

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About
Possession Licenses for Manufacturing
and Distribution

Draft Report for Comment

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Draft Report for Comment

Manuscript Completed: June 2016
Date Published: June 2016

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Any interested party may submit comments on this report for consideration by the U.S. Nuclear Regulatory Commission (NRC) staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG-1556, Volume 12, Revision 1, in your comments, and send them by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

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Federal Rulemaking Website: Go to <http://www.regulations.gov> and search for documents filed under Docket ID NRC-2016-0053. Address questions about NRC dockets to Carol Gallagher at 301-415-3463 or by e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For any questions about the material in this report, please contact: Eric H. Reber, Project Manager, at 301-415-5608 or by e-mail at Eric.Reber@nrc.gov.

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1 **ABSTRACT**

2 This technical report contains information intended to provide program-specific guidance and to
3 assist applicants and licensees in preparing applications for manufacturing and distribution
4 licenses. In particular, it describes the types of information needed to complete U.S. Nuclear
5 Regulatory Commission (NRC) Form 313, "Application for Materials License." This document
6 describes both the methods acceptable to the NRC license reviewers in implementing the
7 regulations and the techniques used by the reviewers in evaluating the application to determine
8 if the proposed activities are acceptable for licensing purposes.

9 **Paperwork Reduction Act Statement**

10 This NUREG contains and references information collection requirements that are subject to the
11 Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were
12 approved by the Office of Management and Budget (OMB), approval numbers 3150-0001,
13 3150-0008, 3150-0009, 3150-0010, 3150-0014, 3150-0016, 3150-0017, 3150-0020, 3150-0035,
14 3150-0044, 3150-0120, 3150-0158, and 3150-0214.

15 **Public Protection Notification**

16 The NRC may not conduct or sponsor, and a person is not required to respond to, a request for
17 information or an information collection requirement unless the requesting document displays a
18 currently valid OMB control number.

FOREWORD

The U.S. Nuclear Regulatory Commission (NRC) NUREG–1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees About NRC Form 241 “Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters” and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator

The current document, NUREG–1556, Volume 12, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution,” is intended for use by applicants, licensees, and NRC Staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 12, issued December 2000. See Appendix A of this NUREG for a list of the documents considered in the development of this NUREG report.

14 This report takes a risk-informed, performance-based approach to licensing the possession and
15 use of radioactive material for manufacturing and distribution. A team composed of staff from
16 NRC Headquarters, NRC regional offices, and Agreement States prepared this document,
17 drawing on their collective experience in radiation safety in general and as specifically applied to
18 licenses authorizing possession for manufacturing and distribution.

19 NUREG–1556, Volume 12, Revision 1, is not a substitute for NRC or Agreement State
20 regulations. The approaches and methods described in this report are provided for information
21 only. Methods and solutions different from those described in this report may be acceptable if
22 the different methods include a basis for the staff to make the determinations needed to issue or
23 renew a license.

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37
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39
40
41
42

TABLE OF CONTENTS

ABSTRACT	iii
FOREWARD	v
FIGURES	ix
TABLES	ix
ACKNOWLEDGMENTS	xi
ABBREVIATIONS	xiii
1 PURPOSE OF REPORT	1-1
2 AGREEMENT STATES	2-1
2.1 Jurisdiction Determination	2-1
2.2 Reciprocal Recognition of Specific Licenses	2-3
3 MANAGEMENT RESPONSIBILITY	3-1
3.1 Commitments and Responsibilities	3-1
3.2 Safety Culture	3-2
4 APPLICABLE REGULATIONS	4-1
5 HOW TO FILE	5-1
5.1 Application Preparation	5-1
5.2 Where to File	5-1
5.3 Paper Applications	5-2
5.4 Electronic Applications	5-2
6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION	6-1
7 APPLICATION AND LICENSE FEES	7-1
8 CONTENTS OF AN APPLICATION	8-1
8.1 Item 1: License Action Type	8-1
8.2 Item 2: Name and Mailing Address of Applicant	8-2
8.2.1 Notification of Bankruptcy Proceedings	8-2
8.3 Item 3: Address(es) Where Licensed Material Will Be Used or Possessed	8-2
8.4 Item 4: Person To Be Contacted About This Application	8-4
8.5 Item 5: Radioactive Material	8-4
8.5.1 Sealed Sources and Devices or Unsealed Radioactive Material	8-4
8.5.2 Financial Assurance and Recordkeeping for Decommissioning	8-7
8.6 Item 6: Purpose(s) for Which Licensed Material Will Be Used	8-10
8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience	8-14
8.7.1 Radiation Safety Officer	8-16
8.7.2 Authorized Users	8-19
8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas	8-21
8.9 Item 9: Facilities and Equipment	8-22
8.10 Item 10: Radiation Safety Program	8-25
8.10.1 Audit and Review of Program	8-25
8.10.2 Radiation Monitoring Instruments	8-27

