basic physics and biological science
- Familiarity with the instrumentation and it's use
- The ability to present information and train other people
- Communication and human relation skills
- Organizational and prioritizing skills
- Self motivation skills
- A broad knowledge of the English language, including composition, spelling, grammar and punctuation
- A broad understanding of the department's and division's administrative rules, policies, and procedures

The following abilities are necessary:

- To interact cooperatively and professionally with coworkers, division and department employees and customers/clients
- To receive and react to changes in priorities and be able to implement these changes into the daily schedule
- To exercise good judgment, especially as it relates to matters of confidentiality
- To organize work and meet deadlines
- To use a personal computer utilizing various software programs
- To work independently

PROBLEM SOLVING:

The problems confronted by this position are more than technical in nature. These problems, in addition to the application of radiation protection principles in inspecting ionizing radiation will include identifying and researching regulatory issues.

FREEDOM TO ACT:

This position has the freedom to act only on these matters outlined previously under the heading principal responsibilities. Any actions taken will conform the Minnesota Department of Health, Rules relating to Radioactive Materials, Chapter 4731. Any actions that would involve determination of policy or would concern

POSITION DESCRIPTION C	EMPLOYEE'S NAME Radioactive Materials Lead	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

other state departments, sections, or federal agencies must be brought to the attention of the unit supervisor. Reporting to the unit supervisor is done routinely through the completed inspection reports and other reports that are submitted.

STATE OF MINNESOTA		EMPLOYEE'S NAME	
POSITION DESCRIPTION A		Health Physicist	
AGENCY/DIVISION		ACTIVITY	
Health/Environmental Health		Radiation Unit	
CLASSIFICATION TITLE		WORKING TITLE (IF DIFFERENT)	POSITION CONTROL #
Health Physicist 1		None	00329640
PREPARED BY:		PREVIOUS INCUMBENT	APPRAISAL PERIOD
George F. Johns, Jr.		None	FROM 01/05 TO 01/06
EMPLOYEE'S SIGNATURE (THIS POSITION DESCRIPTION ACCURATELY REFLECTS MY CURRENT JOB)		DATE	SUPERVISOR'S SIGNATURE (THIS POSITION DESCRIPTION REFLECTS THIS EMPLOYEE'S CURRENT JOB)
POSITION PURPOSE		This position exists to ensure that the public does not receive unnecessary ionizing radiation.	
REPORTABILITY		Radiation Unit Supervisor	
REPORTS TO:		Radiation Unit Supervisor	
SUPERVISES:		None	
DIMENSIONS		Travel and Expenses \$15,000	
BUDGET:			
CLIENTELE:		<ul style="list-style-type: none"> • Owners and users of radioactive materials (167 specific licensees and approximately 250 general licenses). • Members of the general public who are exposed to ionizing radiation. • Nuclear Power Plant Response Operations. 	

POSITION DESCRIPTION B	EMPLOYEE'S NAME	POSITION CONTROL NUMBER
	Health Physicist	00329640

RESP. NO.	PRINCIPAL RESPONSIBILITIES, TASKS AND PERFORMANCE INDICATORS	PRIORITY	% OF TIME	DISCRETION
1.	<p>Training for agreement state inspector position.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Training for NRC agreement state status for the inspection portion as available. • Perform assigned collateral duties. • Attend relevant agreement state meetings. • Work on form development for radioactive material program • Review NRC licenses and licensing guidance documents. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete training for NRC agreement state inspection and licensing portion. • Complete requirements of extra duties for the unit, section, and division. • Written reports of external meetings attended are to be provided to the unit supervisor within one week of the meeting. 	B	5	B
2.	<p>To independently prepare license documents.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review applications for new licenses, license amendments, and license renewals. • Complete deficiency letters as appropriate. • Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Complete deficiency letters for new license, license renewal, or amendment. • Adequately address all comments made by reviewer. • Complete licenses and submit for peer review within 30 days of licensee's response, if appropriate. • Adequately address all comments made by reviewer. • Provided support staff with the documentation necessary to generate a formal license. 	A	50	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Health Physicist	POSITION CONTROL NUMBER 00329640
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3.	<p>To determine compliance with state regulations by independently performing routine and special safety inspections of radiological programs and x-ray equipment.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Independently schedule and conduct radiation safety inspections in areas assigned by the radiation unit supervisor. Respond to questions regarding ionizing radiation sources. Work independently to locate unregistered sources of ionizing radiation. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> Perform radiation safety inspections at a rate to accomplish the team's goal of no significant overdue inspections. Reviews appropriate material to identify unlicensed sources of ionizing radiation. Maintains equipment in calibrated and good operating condition. Wear appropriate dosimetry and PPE. 	A	5	A
4.	<p>To independently prepare written reports on inspections.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Complete reports of inspections. Ensure that the information is complete, accurate, and legible. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> Complete reports of inspections and submit for peer review and issuance within 30 days. Adequately address all comments made by reviewer. Provided support staff with the documentation necessary to generate a formal report. 	A	5	A
5.	<p>To independently monitor deficiencies found during inspections to ensure compliance with Minnesota Rules, Chapter 4731 or applicable agency regulations.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> Advise supervisor of inspections needing further follow up. Provide information for the enforcement process. Prepare Administrative Penalty Orders and present Penalty calculation forms. 	A	5	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Health Physicist	POSITION CONTROL NUMBER 00329640
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	<ul style="list-style-type: none"> • Participate in enforcement forums. • Deliver enforcement forms. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Facilitates issuance of Ten-day letters, APOs, and other enforcement documents. • Ensures that all enforcement documents are issued within ten days of the respective due dates. • Reviews deficiency response letters for compliance. • Performs follow up inspections for compliance as directed. 			
6.	<p>To participate as a member of the MDH Radiological Emergency Program (REP) and non-power plant emergency response team to assist in preventing unnecessary radiation exposure to the public.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Review notification and response procedures and guidelines in the emergency plan. • Maintain a capability for using and reading the appropriate equipment and instruments. • Maintain the capability for interpreting environmental data to determine abnormal data and unusually high readings. • Assist with assessing radiation dose information. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Attend seminars and meetings on emergency response at least annually. • Attend, if assigned, team briefing and debriefing meetings associated with drills, two or four times a year. • Review radiation dose and preventive action information monthly. • Respond to radiation emergencies when notified. 	C	5	B
7.	<p>To perform other work related to the Agreement State Program.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Work on rule and guidance documents. • Assist in rule enforcement meetings <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Participate as a team member in development of new rules and policy. 	A	5	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Health Physicist	POSITION CONTROL NUMBER 00329640
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	<ul style="list-style-type: none">• Identify those rules and policies that need revision or rescission.			
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POSITION DESCRIPTION B	EMPLOYEE'S NAME Health Physicist	POSITION CONTROL NUMBER 00329640
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8.	<p>To participate in training as assigned.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Assist in training new staff. • Train registrants as necessary to facilitate compliance with MDH rules. • Make presentations to the public, the regulated community, and MDH staff as assigned. • Be available to answer questions on health physics (for example, shielding, filtration, dose limits, skin dose, ALARA). <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Provides training to qualify inspection staff to function independently. • Minimizes requests for clarification from the inspected facilities. • Staff questions are answered. 	C	5	A
9.	<p>Oversee the program to monitor the independent spent fuel storage installation (ISFSI) at Prairie Island and the statewide environmental monitoring program.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Ensure that the PIC at the ISFSI are operating properly. • Maintain operating protocols to obtain data from the computer located at MDH. • Analyze ISFSI and environmental monitoring data daily, or as data come in. • Ensure that each new cask that is added to the ISFSI is wiped and surveyed. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • ISFSI data will be reviewed twice daily or whenever there is an indication of a problem with the PIC. • Protocol will be maintained so that individuals can get information from the on-line ISFSI computer at any time. • ISFSI data will be collected, processed, and analyzed; monthly report on ISFSI will be prepared by the tenth day of the following month. • Environmental data will be collected, processed, and analyzed; annual report will be prepared by April of the following year. 	C	5	A

POSITION DESCRIPTION B	EMPLOYEE'S NAME Health Physicist	POSITION CONTROL NUMBER 00329640
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10.	<p>Assess new and developing radiation technologies that concern the public.</p> <p><u>Tasks:</u></p> <ul style="list-style-type: none"> • Respond to inquiries about electromagnetic field and radiation safety (electric power lines, cell phones, food irradiation). • Assist with preparing and conducting presentations and seminars on radiation safety and the MDH role in maintaining radiation protection. <p><u>Indicators:</u></p> <ul style="list-style-type: none"> • Letters, calls and meetings with the public will be responded to. • Assistance will be provided in the preparation of presentation materials, local arrangements and contacts in preparation for seminars. • Written report to unit supervisor within two weeks on any meetings. 	C	5	A
11.	Perform other duties as assigned.	C	5	B
12.	<p>Treat all MDH staff members and clients with respect, patience, and courtesy so that effective and cooperative working relationships with others are established and maintained.</p> <p><u>Tasks</u></p> <ul style="list-style-type: none"> • Interaction with staff members, vendors, and the public is conducted in a professional and responsive manner. • Identify conflicts and develop constructive solutions through discussion, flexibility, and compromise. • Promote and support team building. <p><u>Indicators</u></p> <ul style="list-style-type: none"> • Concerns are taken seriously and issues are resolved. Telephone calls, e-mails, and correspondence are returned within a reasonable time period and requested help, information or appropriate referral is provided courteously. • Conflicts are handled in a constructive manner. • Team commitment is demonstrated on a daily basis. Team members share a mutual respect. • Acquired knowledge is shared. 	C	--	B

POSITION DESCRIPTION C	EMPLOYEE'S NAME	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

RELATIONSHIPS:

This position interacts with the regulated community to conduct specialty inspections; to enforce compliance with the radiation rules; to educate staff, licensees (general and specific), and the general public. The assigned individual also provides technical research and assistance when needed. This position reports to the unit supervisor. Relationships are maintained with staff of the section, staff of other departmental programs, other state and federal agencies, licensing boards, as well as the general public.

KNOWLEDGE, SKILLS, AND ABILITIES:

The following knowledge and skills is essential:

- To be knowledgeable in the basic health physics as well as basic physics and biological science
- Familiarity with the instrumentation and it's use
- The ability to present information and train other people
- Communication and human relation skills
- Organizational and prioritizing skills
- Self motivation skills
- A broad knowledge of the English language, including composition, spelling, grammar and punctuation
- A broad understanding of the department's and division's administrative rules, policies, and procedures

The following abilities are necessary:

- To interact cooperatively and professionally with coworkers, division and department employees and customers/clients
- To receive and react to changes in priorities and be able to implement these changes into the daily schedule
- To exercise good judgment, especially as it relates to matters of confidentiality
- To organize work and meet deadlines
- To use a personal computer utilizing various software programs
- To work independently

PROBLEM SOLVING:

The problems confronted by this position are more than technical in nature. These problems, in addition to the application of radiation protection principles in inspecting ionizing radiation will include identifying and researching regulatory issues.

FREEDOM TO ACT:

This position has the freedom to act only on these matters outlined previously under the heading principal responsibilities. Any actions taken will conform the Minnesota Department of Health, Rules relating to Radioactive Materials, Chapter 4731. Any actions that would involve determination of policy or would concern

POSITION DESCRIPTION C	EMPLOYEE'S NAME	POSITION CONTROL NUMBER 00329640
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NATURE AND SCOPE (RELATIONSHIPS, KNOWLEDGE, SKILLS AND ABILITIES; PROBLEM SOLVING AND CREATIVITY; AND FREEDOM TO ACT.)

other state departments, sections, or federal agencies must be brought to the attention of the unit supervisor. Reporting to the unit supervisor is done routinely through the completed inspection reports and other reports that are submitted.

4.6.3

Current Technical Staff Qualifications

4.6.3

CURRENT TECHNICAL STAFF QUALIFICATIONS

Curriculum Vitae of each current member of the technical staff can be found in this section. Also included in this section is the *Training Schedule*, which outlines each individual's qualifications under the State's written qualification plan.

Timothy Donakowski
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Work Experience

Health Physicist, 1988-present

Minnesota Department of Health, Radiation Unit

- Inspecting NARM facilities
- Coordinating and participating in environmental radioactivity studies and special projects
- Interpret data for the control of radiation in Minnesota

Academic Preparation

M.S. in Public Health, University of Minnesota School of Public Health

- Concentration: Environmental Health

B.S. in Engineering, University of Michigan

- Concentration: Chemical Engineering

Professional Training

2004

- **Teletherapy and Brachytherapy, U.S. Nuclear Regulatory Commission**

2003

- **Safety Aspects of Industrial Radiography, U.S. Nuclear Regulatory Commission**
- **Inspecting for Performance—Materials Version, U.S. Nuclear Regulatory Commission**

2002

- **Root Cause/Incident Investigation Workshop, U.S. Nuclear Regulatory Commission**
- **Minnesota Incident Management System, Department of Public Safety**
- **Multi-Agency Radiation Survey and Site Investigation Manual, U.S. Nuclear Regulatory Commission**
- **Safety Aspects of Well Logging, U.S. Nuclear Regulatory Commission**

2001

- **Licensing Practices and Procedures, U.S. Nuclear Regulatory Commission**

1999

- **Air Sampling for Radioactive Materials, U.S. Nuclear Regulatory Commission**
- **Transportation of Radioactive Materials, U.S. Nuclear Regulatory Commission**
- **Diagnostic and Therapeutic Nuclear Medicine, U.S. Nuclear Regulatory Commission**
- **Inspection Procedures, U.S. Nuclear Regulatory Commission**

- **Technology Transfer of Radiation Risk Assessment, U.S. Environmental Protection Agency**
- 1993
- **Revised 10 CFR Part 20 Training, U.S. Nuclear Regulatory Commission**
- **Minnesota Biomedical Mixed Waste Workshop, U.S. Department of Energy**
- 1992
- **Fundamentals for Radiological Response Team, Minnesota Department of Public Safety**
- 1991
- **Advances Radiological Accident Assessment, Federal Emergency Management Agency**
- 1990
- **Environmental Radiation Surveillance, Harvard School of Public Health**
- 1989
- **Nuclear Testing Equipment, Troxler Electronic Laboratories, Inc.**

Professional Affiliations

Conference of Radiation Control Program Directors, 1988 - present
North Central Chapter of the Health Physics Society, 1988 - present

John Goepferd

Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Work Experience

Radiation Specialist II, 1993-present

Minnesota Department of Health, Radiation Unit

- Surveying x-ray facilities for compliance with Minnesota Rules
- Surveying mammography and level II facilities
- Answering technical calls from regulated community and general public

Chief Radiologic Technologist, 1983-1993

University of Minnesota School of Dentistry, Oral Radiology Program, Minneapolis

- Directing the technical aspects of the Oral Radiology Clinic

Director of Professional Services, 1980-1983

Golden Valley Health Center, Golden Valley, Minnesota

- Directing administrative and technical aspects of radiology program

Acting Chief Radiologic Technologist, 1980

St. Joseph's Hospital, St. Paul, Minnesota

- Directing administrative and technical aspects of radiology program

Assistant Chief Technologist and Director, 1977-1980

St. Joseph's Hospital School of Radiologic Technology, St. Paul, Minnesota

- Directing technical aspects of radiology program

Assistant Instructor and Staff Technologist, 1969-1973

Hennepin County Medical Center, Minneapolis, Minnesota

- Assisting and instructing in the radiology program

Academic Preparation

Graduated from School of Radiographic Technology, Minneapolis, Minnesota, 1975

Bachelor of Applied Studies Degree, University of Minnesota, Minneapolis

- Concentrations: Radiological Studies

Professional Training

2004

- **Industrial Radiography, U.S. Nuclear Regulatory Commission**

2003

- **Licensing Practice and Procedures, U.S. Nuclear Regulatory Commission**
- **Root Cause/Incident Investigation Workshop, U.S. Nuclear Regulatory Commission**
- **Diagnostic and Therapeutic Nuclear Medicine, University of Minnesota**
- **Environmental Monitoring for Radioactivity, U.S. Nuclear Regulatory Commission**

2002

- **Inspecting for Performance Materials Version, U.S. Nuclear Regulatory Commission**
- **Methods of Radiation Shielding Designs for Diagnostic and Therapy Facilities, PET Imaging Techniques**
- **Applied Health Physics, U.S. Nuclear Regulatory Commission**
- **Minnesota Incident Management System Course, MN Department of Public Safety**

2001

- **Air Sampling for Radioactive Materials, U.S. Nuclear Regulatory Commission**

1999

- **Intro to Health Physics, U.S. Nuclear Regulatory Commission**
- **Inspection Procedures, U.S. Nuclear Regulatory Commission**
- **Transportation of Radioactive Materials, U.S. Nuclear Regulatory Commission**
- **Mammography IV Training: Final Regulations, U.S. Food and Drug Administration**

1998

- **Mammography Refresher Course, Conference of Radiation Control Program Directors**

1997

- **Lasers in Medicine Seminar, University of Iowa, Iowa City**

1996

- **Mammography Quality Standard Act Certification Course, U.S. Food and Drug Administration**

1995

- **Compliance Testing for Diagnostic Ionizing Machines, Food and Drug Administration**
- **Radiation Emergency Response Operation Course, Federal Emergency Management Agency**

Professional Affiliations

AART Certified, 1969

George F. Johns, Jr.
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55105-2970

Work Experience

Supervisor, 2003-present
Minnesota Department of Health, Radiation Unit

Health Physicist III and Radioactive Materials Program Coordinator, 1994-2003
Iowa Department of Health, Des Moines, Iowa

- Licensing and inspecting various radioactive materials licensees
- Writing and editing technical guides, documents, and correspondences
- Training radiological response personnel, medical responders, and HAZMAT responders
- Investigating allegations and incidents

Radiological Control Technician and Supervisor, 1984-1994
Portsmouth Naval Shipyard, Portsmouth, New Hampshire

- Supervising radiological oversight of nuclear submarine repair, maintenance, and refueling operations
- Coordinating training for the Radiological Monitoring Division
- Implementing Total Quality Management and Total Quality Leadership (TQM/TQL) programs

Academic Preparation

B.A. in Physics and Philosophy, Franklin College, Franklin, Indiana, 1969

Professional Training

2002

- **Multi-Agency Radiation Survey and Site Investigation Manual**, Environmental Protection Agency
- **Inspecting for Performance—Materials Version**, U.S. Nuclear Regulatory Commission

2001

- **Integrated Materials Performance Evaluation Program Training**, U.S. Nuclear Regulatory Commission

2000

- **Environmental Monitoring Course**, Oak Ridge Associated Universities
- **Hazardous Material for Medical Personnel**, Federal Emergency Management Agency
- **Radiological Series Train-the-Trainer**, Federal Emergency Management Agency

1999

- **Multi-Agency Radiation Survey and Site Investigation Manual, U.S. Department of Energy**
- **TRANSCOM Training, U.S. Department of Energy**
- **Interviews and Interrogations, Iowa Law Enforcement Academy**

1998

- **Instructor Development Course, Iowa Law Enforcement Academy**
- **First Responder Radiological Transportation Emergencies Course, U.S. Department of Energy**
- **Fundamentals Course for Radiological Response Teams, Federal Emergency Management Agency**
- **Fundamentals Course for Radiological Monitors, Federal Emergency Management Agency**
- **Decommissioning Workshop, U.S. Department of Energy**
- **Radiological Emergency Management, Federal Emergency Management Agency**
- **Non-Sworn State of Iowa Investigators, Iowa Law Enforcement Academy**
- **Advanced Radiological Incident Response, Federal Emergency Management Agency**

1997

- **Boiling Water Reactor Fundamentals, Duane Arnold Energy Training Center**
- **Radiological Accident Assessment—Post Plume Phase, Federal Emergency Management Agency**
- **Radiological Accident Assessment—Plume Phase, Federal Emergency Management Agency**

1996

- **Health Physics Engineering, U.S. Nuclear Regulatory Commission**
- **Teletherapy and Brachytherapy, U.S. Nuclear Regulatory Commission**

1995

- **Health Physics Technology, U.S. Nuclear Regulatory Commission**
- **Inspection Procedures, U.S. Nuclear Regulatory Commission**
- **Health Physics and Radiation Protection, U.S. Nuclear Regulatory Commission**
- **Health Physics in Radiation Emergency, U.S. Nuclear Regulatory Commission**

1994

- **Well Logging, U.S. Nuclear Regulatory Commission**
- **Medical Uses of Radionuclides, U.S. Nuclear Regulatory Commission**
- **Radiological Emergency Response, Federal Emergency Response Agency**
- **Licensing Practices and Procedures, U.S. Nuclear Regulatory Commission**
- **Route Cause/Incident Investigation Workshop, U.S. Nuclear Regulatory Commission**
- **Transportation of Radioactive Material, U.S. Nuclear Regulatory Commission**
- **Safety Aspects of Industrial Radiography, U.S. Nuclear Regulatory Commission**

Professional Affiliations

North Central Chapter of the Health Physics Society, 2000 - present

Katherine C. Johnson
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Work Experience

Radiation Specialist I, 2004-present

Minnesota Department of Health, Radiation Unit

- Reviewing licenses for radioactive materials
- Inspecting safety of facilities possessing radioactive materials

Office and Administrative Assistant, 2003-2004

Minnesota Department of Health, Radiation Unit

- Creating inspection reports and forms for equipment registration
- Processing daily deposits, registration forms and data entry materials

Academic Preparation

B.A. in Environmental Studies and Social Justice, Hamline University, St. Paul, MN, 2003

- Concentrations: Communication Studies and Women's Studies

Professional Training

2004

- **Medical Effects of Ionizing Radiation**, Armed Forces Radiobiology Research Institute
- **Radiological Emergency Response**, Federal Emergency Management Agency

2003

- **Radiological Emergency Management**, Federal Emergency Management Agency

Susan McClanahan
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Work Experience

Radiation Specialist III, 2003-present

Minnesota Department of Health, Radiation Unit

- Rule writing for the radioactive materials program
- REP coordinator with the Department of Homeland Security and Emergency Management
- Legislative liaison for radioactive material issues

Supervisor, 1993-2003

Minnesota Department of Health, Radiation Unit

- Supervising radiation inspection staff
- Performing personnel appraisals, hiring, dismissal, scheduling, budgeting, and maintaining equipment

Radiation Specialist II, 1990-1993

Minnesota Department of Health, Radiation Unit

- Surveying x-ray equipment for compliance with Minnesota Rules
- Surveying mammography and level II facilities
- Answering technical calls from the regulated community and the general public

Principal Radiographic Technologist, 1973-1990

University of Minnesota College of Veterinary Medicine, Veterinary Hospital, Radiology Section

- Training junior and senior veterinary students in veterinary radiology and safety
- Civil supervising, including personnel appraising, hiring, dismissal, scheduling, budgeting, and maintaining equipment

Business Owner, 1983-1990

Radiographic Technique Consultants

- Consulting with radiographic facilities on positioning, techniques, and processing problems
- Assisting in specification writing and purchasing of equipment for facilities
- Teaching facilities' staff on QA, positioning, and physics

Radiologic Technologist, 1961-1968, Part-time

Grundy County Memorial Hospital, Grundy Center, Iowa

- Performing radiographic studies
- Assisting full-time technologist with fluoroscopy procedures

Academic Preparation

Graduated from School of Radiology Technology, Swedish Hospital, Minneapolis, Minnesota, 1960

- Concentrations: Radiation Therapy, X-ray and Radiation Physics

Classes taken at University of Minnesota, Minneapolis, 1958, 1973-1990

- Concentrations: Physics and Radiology Science

Classes taken at Metro State University, Minneapolis/St. Paul, Minnesota, 1973-1990

- Concentrations: Management, Public Relations, Writing, and Physics

Professional Training

2003

- CT Training, Conference of Radiation Control Program Directors

2002

- **Gamma Knife Source Installation Training, Mayo Clinic**
- **Shielding, Conference of Radiation Control Program Directors**
- **Licensing Practices and Procedures, U.S. Nuclear Regulatory Commission**