1	8.10.3	Material Receipt and Accountability	8-29
2	8.10.4	Occupational Dose	8-35
3	8.10.5	Public Dose	8-39
4	8.10.6	Safe Use of Radionuclides and Emergency Procedures	8-41
5	8.10.7	Surveys and Leak Tests	8-46
6	8.10.8	Maintenance	8-50
7	8.10.9	Transportation	8-50
8	8.10.10	Security Program for Category 1 and Category 2 Radioactive	
9		Material.....	8-52
10	8.11	Item 11: Waste Management	8-54
11	8.12	Item 12: License Fees.....	8-61
12	8.13	Item 13: Certification	8-61
13	9	LICENSE AMENDMENTS AND RENEWALS	9-1
14	9.1	Timely Notification of Transfer of Control	9-1
15	10	APPLICATIONS FOR EXEMPTIONS.....	10-1
16	11	TERMINATION OF ACTIVITIES.....	11-1
17	APPENDICES		
18	APPENDIX A	LIST OF DOCUMENTS CONSIDERED IN DEVELOPMENT OF	
19		THIS NUREG.....	A-1
20	APPENDIX B	U.S. NUCLEAR REGULATORY COMMISSION FORM 313	B-1
21	APPENDIX C	SUGGESTED FORMAT FOR PROVIDING INFORMATION	
22		REQUESTED IN ITEMS 5 THROUGH 11 OF U.S. NUCLEAR	
23		REGULATORY COMMISSION FORM 313	C-1
24	APPENDIX D	LICENSE TYPES-GUIDANCE.....	D-1
25	APPENDIX E	RADIATION SAFETY OFFICER DUTIES AND RESPONSIBILITIES	E-1
26	APPENDIX F	RADIATION SAFETY TRAINING.....	F-1
27	APPENDIX G	FACILITIES AND EQUIPMENT.....	G-1
28	APPENDIX H	SAMPLE AUDIT PROGRAM.....	H-1
29	APPENDIX I	RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND	
30		MODEL RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM	I-1
31	APPENDIX J	MATERIAL RECEIPT AND ACCOUNTABILITY.....	J-1
32	APPENDIX K	GUIDANCE FOR DEMONSTRATING THAT INDIVIDUAL MEMBERS	
33		OF THE PUBLIC WILL NOT RECEIVE DOSES EXCEEDING THE	
34		ALLOWABLE LIMITS	K-1
35	APPENDIX L	GENERAL TOPICS FOR SAFE POSSESSION AND USE OF	
36		RADIOACTIVE MATERIALS AND MODEL EMERGENCY	
37		PROCEDURES	L-1
38	APPENDIX M	TYPICAL U.S. NUCLEAR REGULATORY COMMISSION (NRC)	
39		NOTIFICATION AND REPORTING REQUIREMENTS FOR INCIDENTS	M-1
40	APPENDIX N	RADIATION SAFETY SURVEY TOPICS	N-1
41	APPENDIX O	MODEL LEAK TEST PROGRAM.....	O-1
42	APPENDIX P	U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS.....	P-1
43	APPENDIX Q	MODEL WASTE MANAGEMENT PROCEDURES	Q-1
44	APPENDIX R	SAFETY CULTURE POLICY STATEMENT	R-1
45	APPENDIX S	MEDICAL DISTRIBUTION	S-1
46	APPENDIX T	CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY	
47		INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)	T-1