2001

- **Radiation Therapy, Conference of Radiation Control Program Directors**
- **Minnesota Incident Management System, Minnesota Department of Public Safety**

1999

- **Mammography Training, Conference of Radiation Control Program Directors**

1998

- **Laser Training, Lawrence Labs, Berkeley, California**
- **Health Physics Society annual meeting, Minneapolis, Minnesota**
- **Conference of Radiation Control Program Directors Annual Meeting, CRCPD**

1997

- **Northeast Mammography Conference, Springfield, Massachusetts**
- **Lasers in Medicine Seminar, University of Iowa, Iowa City**
- **Physics Review Program, CRCPD**

1992

- **Mammography Categorical Course, Radiological Society of North America**
- **Mammography Radiation Measurements Workshop, U.S. Food and Drug Administration**
- **ASPEN computer program training for HCFA report, MN Facility and Provider Compliance**
- **Mammography Training Course, U.S. Food and Drug Administration**
- **Radiological Emergency Response Operation, Federal Emergency Management Agency**

1991

- **Compliance Testing and Physics, U.S. Food and Drug Administration**

1990

- **Survey Inspection Training, Minnesota Department of Health, Radiation Unit**

Achievements and Awards

MSRT speaker on "Radiation in the 21st Century," September 2003

CRCPD speaker on Bone Densitometry, 1998

Published chapter in Lisa Lavin's *Radiography in Veterinary Technology*, 1991

MDH Merit Award, 1990

Minnesota Society of Radiologic Technologists, Continuing Education Director, 1980-2001

Minnesota Society of Radiologic Technologists, First Place Exhibit Winner at Annual Fall Education Conferences, 1981, 1982

Conducted 9 workshops throughout the U.S. for 3M Animal Care Section, 1990-1991

Registered Radiologic Technologist, 1960

Professional Affiliations

Minnesota Society of Radiologic Technologists, 1959-present

American Registry of Radiologic Technologists, 1960-present

American Society of Radiologic Technologists, 1958-present

Conference of Radiation Control Program Directors, 1990-present

North Central Chapter of Health Physics Society, 1990-present

Health Physics Society, 1993-present

Craig Verke

Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Work Experience

Radiation Specialist II, 1996-present

Minnesota Department of Health, Radiation Unit

- Surveying x-ray facilities for compliance with Minnesota Rules
- Surveying mammography and level II facilities
- Answering technical calls from regulated community and general public

Radiographic Technologist, 1995-1996, Part-time Casual

Unity Hospital, Fridley, Minnesota

- Performing general radiographic and fluoroscopic studies

Radiologic Technologist, 1991-1996

North Memorial Medical Center, Robbinsdale, Minnesota

- Performing general radiographic and fluoroscopic studies
- Tech representative for ADIT 1995-1996

Academic Preparation

Professional Training

2002

- **Inspecting for Performance—Materials Version**, U.S. Nuclear Regulatory Commission
- **Applied Health Physics**, U.S. Nuclear Regulatory Commission
- **Mammography Quality Accountability and Responsibility**, Advanced Health Education Center
- **Minnesota Incident Management System**, MN Department of Public Safety

2001

- **Air Sampling for Radioactive Materials**, U.S. Nuclear Regulatory Commission
- **Transportation for Radioactive Materials**, U.S. Nuclear Regulatory Commission
- **NEXT Training**, Conference of Radiation Control Program Directors (CRCPD)

2000

- **Quality Assurance in Radiation Oncology**, American Association of Physicists in Medicine (AAPM)
- **MQSA Continuing Education Course**, CRCPD
- **NEXT Training**, CRCPD

1998

- **MQSA Training, CRCPD**
- **Mammography Physics and Equipment, CRCPD**

1997

- **Level II Training, U.S. Food and Drug Administration**

TRAINING SCHEDULE

Course #	Course Title	Timothy	John	Craig	Katherine
	BASIC	Donakowksi	Goepferd	Verke	Johnson
G-108	Inspection procedures	09/13 - 09/17/99	09/13 - 09/17/99	09/29 - 10/03/03	09/20 - 24/04
G-109	Licensing Practice and Procedures	09/10 - 09/14/01	03/10 - 03/14/03	03/10 - 03/14/03	09/13 - 17/04
G-205	Root Cause/Incident Invest. Workshop	07/08 - 07/12/02	04/28 - 05/02/03	07/08 - 07/12/02	
G-304	Inspecting for performance materials version	04/22 - 04/24/03	06/11 - 06/13/02	06/11 - 06/13/02	
H-109	Applied Health Physics	N/A	03/04 - 04/05/02	03/04 - 04/05/02	
H-122	Basic Health Physics	N/A	N/A	N/A	08/02 - 13/04
H-304	Intro. Health Physics	N/A	08/30 - 09/03/99	N/A	
H-305	Diagnostic & Therapeutic Nuclear Medicine	08/09 - 08/13/99	03/03 - 05/03	03/03 - 05/03	
H-308	Safety Aspects of Industrial Radiography	09/14 - 09/20/03	04/19 - 04/23/04	09/14 - 09/20/03	
H-313	Transportation of Radioactive Materials	06/20 - 06/24/99	06/20 - 06/24/99	06/20 - 06/24/99	
	Teletherapy & Brachytherapy	03/15 - 03/19/04	08/16 - 08/20/04	08/16 - 08/20/04	
	Radiological Emergency Response Operations (RERO)	04/28 - 05/05/89	03/05 - 03/10/95	03/15 - 03/19/04	
	Health Physics in Radiation Accidents (REAC/TS)				
	ADVANCED				
H-111	Environmental Monitoring for Radioactivity	Harvard	06/09 - 06/13/03	06/09 - 06/13/03	
H-119	Air Sampling for Radioactive Materials	06/07 - 06/11/99	06/04 - 06/08/01	06/04 - 06/08/01	
H-121	Multi-Agency Radiation Survey and Site Invest. Manual	05/07 - 05/09/02			
H-201	Health Physics Technology	10/20 - 10/31/03			
H-312	Internal Dosimetry & Whole Body Counting	Univ. of MN			
H-314	Safety Aspects of Well logging*	04/23 - 04/27/02			
H-315	Irradiator Technology*				
	Advanced Radiological Response Operations	08/12 - 08/16/91			
	Gamma knife source Installation 8 hours on 11/4/02				
	Tim Donakowski, John Goepford				
	Sue McClanahan, Craig Verke				
	* Not required				

4.7.1

Event and Allegation Response Procedures

4.7.1

EVENT AND ALLEGATION RESPONSE PROCEDURES

The *Response Manual for Incidents Involving Radiation* includes Minnesota's procedures for responding to events and allegations. These procedures include immediate response and actions to mitigate an event, follow-up inspections and enforcement actions, notifications to licensing staff, reports to the incident file, and notifications to other affected licensees of generic problems.

Appendix A to the Response Manual, "The Handbook on Nuclear Material Event Reporting in Agreement States" has been excerpted and is included in this section. In addition, the *Data Privacy Puzzle* has been included to address the protection of individuals making allegations. It also provides for the protection of other sensitive information.

SUMMARY

The MDH *Response Manual for Incidents Involving Radioactive Material* was created to provide a general outline for MDH staff to follow when incidents involving radioactive material occur. Because every incident has unique circumstances, the intention of the Manual is to provide a generalized structure to be followed for the sake of consistency.

An incident is an unusual occurrence that has an impact on public health and safety. It can include, but is not limited to the following:

- Misuse, loss of control over, or loss of licensed radioactive material
- Medical misadministrations
- Overexposures to radiation

According to MDH rules licensees are required to report incidents on specific occasions. They are listed in the Manual mentioned above. However, members of the public can also report incidents. The majority of these calls are from scrap metal processors that identify radioactive material that set off radiation monitors in a load of scrap metal. Other calls come from individuals who are concerned with something they way, or have knowledge of, that is radiation related.

The manual outlines the steps should be taken in response to an incident call. This includes information that should be gathered, the response that should be taken by staff and the reporting that needs to be done both internally and to the NRC NMED system. In the assessment process, a call back or reassessment may need to be made.

**SA-300 Reporting Material Events
Appendix (Rev. 1)**

Handbook on Nuclear Material Event Reporting in the Agreement States

Final Report

April 24, 2001

(Excerpted and Abridged by the Minnesota Department of Health)

Abstract

The review and analysis of operational event information increases the effectiveness of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State regulatory programs by identifying safety-significant events and concerns, and their causes. The information from reports of medical misadministrations, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by either the NRC or the Agreement States is invaluable in assessing trends or patterns and identifying possible inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement States regulatory programs. The information is also used in preparation of NRC's performance report to Congress. This handbook, which supercedes the previous February 20, 1998-version, has been developed to provide information to the staff of the Agreement and non-Agreement States that are responsible for the preparation of event reports for incidents and events involving the use of nuclear materials that have occurred in their State. Reporting of Agreement State material events to NRC is mandatory for purposes of compatibility. The handbook describes the procedure to be followed in reporting material events to NRC. Guidance is provided on what information should be reported, the level of detail, and where to report. Information is also provided on obtaining Federal assistance for radiological emergencies. Procedures for identifying and reporting Abnormal Occurrences (AOs) are also included. The objective of the handbook is to:

- Improve technical information
- Standardize format
- Ensure consistency
- Facilitate information retrieval

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1. Introduction

This handbook contains guidance for Agreement States on reporting material event information to the Nuclear Regulatory Commission (NRC) for events that have occurred in their State. It also provides guidance for use by non-Agreement States when reporting events involving lost, stolen or found sources of naturally occurring and accelerator-produced radioactive materials. The reported information aids in understanding why the events occurred and in identifying actions to help ensure safety and improve the overall effectiveness of the NRC and Agreement State regulatory programs. Guidance is provided on (1) reporting significant events to the NRC Operations Center; (2) providing 30-60 day notification and follow-up event information; (3) schedule for event reporting; (4) reporting formats (i.e., electronic reporting to the Nuclear Materials Events Database (NMED) or written reports (mail, Fax, or email) to the Director, Office of State and Tribal Programs (STP); and (5) reporting event information for events meeting the abnormal occurrence (AO) criteria. An appendix to the Handbook contains (1) a glossary of terms, and (2) a listing of reference materials. NOTE: This procedure does not contain guidance on NMED data entry (coding). For guidance on data entry, an electronic copy of the NMED users guide has been included under the *Help* support icon in the upgraded Microsoft Access 97/2000 version of the NMED software program.

1.1 Why do we collect event information?

Operating experience is an essential element in the regulatory process for insuring that licensed activities are conducted safely. Reporting operating incidents and events helps to identify deficiencies in the safe use of AEA radioactive material and to ensure that corrective actions are taken to prevent recurrence. The *Government Performance Results Act of 1994 (GPRA)*, required the Agency to establish measurable outcome oriented performance goals linked to Agency programs and activities in a strategic plan. An annual performance report to Congress is prepared that evaluates the materials program against the metric performance goals. The metric goals are based on current and historical event reporting data. A 1993 General Accounting Office (GAO) report identified the compilation and presentation of national materials data as an area for improvement and recommended that NRC take appropriate action to ensure that the information on radiation events is reported completely and accurately. Further, reliable information should be available to NRC, the Congress, and the States to identify patterns and trends and determine appropriate changes for the programs.¹ NRC conducts reviews of all operating experience reports, from both NRC licensees and Agreement States, to identify safety concerns early, and to further evaluate individual safety concerns for any *generic safety issues (GSIs)* that could apply to a broader class of licensees. Prompt reporting of event information, including 30 day report information, helps the staff identify or detect possible safety concerns as early as possible. An event or condition could, by itself appear insignificant, but when compared

¹ Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials, GAO/RCED-93-90.

with national information, could become a generic concern. In-depth analysis of event report data may result in the identification of actions that could lead to improvements in the effectiveness of NRC and Agreement State regulatory programs. Event analysis may also result in the issuance of information notices warning of possible safety concerns and assessment of the need for regulatory changes or revisions. Feedback is provided to Agreement State regulators, the industry, and the public.

NRC publishes a quarterly report that presents information on the results of statistical analysis of event data and any significant or generic issues or concerns. The *Nuclear Materials Events (NMED) Database Quarterly Report* is available in electronic form at the NMED Internet Website: <http://nmed.inel.gov>. A nuclear material newsletter is also published quarterly by NRC's Office of Nuclear Material Safety and Safeguards (NMSS) that includes information on safety concerns identified during that quarter.

1.2 What is the governing regulatory authority?

- Under Section 274 of the AEA, Agreement States have assumed regulatory authority over byproduct source and certain quantities of special nuclear materials. The AEA directs NRC to cooperate with the States in the formulation of standards to protect employees or the general public against hazards of radiation and to assure that State and Commission programs will be coordinated and compatible. Article VI of the Agreement Between the State and the US NRC states that "the State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implications or otherwise be of regulatory interest."
- Under the AEA and the Energy Reorganization Act of 1974 (ERA), as amended, the NRC evaluates material event reports for both and Agreement State licensees, and AOs that have occurred in licensed facilities. In addition, the ERA requires NRC to provide to Congress on an annual basis, information on significant events that meet the AO criteria.
- Due to the importance of operating experience as an essential element in the regulatory process for ensuring that licensed activities are conducted safely, the Commission directed the staff to make Agreement State reporting of events to NRC's NMED database an item of compatibility (See Reference section, June 30, 1997, SECY-97-054). The implementing procedures are contained in STP Procedure SA-200 (See Reference section).
- The guidance contained in this handbook is to assist NRC and Agreement State staff in the joint sharing and analysis of event information. It does not address evaluation of Agreement State programs. The AEA directs the Commission to periodically review actions taken by the States under the Agreements to insure adequacy and compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the *Integrated Materials Performance Evaluation*

Program (IMPEP), which includes an evaluation of event response, reporting, follow-up, and close-out. (See Reference for STP Procedure SA-100 (IMPEP))

1.3 How do you determine if an event is reportable?

Agreement States should report to NRC all events reported to their State by State licensees under State regulations equivalent to NRC's reporting requirements. Section 4 of this guide contains a listing of the *U.S. Code of Federal Regulations (10 CFR)* regulatory reporting requirements for material event information. The 10 CFR reporting requirements form the basis for equivalent reporting requirements in Agreement State regulations. The listing references the specific 10 CFR reporting requirements, followed by a brief description of the types of events that fall under the reporting requirement, and the periodicity for reporting. This list begins on page 11 of the "Handbook."

New Please note the new reference in All Agreement State Letter SP-98-038, dated May 5, 1998, regarding expansion of the Federal Bureau of Investigation (FBI) criminal investigative jurisdiction to include byproduct material. A revision to the U.S. Code assigns lead responsibility for material events involving *theft or terrorist activities* to the FBI.

The States are encouraged to voluntarily report an occurrence that actually happened (event) or something that may happen (condition) that does not meet the regulatory reporting criteria that the State believes might be of safety significance or of generic interest or concern, or involves media interest.

1.4 What is the Nuclear Materials Events Database (NMED)?

The NMED database contains a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States (source, byproduct, special nuclear material, naturally occurring, and accelerator-produced radioactive material). NMED accommodates the sharing of material event data submitted by Agreement and non-Agreement States and the NRC. The data includes information on material events from January 1990 through the present. The database is maintained by NMSS through a contractor, Idaho National Engineering and Environmental Laboratory (INEEL).

1.5 Reporting Lost, Stolen and Abandoned Sources

New The NMED database has been expanded to include additional information on *lost, stolen, and abandoned sources* in coordination with a national effort led by the *Conference of*

Radiation Control Program Directors, Inc., (CRCPD) to track lost and found radioactive material (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. The data will be collected from all States, and in some cases non-licensee organizations and members of the public. Non-Agreement States should follow the guidance provided in Section 2 . "Reporting Material Events," to report any lost, stolen and abandoned non-AEA and unlicensed material. (See All Agreement State Letter SP-98-018, March 17, 1998).

NOTE: FBI notification should be considered if the event involves the possibility of theft or terrorist activities. Based on health and safety significance the issuance of a press release should also be considered.

2. Reporting Material Events

In accordance with the provisions of compatible Agreement State regulations, Agreement State licensees are required to report the occurrence of material incidents and events to the Agreement State regulatory agency. As an item of compatibility, the Agreement States provide reports of incidents and events involving the use of nuclear materials by Agreement State licensees to NRC. Non-Agreement States have been requested by CRCPD to voluntarily report any lost, stolen and abandoned non-AEA and unlicensed material. This section presents information on reporting (1) significant events to the NRC Operations Center, (2) 30-60 day reportable events, and (3) follow-up event information.

2.1 Reporting Significant Events (Reportable within 24 hrs. by Agreement State licensee)

Agreement States should report significant events to the NRC Operations Center within 24 hours of notification by an Agreement State licensee. Significant events are those requiring prompt notification as determined under applicable Agreement State regulations. Information should be reported to the NRC Operations Center via voice at (301) 816-5100 or (301) 951-0550 or by FAX at (301) 816-5151. A Sample FAX page has been included at the end of Section 2, see Table 1. (For reference, NRC reporting requirements for significant events are presented in Section 4.)

2.2 Initial NMED Record for Significant Events

A copy of the initial event notification information received from an Agreement State on significant events is used by INEEL to establish an initial record in the national NMED database. INEEL will use the *Event Report Identification No.*, consisting of the State ID, year, and a sequential ID No., e.g., (TN-00-001) when entering the initial event record into NMED. The State should use that Event Report Identification number when providing

updates to the initial NMED event record using the State's local Microsoft Access, NMED database. (See Section 2.5, of this Handbook for guidance on reporting follow-up event information to NMED.)

2.3 Radiological Emergency Response Assistance Available to the States for Significant Material Events

States may request Federal assistance through the NRC Operations Center staff. The Federal government, upon request, has the capability to provide assistance to States in responding to radiological emergencies. Under the Federal Radiological Emergency Response Plan (FRERP), NRC is the lead Federal agency (LFA) for radiological emergencies involving AEA material where the material can be traced back to an individual NRC or Agreement State licensee. As the LFA, NRC is responsible for coordination of the Federal response, including providing assistance from NRC and arranging for assistance from other agencies, e.g., FEMA, DOE, etc., as requested by the States. Federal assistance is available to provide ground and aerial radiological monitoring (e.g., missing source), medical advice on radiation effects and treatment, consequence projection, and protective action assessment.

FAX TO: NRC OPERATIONS CENTER

Agreement State Agency: [State] Dept. of Health, Division of Radiation Protection

Event Report ID No.: State ID, YR, No., e.g. WA-00-002

License No.: CL-Z00X-1
Licensee: County Inspection Inc.

Event date and time: April 6, 2001, between 4:00 and 5:00 am

Event location: City, State

Event type: Stolen Radiography Device
Notifications: [State] Dept. of Health has notified local police, and the FBI due to possibility of unlawful criminal activity. Press release has not been issued at this time.

Event description: [State] Dept. of Health was notified on [date], by a representative from [licensee], of the theft of a radiography camera from a locked equipment trailer on Thursday morning, April 6, 2001. The locked camera and the keys to the camera were stolen. The radiography camera is identified as XYZ Company, Model 160B, serial No. B-3333, containing [isotope] [activity, when known] 88.3 curies of Iridium-192. The device cables were not stolen.

The State has an inspector on site and will continue to keep NRC informed of the status of our investigation.

Transport vehicle description: N/A

Media attention: [State] Dept. of Health has received inquiries from the media

Point of contact: Bob Brown, 301-415-0001

Table 1. Sample FAX Sheet to NRC Operations Center

2.4 30 - 60 Day Event Notification

Agreement States should report events requiring greater than 24 hours notification by Agreement States licensees, as determined under applicable Agreement State regulations, to NRC on a monthly basis. (For reference, NRC reporting requirements for events are presented in Section 4.) Reports may be made either electronically or in written form. NRC staff encourages Agreement States to electronically report all events using the NMED database software and entry screens.

The following paragraphs provide additional information on reporting events and NMED. For guidance on data entry (coding), an electronic copy of the NMED users guide has been included under the *Help* support icon in the upgraded Microsoft Access 97/2000 version of the NMED software program. The upgrade NMED software program also contains downloadable sample NMED data entry screen (previously included in this Handbook).

a. ***Assign Event Report Identification No.***

This number should appear on all reports, including preliminary, initial notification reports, and any follow-up reports. The Event Report Notification No. should consist of the State or State agency ID, year, and a sequentially assigned ID number, e.g., (NYDOL-99-001), (NYC-99-001), (TX-00-001), (GA-00-001), (NE-00-001), (CA-00-001) for each agency in your State. NOTE: The Agreement State ID number field in NMED can accommodate up to four characters for the State or agency identifier. The "Agreement State ID No." should be specified by the State for all telephone, electronic or written notification involving each specific event.

b. ***Basic Event Information***

Section 3 provides a listing of the minimum event information that should be provided. When submitting an initial event report, please provide as much information as is known at the time the report is prepared regarding the items indicated in Section 3. Updated information should be subsequently provided in follow-up reports (see Section 2.5).

c. ***Electronic Reporting to NMED***

Provide an electronic NMED report via E-mail or PC diskette to the NMED contractor, based on the information provided by the Agreement State licensee in the 5, 15, 30 or 60 day report. If you need additional help, you may contact the INEEL NMED Project Manager, Dante Huntsman, electronically via Internet email at: dhun@inel.gov, or by telephone at 208-526-2741, or the NRC NMED Project Manager, Sam Pettijohn, via e-mail SLP@nrc.gov or telephone: 301-415-6822.

d. *Internet Access to NMED*

An Internet (query only) version of NMED with several drop-down point-and-click menus is available. The Internet version of the NMED program eliminates the need for INEEL to provide users with periodic diskette updates of the national NMED data. Users may download the latest NMED national database information via Internet file transfer. Internet access to the NMED is currently controlled either by a user -ID and password, or a user -ID and Internet Protocol (IP) Addresses. If passwords are required contact Dante Huntsman, INEEL by e-mail message at: dhun@inel.gov or by telephone at 208-526-2741. Future plans include upgrading the Internet version of NMED to provide open public access to material event information. *NOTE: Agreement States should continue to use the Microsoft Access data entry program for maintaining a local events database and for submitting NMED event reports to INEEL.*

e. *Written Event Reports*

Written event reports, including e-mail or fax, should be sent to the Director, STP. Written report information should be comparable to the minimum basic information identified in Section 3. Reports should be provided in an optical character recognition (OCR) scannable format. Please include an *Event Report Cover Page* for all written form event information provided to NRC. Use of the Event Report Cover Page helps ensure our Document Control staff can readily identify, classify and appropriately record the document. A sample cover page is provided on page 10 of this Handbook.

2.5 Reporting Follow-up Event Information

Follow-up material event reports--providing the results of investigations into what, where, when and how the event or conditions occurred--through resolution and close out, should be provided for all events, both significant (24 hr. reportable) and 30-60 day reportable events.

- a. Follow-up reports through a closeout of the event should be provided electronically or in writing to NRC on a monthly basis. Enter any new or supplemental information to the initial NMED record. A complete event report should include all investigative and medical information through closeout. (See minimum basic event information in Section 3.)
- b. The initial event report identification number (State\Yr.No.) should be included whenever additional follow-up event information is provided. Indicate that it is a follow-up report.
- c. Additionally, when providing follow-up NMED event information, provide clear reference to documents on file that the State used to generate the NMED event report, e.g., a licensee inspection report dated mm/dd/yr., if applicable and appropriate.

- d. Any follow-up information that revises earlier information or provides additional information on a given event should be provided to ensure a complete historical NMED record.

3. Minimum Basic Event Information for a Complete Report

The following listing identifies the minimum basic information that should be provided for all events.