1

FIGURES

2	Figure	Page
3		
4	2-1 U.S. Map: Locations of NRC Offices and Agreement States.....	2-1
5	8-1 Location of Possession or Possession and Use.....	8-3
6	8-2 Financial Assurance for Decommissioning	8-8
7	8-3 Records Important to Decommissioning	8-9
8	8-4 Example of a Product Produced Under Possession for Manufacturing and	
9	Distribution Authorization.....	8-14
10	8-5 Typical Duties and Responsibilities of RSOs	8-17
11	8-6 Diagram Showing Information Related to Radiation Safety	8-25
12	8-7 Material Receipt and Accountability	8-32
13	8-8 Annual Dose Limits for Adult Radiation Workers.....	8-37
14	8-9 Calculating Public Dose.....	8-41
15	8-10 Use of Appropriate Shielding	8-43
16	8-11 Types of Surveys.....	8-46
17	8-12 Personnel Surveys	8-47
18	8-13 Air and Water Effluents from a Manufacturing Facility.....	8-57
19	L-1 Storage of Food and Drink.....	L-1
20	N-1 Laboratory Layout.....	N-9

21

22

23

TABLES

24	Table	Page
25		
26	2-1 Who Regulates the Activity?	2-2
27	3-1 Traits of a Positive Safety Culture.....	3-3
28	8-1 Sample Format for Providing Information About Requested Radionuclides	8-11
29	8-2 Package Monitoring Requirements.....	8-30
30	8-3 Record Maintenance.	8-34
31	8-4 Guidance on Personnel Monitoring and Bioassay	8-38
32	A-1 List of Documents Considered in the Preparation of this Report.....	A-1
33	C-1 License Reviewer Checklist.....	C-1
34	K-1 Standard Occupancy Factors	K-3
35	M-1 Typical NRC Notification and Reporting Requirements for Incidents	M-1
36	N-1 Suggested Contamination Survey Frequency	N-2
37	N-2 Survey Frequency Category	N-3
38	N-3 Survey Frequency Category Modifiers	N-3
39	N-4 Isotope Groups.....	N-4
40	N-5 Acceptable Surface Contamination Levels for Equipment.....	N-5
41	N-6 Screening Values for Building Surface Contamination.....	N-7

42

43

ACKNOWLEDGMENTS

The working group thanks the individuals listed below for assisting in the review and update of the report. All participants provided valuable insights, observations, and recommendations.

The working group would like to thank the staff in the regional offices of the U.S. Nuclear Regulatory Commission and all of the States who provided comments and technical information that assisted in the development of this report. The working group thanks Tomas Herrera for the pivotal role that he played in the development of this report.

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1

ABBREVIATIONS

2	ADAMS	Agencywide Document Access and Management System
3	AEA	Atomic Energy Act of 1954, as amended
4	ALARA	as low as is reasonably achievable
5	ALI	annual limit on intake
6	ANSI	American National Standards Institute
7	AU	authorized user
8	bkg	background
9	Bq	becquerel = 1 disintegration (transformation) per second
10	Ci	curie = 3.7×10^{10} disintegrations per second
11	CFR	<i>Code of Federal Regulations</i>
12	cpm	counts per minute
13	DAC	derived air concentration
14	DFP	decommissioning funding plan
15	DIS	decay-in-storage
16	DOE	U.S. Department of Energy
17	DOT	U.S. Department of Transportation
18	dpm	disintegrations per minute
19	EA	environmental assessment
20	EDE	effective dose equivalent
21	EPA	U.S. Environmental Protection Agency
22	FA	financial assurance
23	FDA	U.S. Food and Drug Administration
24	FR	<i>Federal Register</i>
25	GBq	gigabecquerel
26	IAEA	International Atomic Energy Agency
27	IN	information notice
28	L/C	license condition
29	LLW	low-level radioactive waste
30	LSA	low specific activity
31	mBq	millibecquerel
32	mCi	millicurie
33	mR	milliroentgen
34	mrem	millirem
35	mSv	millisievert
36	NaI(Tl)	sodium iodide crystal doped with thallium
37	NCRP	National Council on Radiation Protection and Measurements
38	ND	not detectable
39	NIST	National Institute of Standards and Technology
40	NMSS	Office of Nuclear Materials Safety and Safeguards
41	NR	not required
42	NRC	U.S. Nuclear Regulatory Commission
43	NVLAP	National Voluntary Laboratory Accreditation Program
44	NSTS	National Source Tracking System
45	OMB	Office of Management and Budget
46	OSL	optically stimulated luminescence
47	PII	personally identifiable information
48	QA	quality assurance
49	R	roentgen