A. What happened, and when?	
1. Agreement State, Event Report ID No.	7. Sealed source, device, etc, (make, model #, serial #)
2. Licensee (Name, address), License No.	8. Leak test information, when applicable
3. Event date and time of occurrence	9. Equipment (make, model #, serial #), and clear description of any equipment problems.
4. Date notified of event by licensee or non-licensee	10. Persons involved, consequences
5. Radionuclide, activity	11. Transportation, identify shipper, package type and ID No.
6. Any exposures (indicate short and long-term effects.)	12. Abnormal occurrence (Y/N)
B. Why did it happen?	
13. Cause, and contributing factors	
C. What actions did the licensee take to prevent recurrence?	
14. Notifications: patient, physician	15. Licensee corrective actions
D. Events involving lost, stolen or abandoned material	
16. Provide status through resolution (update record when found)	
E. What actions did the State take?	
17. Notifications: local police, FBI, and other States; as needed	18. Enforcement actions
F. Describe any generic implications	
19. Identify any possible generic safety concerns	20. Potential for others to experience the same event

EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT ID NO.: MN - ___ - ____
(State\Yr.\No.)

DATE:

TO: _____
Director
Office of State and Tribal Programs

SUBJECT:

STATE:

Signature and Title: _____

Public Availability of Event Information: Any event information that is considered preliminary pre-decisional information by the State should be clearly identified on the cover page as follows: "Preliminary, Not for Public Disclosure." For event information in NRCs possession, the final determination on whether to withhold from public disclosure will be made by NRC on a case-by-case basis in accordance with the requirements of 10 CFR Part 9.

Table 2. Event Report Cover Page

Regulatory Reporting Requirements
 NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides complete listing of the current 10 CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
20, Standards for Protection Against Radiation	20.1906(d)(1)		reports of removable contamination on package >limits in 10 CFR 71.87.	Immediate
	20.1906(d)(2)		radiation levels on package > limits in 10 CFR 71.47	Immediate
	20.2201(a)(1)(i)		reports of theft or loss of licensed material > 1000 X App C value	Immediate
		20.2201(a)(1)(ii)	reports of theft or loss of licensed material > 10 X App. C value	30 days
	20.2202(a)(1)		exposure (real or threatened) ≥ TEDE of 25 rem (.25 Sv), or eye or lens dose equiv. of 75 rem (.75 Sv) or shallow dose equiv. (skin\extremities) of 250 rads (2.5 Gy).	Immediate
	20.2202(b)(1)		exposure (real or threatened) ≥ TEDE of 5 rem (.05 Sv), or eye or lens dose equiv. of 15 rem (.15 Sv), or shallow dose equiv. (skin\extremities) of 50 rads (.5 Gy).	24 hours
	20.2202(a)(2)		release where individual could have intake > 5 X ALI over 24 hours.	Immediate
	20.2202(b)(2)		release where individual could have intake > 1 X ALI over 24 hours	24 hours
			3(a), (b)	radiation exposures, releases or concentrations of radioactive material that exceed the limits.
21, Reporting of Defects & Noncompliance)(1-2)	ng of defect in basic component, structure or system. ²	60 days
30, Rules of General Applicability to Domestic Licensing of Byproduct	30.50(a)		events involving prevention of immediate protective action, involving exposures or releases that could exceed regulatory limits	4 hours

² Not a compatibility requirement for Agreement States, but States voluntarily provide information on equipment failure and defects.

Event Reporting Handbook

Regulatory Reporting Requirements

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides complete listing of the current 10 CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
Material				
	30.50(b)(1)		event involving unplanned contamination restricting access >24 hours (no isotopes with half-lives <24 hrs)	24 hours
	30.50(b)(2)		event involving equipment failure or disability to function as designed when equipment is required to be available and operable and no redundant equipment is available and operable	24 hours
	30.50(b)(3)		event involving unplanned medical treatment of contaminated person	24 hours
	30.50(b)(4)		involving fire, explosion affecting integrity of material, device or container, and material exceeds 5Xs ALI	24 hours
31, General Domestic Licenses for Byproduct Material		31.5(c)(5)	failure or damage to shielding, on-off mechanism or indicator, or ≥ 0.005 microcuries (185 Bq) removable radioactive material for generally licensed device	30 days
34, Licenses for Radiography & Radiation Safety Requirements for Radiographic Operations	34.27(d)		ing of leaking sources, leak test results ≥ 0.005 microcurie (185 Bq)	5 days
		34.101(a)	radiography source disconnect, inability to retract source, or component failure (critical to safe operation of device)	30 days
35, Medical Use of Byproduct Material	35.33(a)		notifications and reports of misadministrations ³	Next day (24 hours)
	35.59(e)(2)		leak testing sealed sources and brachytherapy sources	5 days

³ Misadministration events require 15 day licensee event report and 24 hour notification to referring physician and patient.

Regulatory Reporting Requirements

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides complete listing of the current 10 CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
36, Licenses & Radiation Safety Requirements for Irradiators	36.83		irradiator events, release of material, defective components, systems or structures; (if not reported under other 10 CFR reporting requirements)	24 hours
39, Licenses & Radiation Safety Requirements for Well-Logging	39.35		leaking sealed sources found during periodic leak testing requirement	5 days
	39.77 (a)		well logging source rupture	Immediate
		39.77(b)	theft or loss, exposures, excessive concentration of rad material	30 days
		39.77(c) and (d)	when apparent recovery impossible, irretrievable source, abandonment	60 days
40, Domestic Licensing of Source Material	40.26(c)(2)		tailings or waste retention system failure that results in a release of material into unrestricted areas, or unusual conditions	Immediate
	40.60(a) (b)(1)-(b)(4) (c)(1)-(c)(2)		requirements for domestic licensing of source material to receive, possess, use, transfer, or deliver source and byproduct material (NOTE: Same as 30.50 above)	
70, Domestic Licensing of Special Nuclear Material	70.50(a)	70.50 (b) (c)	events involving special nuclear material (SNM)	(a) 24 hours (b) 30 days (c) 60 days

Table 3. EXAMPLES OF REPORTABLE EVENTS

This Table provides examples of reportable material events or occurrences that are required to be reported by both NRC and Agreement State material licensees. The Table addresses specific reporting requirements for either immediate notification (within 24 hours or less) or 30 day written reports.

<p>Immediately reportable under 10 CFR 20.2201</p>	<p>Stolen Portable Moisture Density Gauge</p> <p>Licensee reported that a [Manufacturer] [Model #] [serial #] portable gauge containing 10 millicuries of Cesium-137 and 50 millicuries of Americium-241:Beryllium was stolen from the licensee's vehicle parked at the licensee's facility. The gauge was padlocked in its original carrying case. The State is following the incident and working with local authorities to develop a press release. Local law enforcement and the FBI have been notified. Follow-up information will be provided to NRC on the recovery of the stolen gauge and entered into NMED.</p>
<p>Reportable within 24 hours under 10 CFR 30.50(b) (2) and 20.2201</p>	<p>Possible Loss of Control and Damage to Portable Gauge</p> <p>Licensee reported that a [Manufacturer] [Model #] [serial #] moisture density gauge had been damaged on March 28, 2001. The gauge contained 7.9 millicuries of Cesium-137 and 40 millicuries of Americium-241. A technician left the gauge unattended for a brief time and upon returning found that a construction vehicle had run over the gauge. The source rod was broken but the source was undamaged and remained in the shielded position. Wipe tests and instrument survey verified no leakage. The gauge was returned to the manufacturer for repair. The licensee was cited for not keeping licensed material under constant surveillance in an unrestricted area. Report has been entered in NMED.</p>
<p>Reportable within 30 days under 20.1906</p>	<p>Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits</p> <p>A medical licensee reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages with an ion chamber detector found radiation levels of 250 millirem per hour on one package, which exceeds the State and Federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultant's review of the event, and the information will be entered into NMED.</p>
<p>Reportable within 24 hours under 10 CFR 20.1301, 20.2203</p>	<p>Exposure to Non-radiation Worker at a Licensed Facility</p> <p>A licensee reported to the State that a non-radiation worker had received an exposure as a result of picking up a 5 curie Americium-241:Beryllium neutron source used for well logging and placing it in his pocket. The worker, a temporary contractor employee, was cleaning a well logging tool at the licensee facility. (The licensee was under the assumption that all of the source material had been removed from the equipment.) While cleaning the tool, the source fell out, and the worker picked it up and placed it his pocket. The worker was not a radiation worker and had no knowledge of what the object was. Preliminary calculations performed by [identify Consultant/Contractor] indicate that the individual may have received a dose of 4-6 Rem. The licensee's RSC is investigating the incident. The State plans to keep NRC informed of the ongoing</p>

<p>Reportable within 24 hours under 10 CFR Part 35 and 30.50(b)(2)</p>	<p>results of the investigation, and the information will be entered into NMED.</p> <p>Possible Misadministration Involving a Teletherapy Unit Malfunction</p> <p>A patient undergoing a Cobalt-60 Teletherapy treatment with a [Manufacturer][Model Number] received an unintended exposure. The RSO estimated that the patient received an exposure of 138 centiGray (Rads) to a depth of 0.5 centimeters to the wrong treatment site, based on a possible total treatment time of 1.5 minutes. The exposure occurred as a result of two power disruptions during a thunderstorm. The loss of electrical power caused the unit table to move which resulted in treatment to the wrong site. The patient received 0.35 minutes of the intended fractionated treatment time of 1.5 minutes. The patient was prescribed a total dose of 5040cGy to be given in 28 fractions of 180 cGy per day at the rate of 5 fractions per week. The prescribing physician elected not to make up the missed dose. The prescribing physician indicated that the patient is not expected to have any adverse effects from the misadministration. The patient and referring physician were notified of the event. The licensee was able to recreate the event to demonstrate how the event occurred. The licensee has contacted the manufacturer. The State will keep NRC informed of the results of the review for any generic implications.</p>
<p>Reportable within 24 hours under 10 CFR 36.83(a)(9)</p>	<p>Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility</p> <p>Licensee notified the State that the controls at a Co-60 irradiator facility were indicating that the water level was low, circulating pump off, and fill valves were open. The pool water level gauge indicated a pool water level of 93 inches, well below the normal level of 137 inches. Previous incidents indicated that a loss of compressed air pressure to the water level gauge could result in an erroneously low water level gauge reading, causing the automatic pool fill valves to open, and the pool water circulating pump to turn off. The compressed air system pressure was found to be in the normal range, but the operator found water and congealed oil in the air line supplying the pool water level gauge, and the air line supplying the elevator control valve. Further investigation found that the compressed air line water traps were full of water. A past similar incident resulted in a failure to raise the elevator. The operator then verified that the pool water level was in fact normal. The licensee requested the building maintenance personnel to diagnose and repair the compressed air supply immediately, to prevent the conductivity in the pool water from reaching abnormal levels as a result of the resin filter circulating pump being automatically turned off by the false low pool water level meter reading. Maintenance personnel responded and replaced a failed compressed air dryer, and monitored the open air lines to clear the lines of water. A float activated automatic water drain was installed in the air line to prevent a possible recurrence by allowing any water to automatically drain from the air line.</p>

5. NRC Publication and Distribution of Event Notifications

5.1 Event Notifications (ENs) are Available on Internet

All events reported to the NRC Operations Center are currently entered into the NRC Event Notification (EN) database. ENs are publicly available through Internet on NRC's external home page at (<http://www.nrc.gov/opa>) under *Event Reports*, within one workday of notification. As a result of public access to this information, Agreement and non-Agreement States may receive contacts from the public or media regarding events and requesting additional information.

5.2 Preliminary Notifications (PNs) are Used to Distribute Event Information

Preliminary Notifications (PNs) are brief summary reports of significant events issued by the NRC staff to notify the Commission of the occurrence of a significant event. PNs are based on information provided by State radiation control program staff. PNs are usually issued within approximately two hours of notification of the occurrence of a significant event. The PN will be publicly available through Internet on NRC's external home page under PN Reports at (<http://www.nrc.gov/opa>). Updates to PNs occur when significant additional information about an event is provided to NRC. When preparing PNs, NRC staff may contact the State for additional information on the event.

6. NRC Safety Reviews of Material Event Reports

6.1 NRC Review of Material Events for Safety Significance and Generic Issues

- A. A *Generic Assessment Panel (GAP)* has been established within NRC to review all material event information. A weekly review of all new NRC or Agreement State licensee event information that has been entered into NMED is conducted by NRC staff. The objective of the review is to identify any events that may be safety significant or may involve GSIs, i.e., equipment malfunction or failure, significant exposures, etc. GSIs are defined as a safety concern that may affect the design, construction, operation, or decommissioning of all, several, or a class of regulated operations, and may have the potential to require licensees or certificate holders to make safety improvements and/or require new or revised requirements or guidance.

B. **Requests for additional information:** Based on the results of the GAP review, Agreement State staff may be contacted by the Regional State Agreements Officer (RSAO) by voice or email to discuss the event. Additional information may be requested to help determine the safety significance and any possible generic implications (e.g., equipment malfunction or failure, significant exposures). Specific issues identified as a result of the review are tracked through close-out of the event. To provide the States reasonable time for review and investigation of reported events, any requests for additional information to States will be conducted within the following schedule.

1. Schedule for requesting additional information:

If necessary, NRC staff may contact Agreement States for additional information on *significant events* that pose or could pose public health and safety risks. Such requests would occur on an as needed basis, possibly within hours to a few days of notification of the occurrence of the event, based on the safety significance.

For events that have not been identified as safety significant, when necessary, the RSAO, or a designee, may contact Agreement States for additional information within 30 days for a (15 day event notification) and within 60 days for a (30 day event notification) after NRC's receipt of the initial notification from the State. A request for follow-up information may also be sent routinely via email by the NMED contractor, (e.g., when the NMED record is incomplete after 60 days from receipt of the initial record).

6.2 Quarterly Operational Events Briefing Review of "Significant" Events

A. Events identified as having a "significant" potential risk to public health and safety may receive additional NRC management review at the quarterly NRC Operational Events Briefing. The quarterly briefing, attended by managers and staff from the offices of NMSS, STP, Incident Response Operations (IRO), Nuclear Regulatory Research (RES), and the Regions is convened to review and assess health and safety-related issues, e.g., cause, effects, generic implications, mitigating actions, etc. NRC headquarters and region staff continue to follow-up and review material events discussed at the *operational events briefing* through closure of the event, which includes checking to see that the final report information has been entered into NMED. Based on potential safety risks identified as a result of event review and analyses, NRC may take actions to reduce potential health and safety risks to the public by issuing safety-related notifications to licensees, concerning software problems, equipment modifications, etc. Further research and analysis may result in regulatory or programmatic changes.

B. Agreement State staff may be requested to participate in the briefings by telephone to discuss specific events, the status, results of licensee or State investigation activities and licensee corrective actions, and the potential generic significance of the event. Agreement State participation helps in the exchange of event information and in follow-up actions if generic implications are identified.

7. Abnormal Occurrence Guidelines and Criteria

7.1 Introduction

This section presents the guidelines and criteria to be followed when assessing the significance of an event or occurrence to see if it meets the criteria established to identify an abnormal occurrence (AO). Section 208 of the Energy Reorganization Act of 1974 (ERA) (Public Law 93-438, 42 USC 5848) identifies an abnormal occurrence as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety. Section 208 of the Act also requires that the Commission inform Congress of any abnormal occurrences. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect public health or safety by providing information on proposed AOs that have occurred in their State.

7.2 AO Policy Information

The Commission submits a report to Congress identifying any AOs. The Federal Reports Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis (see "Report to Congress on Abnormal Occurrences, Fiscal Year 1996," NUREG-0090, Vol. 19). Section 208 of the ERA indicates that each report shall contain:

- (1) The date and place of each occurrence;
- (2) The nature and probable consequence of each occurrence;
- (3) The cause or causes of each; and
- (4) Any action taken to prevent recurrence.

As specified in Section 208, within 15 days of receiving information of each AO, the Commission shall provide as wide dissemination to the public as reasonably possible as soon as such information becomes available.

A final AO policy statement containing criteria for determining an AO was published in the *Federal Register* on December 19, 1996, (61 FR 67072). Revised AO criteria were published in the *Federal Register* on April 17, 1997 (62 FR 18820) to incorporate minor changes and to revise criterion III covering Fuel Cycle Licensees.

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. This type of incident or event would have a moderate or severe impact on the public health or safety and could include, but need not be limited to the following:

- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
- (2) Major degradation of essential safety-related equipment; or
- (3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

7.3 AO Criteria

Agreement State staff should routinely screen events against the AO criteria as part of their routine program. Any events identified as potential AOs should be reported to NRC. Additionally, Agreement States are requested to prepare a special written report for potential AOs. Agreement State staff should follow the guidelines for preparing AO write-ups contained in Section 7.4 of this Handbook. When questions arise on a given event, it may sometimes be necessary for NRC to directly contact an Agreement State representative and request additional information.

The criteria for determining an AO and the guidelines for "Other Events of Interest" were stated in an NRC Policy Statement. The following AO criteria was published in the *Federal Register* on December 19, 1996, (61 FR 76072). The policy statement was revised to include criteria for gaseous diffusion plants and published in the *Federal Register* on April 17, 1997, (62 FR 18820).

The guidelines were revised for Appendix C "Other Events of Interest" by the Commission in a Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.

AO Criteria

As published in the Federal Register on December 19, 1996 (61 FR 67072) and as revised and published on April 17, 1997 (62 FR 18820) to incorporate gaseous diffusion plants.

Criteria by types of events used to determine which incidents or events will be considered for reporting as AOs are as follows:

I. For All Licensees.

A. Human Exposure to Radiation from Licensed Material.

1. Any unintended radiation exposure⁴ to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.
2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.
3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement.

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee

⁴ An "unintended radiation exposure" includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in §35.2) involving the wrong individual that exceeds the reporting values established in the regulations.

All other reported medical misadministrations will be considered for reporting as an AO under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.

has demonstrated compliance with 20.1301 using 20.1302(b)(1) or 20.1302(b)(2)(ii).

2. Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material; (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.⁵

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/non-dispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.
2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.
3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

⁵ Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

D. *Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials).*

1. An accidental criticality [10 CFR 70.52(a)].
2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.
3. A serious deficiency in management or procedural controls in major areas.
4. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.

II. *For Commercial Nuclear Power Plant Licensees.*

A. *Malfunction of Facility, Structures, or Equipment.*

1. Exceeding a safety limit of license technical specification (TS) [50.36(c)].
2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.
3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. *Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy.*

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.
2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

III. For Fuel Cycle Facilities.

1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.
2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.
3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

IV. For Medical Licensees.

A medical misadministration that:

- (a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and
- (b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,⁶ or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

V. Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an Appendix to the AO report as Other Events of Interest. Guidelines for events to be included in the AO report for this purpose may include, but not necessarily be limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.⁷

⁶ The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

⁷ Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.

Glossary

- DPC** The Document Processing Center (DPC) is an internal NRC automated document search and retrieval system, indexed by a unique identification (Accession) No. for use by the staff of the NRC.
- EN** The Event Notification (EN) system is an internal NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have or may affect public health and safety. Significant material events are reported to the NRC Operations Center by NRC licensees, staff of the Agreement States, other Federal agencies, and the public. The EN's are published each workday through the Internet.
- Gray** Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
- Metric System** The metric system is now included in all Federal documents. All event reports should include the dual system of Units (SI) in the following order. First, use the International System of Units (SI) with the English System unit equivalent following in parentheses. Spell out the first time it appears; continue with an abbreviation, (see examples below). 1000 centigray (cGy) (1000 rad) the first time, and continue with 1000 cGy (1000 rad). 50 millisieverts (mSv) (5 rem) 730 megabecquerel (MBQ) (20.4 mCi)
- NMED** The Nuclear Materials Events Database (NMED), maintained by NRC, is a historical collection of incidents and events that have occurred throughout the United States involving the use of radioactive material covered under the Atomic Energy Act. This excludes events occurring at nuclear power plants.
- NRC Ops Center** The NRC Operations Center in Rockville, Maryland, serves as the focal coordination point for communicating with NRC licensees, State agencies, and other Federal agencies about operating events in both the nuclear reactor and nuclear material industry. The Operations Center is staffed 24 hours a day by an NRC Headquarters Operations Officer (HOO), who is trained to receive, evaluate, and respond to events reported to the Operations Center.
- PN** Preliminary Notifications (PN) are brief summary reports of significant events issued by the NRC staff to notify the Commission of the occurrence of a significant event that appears to have health and safety significance or major public or media interest. PNs are based on information provided by State radiation control program staff. These reports are publicly available through Internet on NRC's external home page under PN Reports at (<http://www.nrc.gov/opa>).
- RSAO** The Regional State Agreements Officer (RSAO) is a designated staff member, in an NRC regional office, who serves as the point of contact for the region and the Office of State

and Tribal Programs regarding Agreement State radiation control programs, and who participates in technical reviews of Agreement State radiation control programs.

- Rad** Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/grams or 0.01 joule/kilogram (0.01 gray)
- Rem** Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem. is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).
- Sievert** Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem.).

Radiation Measurements

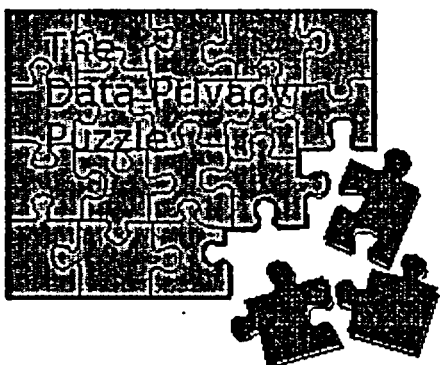
	Radioactivity	Absorbed Dose	Dose Equivalent	Exposure
Common Units	Curie (Ci)	Rad	rem	Roentgen (R)
SI Units	Becquerel (Bq)	Gray (Gy)	Sievert (Sv)	Coulomb/kilogram

Conversion Equivalence

1 Curie = 3.7×10^{10} disintegrations per sec.		1 becquerel = 1 disintegration per sec.
1 millicurie (mCi)	equals	37 Megabecquerels (MBq)
1 rad	equals	0.01 gray
1 rem	equals	0.01 Seivert (Sv)
1 roentgen (R)	equals	0.000258 coulomb/kilogram
1 megabecquerel (MBq)	equals	0.027 millicuries (mCi)
1 gray (Gy)	equals	100 rad
1 sievert (Sv)	equals	100 rem
1 coulomb/kilogram (C/kg)	equals	3876 roentgens (R)

Conversion Factors

To Convert From	To	Multiply By
Curies (Ci)	becquerels (Bq)	3.7×10^{10}
millicuries (mCi)	megabecquerels (MBq)	37
microcuries (μ Ci)	megabecquerels (MBq)	0.037
millirads (mrads)	milligrays (mGy)	0.01
millirems (mrems)	microsieverts (μ Sv)	10
milliroentgens (mR)	microcoulombs/kilogram (μ C/kg)	0.258
becquerels (Bq)	Curies (Ci)	2.7×10^{-11}
megabecquerels (MBq)	millicuries (mCi)	0.027
megabecquerels (MBq)	microcuries (μ Ci)	27
milligrays (mGy)	millirads (mrads)	100
microsieverts (μ Sv)	millirems (mrems)	0.01
microcoulombs/kilogram (μ C/kg)	milliroentgens (mR)	3.88



Data Privacy Standards and Guidelines for Environmental Health Staff

Introduction

The Minnesota Government Data Practices Act, Minnesota Statutes, chapter 13, requires public agencies to:

- safeguard the privacy rights of data subjects about whom state and local governments collect, store, and use data; and
- facilitate access to all government data which should be rightfully disclosed.

All Environmental Health Division (EHD) programs and staff must comply with the Minnesota Government Data Practices Act. Chapter 13 applies to all EHD programs that collect data. In addition, some EHD programs have specific statutory authority or requirements pertaining to data practices. How you use and maintain the data will vary depending on how the data are classified. Your supervisor, who is responsible for the security of data your program collects and maintains, may authorize data access to you, other EHD staff, and the staff of other agencies or private entities. As staff who may be responsible for program data, you must familiarize yourself with how data are classified and when and to whom data can be released. This document will help to guide you in releasing or not releasing data to those who may request access to data you maintain.