1	rad	special unit of absorbed dose; one rad is equal to 100 ergs/gram or
2		0.01 joule/kilogram (0.01 gray)
3	rem	special unit of any of the quantities expressed as dose equivalent; the
4		equivalent in rems is equal to the absorbed dose in rads multiplied by the
5		quality factor (1 rem=0.01 sievert)
6	RG	regulatory guide
7	RIS	regulatory issue summary
8	RQ	reportable quantities
9	RSO	Radiation Safety Officer
10	SI	International System of Units (abbreviated SI from the French "Systeme
11		Internationale d'Unites")
12	SNM	special nuclear material
13	SSD	Sealed Source and Device [registration certificate]
14	std	standard
15	Sv	sievert
16	$T_{1/2}$	half-life
17	TAR	technical assistance request
18	TEDE	total effective dose equivalent
19	TI	transportation index
20	TLD	thermoluminescent dosimeters
21	U.S.C.	United States Code
22		

1 PURPOSE OF REPORT

2 This report provides guidance on an applicant applying for several types of licenses associated
3 with the manufacturing and distribution of radioactive materials and products containing
4 radioactive materials and also provides the U.S. Nuclear Regulatory Commission (NRC) staff
5 with the criteria for evaluating such applications. This document uses the terms “byproduct
6 material,” “licensed material,” and “radioactive material” interchangeably.

7 The report addresses the variety of radiation safety issues associated with manufacturing and
8 distribution. The body of this document provides guidance to an applicant in preparing a license
9 application for possession and use for manufacturing and distribution, and possession incident
10 to distribution only. Appendix S of this NUREG provides guidance for the distribution and
11 transfer of radioactive drugs, sealed sources, and devices directly to medical use licensees by
12 non-radiopharmacy entities. Note that this guidance does not apply to those quantities of
13 special nuclear material exceeding those listed in Title 10 of the *Code of Federal Regulations*
14 (10 CFR) 70.22(h)(2)(i)(1).

15 For the purpose of this NUREG, manufacturers and distributors are those licensees that
16 process raw material and/or sources and distribute those processed materials or manufactured
17 products to users as finished products. Examples include major radiopharmaceutical
18 processor/manufacturers (not radiopharmacies), sealed source fabricators, device
19 manufacturers, and other manufacturing licensees that possess and use irradiated bulk
20 quantities of raw materials or sources.

21 Distribution-only licensees are not involved in the processing of raw materials or sources or in
22 the manufacturing of devices. Normally, imported products require a distribution and
23 possession license to enable imported products to be distributed within the U.S. states
24 and territories.

25 Quality control for finished products are described in the regulations of 10 CFR Part 32. The
26 distribution of materials to persons exempt from licensing and distribution of materials to
27 generally licensed persons and additional quality control guidance for these products are
28 described in NUREG–1556, Vol. 8, “Consolidated Guidance About Materials Licensees:
29 Program-Specific Guidance About Exempt Distribution Licenses” and NUREG–1556, Vol. 16,
30 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses
31 Authorizing Distribution to General Licensees.”

32 Chapter 8, “Contents of an Application,” of this report identifies the information needed to
33 complete NRC Form 313, “Application for Material License” (see Appendix B of this NUREG) for
34 the possession and use of byproduct, source, and/or special nuclear materials for
35 manufacturing and distribution, and for distribution (only) for medical use (not radiopharmacies).
36 If a license of broad scope is being sought [under 10 CFR 33, “Specific Domestic Licenses of
37 Broad Scope for Byproduct Material”), also refer to NUREG–1556, Vol. 11, “Consolidated
38 Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad
39 Scope.” The Office of Management and Budget has approved the information collection
40 requirements in Title 10 CFR Part 30, Part 32, Part 40, Part 70, and NRC Form 313 under the
41 Clearance Nos. 3150-0017, 3150-0001, 3150-0020, 3150-0009, and 3150-0120, respectively.

1 The format within this document for each item of technical information is as follows:

- 2 • Regulations—references the regulations applicable to the item.
- 3 • Criteria—outlines the criteria used to evaluate the applicant’s response.
- 4 • Discussion—provides additional information about the topic.
- 5 • Response from Applicant—provides suggested response or responses, offers the option
6 of an alternative reply, or indicates that no response is needed on that topic during the
7 licensing process.

8 Notes and references are self-explanatory and may not be found for each item on
9 NRC Form 313.

10 NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5
11 through 11, as indicated on the form. Applicants should address those items on separate
12 sheets of paper and submit them along with the completed NRC Form 313. For the
13 convenience and streamlined handling of applications, Appendix C of this NUREG, “Suggested
14 Format for Providing Information Requested in Items 5 through 11 of the NRC Form 313,” may
15 be used to provide supporting information.

16 Appendices D through T of this NUREG contain additional information on various radiation
17 safety topics. Appendix D of this NUREG provides information on the types of licenses.
18 Appendix S of this NUREG provides guidance in applying for distribution (only) to medical
19 use licensees.

20 In this document, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective
21 dose equivalent, committed dose equivalent, committed effective dose equivalent, or total
22 effective dose equivalent, as defined in 10 CFR Part 20, “Standards for Protection Against
23 Radiation.” To describe units of radiation exposure or dose, rem and its International System of
24 Units equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used. This is done because 10 CFR
25 Part 20 sets dose limits in terms of rem (Sv), rather than rad or roentgen. When the radioactive
26 material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed
27 to equal 1 rem. For alpha and neutron emitting radioactive material, 1 rad is not equal to 1 rem.
28 Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and
29 neutrons requires the use of an appropriate quality factor (Q) value. These Q values are
30 used to convert absorbed dose (rad) to dose equivalent (rem). Tables 1004(b).1 and .2 in
31 10 CFR 20.1004, “Units of radiation dose,” address the Q values for alpha particles
32 and neutrons.

2 AGREEMENT STATES

2.1 Jurisdiction Determination

Certain States, called Agreement States (see Figure 2-1), have entered into agreements with the U.S. Nuclear Regulatory Commission (NRC) that give them the authority to license and inspect byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive Federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