Definitions

The following definitions were adapted from those found in Minnesota Statutes and legal dictionaries.

Authorized Representative. Any individual authorized in writing by a data subject to receive government data about the data subject.

Civil Investigative Data. Data collected by state agencies, political subdivisions, or statewide systems as part of an active investigation undertaken for the purpose of the commencement or defense of a pending civil legal action, or which are retained in anticipation of a pending civil legal action.

Civil Legal Action(s). Legal actions undertaken by state agencies, political subdivisions, or statewide systems under the State civil law (torts) as opposed to criminal law, including but not limited to administrative penalty orders, notices of violation, license revocations, and civil lawsuits.

Confidential Data. Data on an individual that are (a) not public and (b) not available to the individual.

Credential. A document granting specific permission from the Commissioner to perform or engage in a certain controlled activity, e.g. a license or a certification.

Data Steward. An entity or individual maintaining data. Usually also involved in processing or collecting data.

Data Subject. Individual or entity about whom data are collected or maintained.

Designees. EHD staff designated to oversee individual files or systems containing data and to help handle data requests.

EHD. The Environmental Health Division, an operating division of MDH.

Government Data (Data). All data, information, or records collected, created, received, maintained, or distributed by public agencies regardless of its physical form, storage media, or conditions of use. Government data is not just the information collected under the authority of a specific statute authorizing a public health study or a credentialing program. It is all data received by the government including complaints and information from citizens.

Inactive Civil Investigative Data. Civil investigative data become inactive upon the occurrence of any of the following events:

- a decision by the state agency, political subdivision, or statewide system or by the chief attorney acting for the state agency, political subdivision, or statewide system not to pursue the civil action;
- expiration of the time to file a complaint under the statute of limitations or agreement applicable to the civil action; or
- exhaustion of or expiration of rights of appeal by either party to the civil action.

Individual. A person. For a minor (person under 18) or an individual judged mentally incompetent, it is a parent or guardian.

Informed Consent. An individual's voluntary authorization to release data. Informed consent must include all of the following:

- the agency or person requested to provide data;
- the nature of the data to be released;
- the party(ies) to whom the data may be released; and
- the purpose(s) for which data may be used.

You might need informed consent to collect data about an individual from a third party, or you might need informed consent to release to a third party data the EHD has about an individual.

MDH. The Minnesota Department of Health.

Nonpublic Data. Data not on individuals that are (a) not public and (b) accessible to the data subject. Also information about information systems and networks that might be used to compromise this data.

Personnel Data. Data about:

- paid government employees
- applicants for government employment
- members of, or applicants for, advisory boards or commissions
- volunteers to government agencies
- private individuals under government contract

Private Data. Data on an individual that are (a) not public and (b) accessible to the individual.

Protected Nonpublic Data. Data not on individuals that are (a) not public (b) not accessible to the data subject.

Public Data. Data accessible to anyone for any reason.

Real Property. "Real property" means one or more defined interests, benefits, and rights inherent in the ownership of real estate. Lands, tenements and hereditaments which, on the death of the owner intestate, passes to his/her heir. It is either corporeal and incorporeal. Land and anything permanently affixed to the land, such as buildings, fences, and those things attached to the buildings, such as light fixtures, plumbing and heating fixtures, or other such items which would be personal property of not attached to the building or land. For example, a built in refrigerator would be real property whereas a dorm size fridge would be personal property.

Responsible Authority. The MDH Commissioner is ultimately responsible for the collection, use, and dissemination of MDH's data on individuals, government data, and summary data. Summary Data. Statistical records and reports compiled from data on individuals but in which individuals are not identified and from which an individual cannot be identified. (Also known as "aggregate data.")

Tennessee Warning. A notice you must give to an individual who is asked to supply private or confidential data about himself or herself.

Persons with Data Practices Related Responsibilities

Responsible Authority. According to Minnesota Rules, part 1205.0200, subpart 13, the Responsible Authority for MDH is the Commissioner. The Responsible Authority is the individual who assures the agency complies with the Data Privacy Act. Responsibilities include the collection, use and dissemination of any set of data on individuals, government data or summary data, and the implementation and administration of the Act. Most, but not all, of the Responsible Authority duties are detailed in Minnesota Statutes, section 13.05. Others are outlined in Minnesota Rules, chapter 1205.

Designees. A designee is a person appointed in writing by the Responsible Authority to be in charge of individual files or systems containing governmental data and to comply with requests

for governmental data. See Minnesota Statutes, section 13.02, subd. 6.

Commissioner of Administration. In 1993, the legislature granted to the Commissioner of the Department of Administration the authority to issue written advisory opinions, upon request of any person, on questions of public access to governmental data, rights of data subjects, and classifications of data. See Minnesota Statutes, section 13.072. Opinions issued by the Commissioner of Administration are not binding on the state agency, but must be given deference by a court in a proceeding involving the data. The Commissioner of the Department of Administration also grants or denies requests for a temporary classification.

The Attorney General. A formal written opinion by the Attorney General takes precedence over an advisory opinion of the Commissioner of the Department of Administration. Agency staff may seek informal advice from attorneys in the Office of the Attorney General on data practices issues but this advice is not entitled to any precedential value in a legal dispute.

The Courts. The Act creates a procedure for when data that is not public can be released by Court order. See Minnesota Statutes, section 13.03, subd. 6. The Act affords remedies to individuals who maintain that a governmental agency is violating or not properly administering the provisions of the Act. Agencies who violate the Act and cause damage to an individual can be sued. The individual may recover actual damages, costs and attorney fees. In cases of willful violations, the individual may recover up to \$10,000 in exemplary damages. See Minnesota Statutes, section 13.09. Any person who willfully violates the provisions of Chapter 13, or any rule adopted under this chapter, is guilty of a misdemeanor. Willful violation of this chapter by any public employee constitutes just cause for suspension without pay or dismissal. See Minnesota Statutes, section 13.09.

EHD General Data Practices Requirements

- All data collected, created, received, maintained, or disseminated by EHD are public unless otherwise classified by statute.
- Before collecting private and confidential data on individuals, you must inform them of their rights using a Tennessee warning.
- You must only release private, confidential, nonpublic, and protected nonpublic data under the conditions described in this document. If you receive any of these types of data unsolicited or unnecessarily, you must destroy it or return it to the person or entity who submitted it.
- If you violate the provisions of the Minnesota Government Data Practices Act you may be subject to disciplinary action and/or civil penalties.
- You must complete basic data practices training. Training will be provided by your supervisor. Your training will include specific information about the data maintained by your program. Staff from the Department of Administration and the Office of the Attorney General may also provide training opportunities.
- You must refer non-routine data practices questions to your supervisor, manager, assistant division director or the policy, planning and analysis unit. Don't guess get a second or third opinion if you are in doubt of the status of the data in question.
- Your section or program must maintain a list of the data you collect or maintain that is not available to the public. The list must include statutory references defining it as not available to the public. The document must also contain copies of the forms you use to collect this data.

Collecting and Storing Data on Individuals

You must limit the collection and storage of data on individuals and the use of these data to that necessary for the administration of EHD programs or as mandated by law. If you collect private or confidential data from an individual, the data can only be used for the purposes stated to the individual at the time of collection. If you receive confidential, private, nonpublic and/or protected nonpublic data unsolicited, contact the party who sent the data as soon as possible, describe the situation and agree whether to return the data or to shred it.

Data Protection and Security

To comply with the Minnesota Government Data Practices Act and adequately protect EHD's data assets, you must:

- Put private and confidential data away when you leave your desk and close client files when being visited.
 - Use screen savers that are protected by secure passwords.
 - Back up, and keep secure, data files containing private or confidential data.
 - Keep the data behind two locks, such as the locked entrance door and a locked file cabinet or password.
 - Use applicable data classifications and statutes to determine if and how data can be released.
 - Seek advice from your supervisor, manager, assistant division director or the policy, planning and analysis unit when in doubt about data classification or security.
 - Dispose of records containing private and confidential data according to the records retention schedule. Establish a schedule if one does not exist.
 - Make copies of private data only when necessary and shred copies when they are no longer needed. Please check with your administrative support staff regarding shredding procedures.
-

Rights of Data Subjects: Tennesen Warning

You must issue a Tennesen warning to individuals before asking them to provide private or confidential data about themselves. This includes recording a complaint. To avoid repeating the warning each time additional information is requested, the initial Tennesen warning must include a reference to future data requests.

The content of the Tennesen warning must include the following points:

- the purpose and intended use of the requested data;
- whether individuals may refuse or are legally required to supply the requested data;
- the consequences of supplying or refusing to supply the requested data; and
- the identity of other persons or agencies authorized by law to receive the data.

If possible, the Tennessee warning should be written at the seventh grade reading level. You may give the Tennessee warning either verbally or in writing. If you give the warning verbally, what is said should be documented, signed, dated, and filed. If possible it is best to give the warning in writing, have the individual sign it, make a copy for the individual to keep, and file the original. If it is not possible to provide a written warning, please read from a written text to ensure that all essential items are covered.

Additional Information. A sample Tennessee warning from the Indoor Air Unit.

Releasing Public Data

Public data can be released to anyone. When requested, you must provide documents that are produced for public distribution. Programs may limit the number of free copies provided. If the requester wants public data not produced for public distribution or large quantities of documents produced for public distribution, employees must explain costs and inform the requester that payment will be required.

Releasing Private and Nonpublic Data

Individuals or entities about whom EHD has data may request access to those data. As a general rule, unless the data has been classified as confidential or protected nonpublic, the data is available to the data subject or an authorized representative upon request as described below.

Written, Faxed, or E-mail Requests. You may release private or nonpublic data to the data subject if a written, faxed or e-mailed request includes:

- the requester's name and address
- a form of identification or similar identifier that only the data subject should know
- an informed consent from the data subject if the writer is an authorized representative
- a description of the data requested

You must not send private or nonpublic data via e-mail. E-mail is not a secure means of transmitting data.

You must ensure the return fax number is that of the data subject or authorized representative. If you cannot verify this, you must mail the data to the data subject or ask the requester to appear in person.

Telephone Requests. If you receive requests for private or nonpublic data via telephone, you must not provide the data over the phone unless you are certain the person is the data subject or an authorized representative. Data must never be left on an answering machine or voice mail system. If you are uncertain, mail the data to the data subject or ask the requester to appear in person.

Drop-In Requests. Upon request, an individual who is the subject of stored private or public data on individuals must be shown this data without any charge. If they desire, we also must inform them of the content and meaning of that data. We are required to comply immediately, if possible with these types of requests. If we are unable to make the data available to them

Immediately for example, the data may be stored off-site and need to be retrieved we have ten working days from the date of the request to make it available. See Minnesota Statutes, section 13.04.

Drop-in requests by others are not generally allowed. An appointment must be made to examine the data. To protect the privacy rights of data subjects, you must allow yourself time to examine the data to ensure it does not contain information the requester is not authorized to see. The data may also not be stored on-site and need to be retrieved.

To verify the Identity of a requester, ask to see a picture identification (driver's license, state ID, etc.) before releasing private or non-public data to an unknown requester. If that is not available, ask questions of the requester to ensure identity. An authorized representative must have a signed statement from the data subject authorizing access. You or another EHD staff member must be present while requesters examine any data to prevent loss or tampering. You cannot charge any type of access or inspection fee.

Written informed consent is required for release of private or nonpublic data to persons other than the subject of the data, unless there is statutory authority allowing for the data to be treated differently. The written consent must include the items found in Minnesota Statutes, section 13.05, subd. 4(d).

Sharing Data with Other Government Agencies. Without specific statutory authority or a court order, we cannot share confidential, private, nonpublic or protected nonpublic data with other state, federal or local agencies. Specific program statutes may give you direction on what, if any, other entities with whom you may share data. For example, the lead statute specifically states what agencies MDH can share elevated blood lead data with. Otherwise, contact your supervisor or manager to discuss.

Court Orders and Search Warrants

Private or nonpublic data may be released pursuant to a court order or search warrant. Court orders and search warrants are signed by a judge of either a state or federal court and specify the data to be released. If presented with a court order or search warrant, contact your supervisor immediately. Your supervisor will then contact your manager, the assistant division director and the division director to discuss the release of the data. There may be a basis on which EHD opposes its release. If that is the case, your assistant attorney general should be informed to provide counsel.

Subpoenas

A subpoena in and of itself is not a court order allowing for the release of private or nonpublic data. If you are served with a subpoena requesting the release of private or nonpublic data, the data should not be released and your supervisor, manager or assistant division director should assist you to inform the court about the statutory provision restricting the disclosure of the data.

Releasing Confidential or Protected Nonpublic Data

Data that are classified as confidential or protected nonpublic are not to be released unless the requester has authority under the law or a court order. Contact your supervisor immediately if you receive a request for either of these types of data.

Releasing Personnel Data

Employees. The following data about public employees (including contract employees or staff of contractors) are public and must be released to anyone if requested:

- name
- salary, expense reimbursement, pension
- job title, job description, education and training, previous work experience
- value and nature of employer-paid fringe benefits
- date of first and last employment
- the existence and status of any complaints or charges against the employee
- the final disposition of any disciplinary action
- work location, work telephone number
- honors and awards received
- payroll time sheets
- city and county of residence

The following data about public employees are private and must not be released without written and signed consent of the employee:

- home address, home telephone number
- name and number of dependents
- marital status
- performance reviews, other evaluations of job performance
- bank account numbers
- Social Security numbers (employee, dependents)
- birth date
- information about disciplinary action that has not reached a final disposition
- informal notes in personnel file
- reasons for use of sick or other medical leave
- medical information

Applicants for Employment. The following data about applicants for public employment are public and must be released if requested:

- veteran status
- relevant test scores
- rank on eligible list
- job history
- education and training
- work availability

The names of applicants are private data if they have not been certified eligible for appointment

to a vacancy, or are not considered to be finalists for a position in public employment. (A finalist is an applicant who has been selected for an interview.) The names of applicants who have been certified eligible or are finalists are public.

Applicants for Credentials

All applications for credentials must contain a Tennessean warning. While an application for a credential is pending, all of the information submitted on the application, except the name and address, are not be released outside of EHD, unless authorized or required by law. Talk to your supervisor for specific authorizations or requirements to provide pending credentialing data with outside parties.

Note that applicants do not have to provide their home address and telephone number, but can give a business address and telephone number. See Minnesota Statutes section 13.41, subd 2(b).

If the credentialing process becomes contested, all of the information submitted by the applicant may become public, e.g. during the hearing process. After a credential is issued by EHD, all information from the application becomes public information, except for any social security numbers. Social security numbers are always private data.

Examination Data

Testing, examination materials, and scoring keys used solely to determine individual qualifications for credentialing are classified as nonpublic, except pursuant to court order. Completed versions of credentialing examinations are accessible to the individual who completed the examination, unless we determine that access would compromise the objectivity, fairness, or integrity of the examination process. We are not required to provide copies of completed examinations or answer keys to any individual who has completed an examination.

Credit Card Information

Some EHD programs allow payment of certain costs and fees with credit cards. Pursuant to Minnesota Statutes, section 16A.626, item (f), all credit card, charge card, debit card, or other method of electronic funds transfer account numbers are nonpublic data not on individuals as defined in section 13.02, subdivision 9, or private data on individuals as defined in section 13.02, subdivision 12.

Debtor Information

If entities owe money to the state and are referred to the Attorney General and/or the Department of Finance for debt collection, Minnesota Statutes, section 16D.06 outlines the following requirements.

- Upon request from the finance commissioner or the attorney general, state agencies, political subdivisions, and statewide systems shall disseminate not public data to the finance commissioner or the attorney general for the sole purpose of collecting debt. Not public data disseminated under this provision is limited to financial data of the debtor or data related to the location of the debtor or the assets of the debtor.
 - Data received, collected, created, or maintained by the finance commissioner or the attorney general to collect debts are classified as private data on individuals under section 13.02, subdivision 12, or nonpublic data under section 13.02, subdivision 9. The commissioner or the attorney general may in certain cases disclose not public data. See section 13.02 for more information.
 - The finance commissioner and the attorney general may not disclose data that is not public to a private collection agency or other entity with whom the commissioner has contracted under section 16D.04, subdivision 4, unless disclosure is otherwise authorized by law.
-

Advisory Boards and Commissions

Names and home addresses of applicants for appointment to and members of advisory boards or commissions are public.

Inspection Data

After a routine inspection is performed, the inspection report is public and always remains public, unless a judge orders otherwise. If based on the inspection, you determine that an investigation and/or disciplinary action is not required or not required at this time, the closed inspection file is entirely public.

A routine inspection is not the same as an investigation. If you determine that an investigation and/or disciplinary action is necessary, the requirements discussed below apply.

Complaints and Investigations

This section applies to all EHD data collected related to a complaint regardless of whether we have specific statutory authority to collect such data. Note that before recording any complaint, you must provide a Tennessee warning to the complainant.

Data practices requirements vary based the type of entity being investigated.

Investigations of Credentialed Individuals. If you receive a complaint against an individual or an individual doing business under an assumed name and that individual is credentialed, then the entire complaint file is confidential while the complaint is under investigation. The complainant has access to any statement that he or she provided to you.

If no disciplinary action is required the file becomes inactive investigative data and is entirely

private. Specifically, the nature or content of unsubstantiated complaints when the information is not maintained in anticipation of legal action; the nature or content of unsubstantiated complaints when the information is not maintained in anticipation of legal action is private. If disciplinary action is taken, once the investigation becomes inactive, the inactive investigative data are private, except that the following data are public:

- the final disciplinary action;
- any agreement that was reached to resolve the matter without a hearing, along with the specific reasons for the agreement; and
- if there has been a public hearing regarding the disciplinary action, then the entire record concerning the proceeding is public unless the administrative law judge has ordered any part of the record closed.

Investigations of Credentialed Companies and Noncredentialed Entities. If you receive a complaint against a corporation or partnership that is credentialed or any type of entity that is not credentialed, as long as the investigative data are active, the entire file is protected nonpublic or confidential data. Except the complainant may access any statement that he or she made to you.

Regardless of whether any discipline ensues, when the investigative data becomes inactive the file becomes public unless classified differently elsewhere in statute, or release would jeopardize other pending civil actions or the data have been presented as evidence in court. The one exception is that the identity of the complainant may be confidential under Minnesota Statutes, section 13.44.

Specifically, if an individual complains about violations or alleged violations of law concerning the use of real property, their identity is classified as confidential. A large number of the complaints you receive most likely concern the use of real property. The definition of real property is very broad. Please consult your supervisor, manager or PPA staff if you have questions.

Procurement by State Agencies

There are two important items related to data privacy and the procurement process.

- Sealed bids received, along with the number of bids, received during a procurement process are nonpublic data prior to the opening of the bids.
- Most state professional/technical contracts do not contain accounting information as part of the actual contract document. In order to insure that agency personnel are able to correctly encumber the contract, a worksheet has been created. The worksheet is considered to be a stand alone document and not a part of the contract. Some of the information, such as the Employer Identification Number (EIN), contained on the worksheet is considered to be private data. The encumbrance worksheet must be kept separate from the contract document. This will reduce the chance of inadvertent release.

Other data privacy requirements may apply to specialized procurement processes and documents. MDH Finance and Administration Division (F&A) staff are knowledgeable about these requirements. Please work closely with the appropriate F&A staff to insure compliance.

Calendars

The data in appointment calendars, either paper or electronic are classified as private personnel data, pursuant to Minnesota Statutes, section 13.43. However, if you record, in your calendar, information from telephone calls and meetings relevant to some work issue or concern, that information would not be classified as private personnel data. If the data meets the definition of public data, anyone has the right to see the data. If the data are not public, you must safeguard as required.

Attorney/Client Privileged Information

Certain communications between the division and its attorneys are subject to the attorney/client privilege and are not public data subject to disclosure under the Minnesota Government Data Practices Act. Data that may be covered by the attorney/client privilege, such as letters, memos, electronic messages, reports and other documents that may contain either a request for legal advice or legal advice, will not be maintained in public files. If there is a question about the release of attorney/client data, the division staff person will contact the attorney who is handling the matter for the division. Once data has been released, it cannot be claimed as attorney/client privileged information. Only the MDH Commissioner has authority to waive the attorney/client privilege.

Information Systems and Networks

Any information about information systems and networks, including but not limited to access codes, specifications, programming notes and procedures that might be used to compromise protected data is nonpublic data and must be treated as such. The Information Resources Management (IRM) Unit is responsible for safeguarding this data or providing appropriate training to staff who work with this data. Please see your supervisor or manager if you feel you need this training.

Denying Access to Data

If the requested data are classified in such a way that the requester must be denied access, you must inform the requester in writing that the data cannot be released and the statutory provision that prohibits the release of the data. You may do this either at the time of the request or in writing as soon after as possible. Your supervisor or section manager can assist you in preparing this response. A requester who disagrees with the determination may appeal the decision by writing to the Commissioner, Department of Administration, 50 Sherburne Avenue, St Paul, MN 55155

Correcting Data

When a data subject believes his or her file contains inaccurate or incomplete data, the data subject must notify you in writing of the dispute within 30 days. After consulting with your supervisor, you will either correct the data found to be inaccurate and attempt to notify past recipients of incorrect data, or notify the data subject that EHD believes the data to be correct. The data subject may appeal the decision by writing to the Commissioner, Department of Administration, 50 Sherburne Avenue, St Paul, MN 55155

Fees for Providing Data

Fees cannot be charged to inspect data, however, fees must be charged for retrieving and providing data. Fees are not intended to earn income for EHD but to offset our incurred costs. MDH has made a decision, however, to waive charges if the cost to provide the data is less than the cost to process the payment.

The following actual costs can be included in the fee:

- employee time or other costs searching for and retrieving the data, whether the data is kept in hard copy or electronically
- employee time or other costs for enhancing the data at the request of the person seeking access
- employee time for electronically transmitting the data
- employee time for making and putting copies together along with photocopying charges (July 2000: \$0.035 per image)
- postage

Costs cannot be charged for separating public data from private, confidential, nonpublic, or protected nonpublic data. Refer to MDH Policy #203.01 for billing information. (July 2000: The finance and administration division contact is John Masiulis.)

Conclusion

Five Important Items to Remember:

- Data are public UNLESS the law explicitly states otherwise.
- Data practices laws are frequently changed. Be aware of the current requirements.
- Maintain written records of all requests for data.
- If you have questions or doubts, ASK your supervisor, manager, or policy, planning and analysis unit staff.
- When dealing with people from outside MDH on data practices matters, always clearly explain the reasons why the data are being collected or released or why the request for release is being denied.

4.7.2 Event Reporting Procedures

4.7.2

EVENT REPORTING PROCEDURES

Minnesota's procedures for generating event reports are located in section 3 of the *Response Manual for Incidents Involving Radioactive Material*. Also included in this manual are procedures for entering reports into the NMED database. These procedures assign responsibility for the completion of the reports and for assuring the quality of the reports. They specify times for completion and submission of the reports, provide guidance for identifying reportable events. These procedures are consistent with the STP Procedure SA-300 Handbook, Nuclear Medical Event Reporting in the Agreement State. At present time, the supervisor will be processing all the data entry for this procedure, as no others have been trained yet.

The MDH staff that documents the incident must prepare a chronological report. This report and any supporting documentation will be filed in the incident file.

In addition to the report and documentation being filed in the incident file, and for uniformity in reporting, incidents should be entered into NMED. Entry into this system will also provide information to other regulatory entities. The licensee or persons involved in the incident should be informed that the information will be made available to parties outside MDH. However, they should be assured that individuals will not be mentioned by name.

MDH staff should ensure that the information is included in NMED as soon as practicable. In addition the database should promptly be updated to indicate any status changes. Obviously, response operations have priority over the data entry. However, it is imperative that NMED information be kept as current.

Other procedures for incidents can be found in the *MDH Response Manual for Incidents Involving Radioactive Material*.