¹Locations of NRC Offices and Agreement States

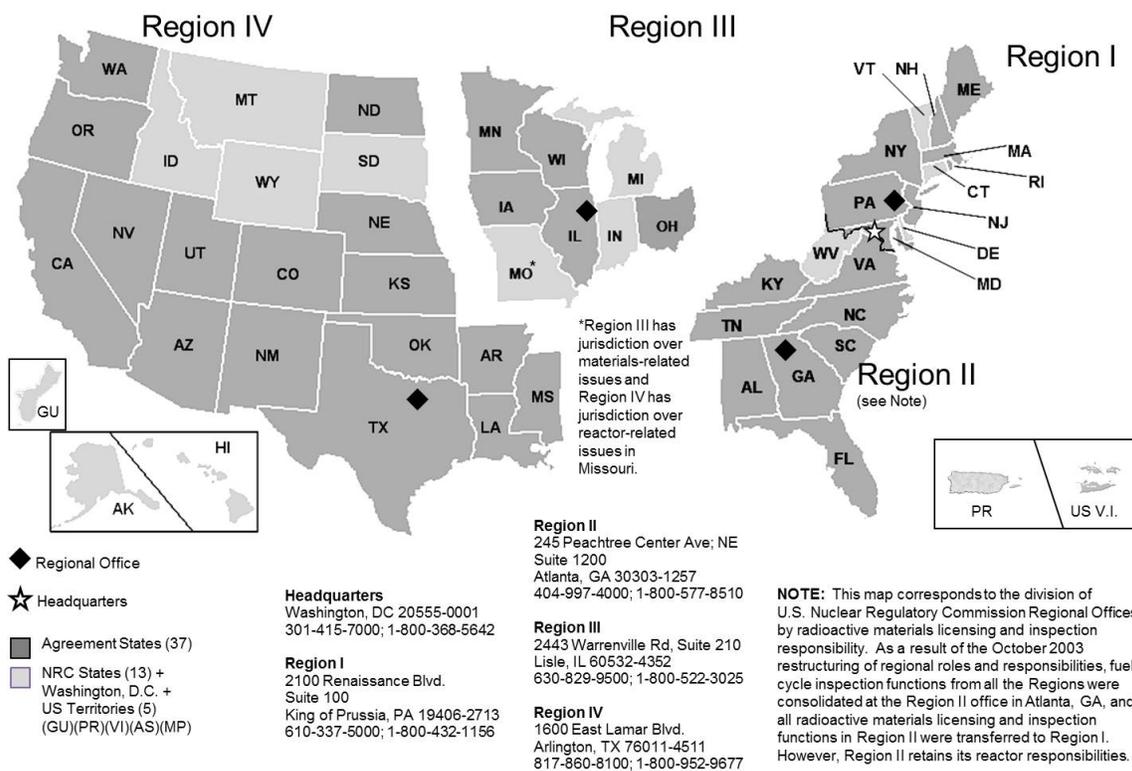


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include tribal lands of Federally recognized Indian Tribes.²

²For the purposes of this guidance, an "Indian Tribe" is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe, pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of Federally recognized tribes is available at www.bia.gov.

1 The NRC has regulatory authority over land determined to be “exclusive Federal jurisdiction,”
 2 while the Agreement State may have jurisdiction over nonexclusive Federal jurisdiction land.
 3 Applicants are responsible for determining, in advance, the jurisdictional status of the specific
 4 areas where they plan to conduct licensed operations. Additional guidance on determining
 5 jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS)
 6 procedures in the State Agreement series, SA-500, “Jurisdiction Determination,” which is
 7 available at <https://scp.nrc.gov>. Once on the Web site, use the link for “NMSS Procedures” in
 8 the left-hand column under “Resources & Tools.”

9 Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has
 10 regulatory authority.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with 10 CFR 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts”; also, see 10 CFR 40.11, and/or 10 CFR 70.11, if applicable)	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or tribal member on Indian Tribal land	NRC
Non-Federal entity on Federally recognized Indian Tribal land	NRC ³
Federally recognized Indian Tribe or tribal member outside of Indian Tribal land in Agreement State.	Agreement State
Non-Federal entity in Agreement State	Agreement State ⁴
Non-Federal entity in Agreement State at Federally controlled site not subject to exclusive Federal jurisdiction	Agreement State ⁴
Non-Federal entity in Agreement State at Federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor	NRC

11

³The NRC can exercise jurisdiction as the regulatory authority on tribal land of a Federally recognized Indian Tribe. Section 274b. agreements do not give States the authority to regulate nuclear material in these areas. However, there may be States that exercise regulatory authority over these areas based on treaties or agreements with specific tribes. Companies owned or operated by Federally recognized Indian Tribe members or non-Indians that wish to possess or use licensed material on tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.

⁴Section 274m. of the Atomic Energy Act (AEA) withholds to the NRC regulatory authority over radioactive materials covered under the Section 274b. agreements when the activity can affect the Commission’s authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of special nuclear material. (This is an uncommon situation that NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	Regulatory Agency
Non-Federal entity in Agreement State using radioactive materials not directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor	Agreement State ⁴

1 **Reference:** A current list of Agreement States (including names, addresses, and telephone
2 numbers of responsible officials) is available at the NMSS public Web site, <https://scp.nrc.gov>.
3 A request for the list can also be made to an NRC regional office.

4 **2.2 Reciprocal Recognition of Specific Licenses**

5 Performing licensed activities in other jurisdictions is possible through reciprocal recognition of
6 specific licenses (i.e., reciprocity). Agreement States have reciprocity provisions that permit
7 NRC licensees to perform licensed activities under circumstances when an Agreement State is
8 the regulatory authority (See Section 2.1). NRC licensees and Agreement State licensees are
9 subject to the regulations of the regulatory authority as indicated in Section 2.1. To ensure
10 compliance with an Agreement State’s reciprocity requirements, licensees are advised to
11 request authorization from the appropriate Agreement State radiation control program office well
12 in advance of the scheduled use of licensed material.

13 Agreement State licensees that wish to conduct licensed activities in areas under NRC
14 jurisdiction must either obtain a specific NRC license or file for reciprocity with the appropriate
15 NRC regional office for the Agreement State that issued their license. Failure to file for
16 reciprocity or obtain a specific NRC license before working in areas under NRC jurisdiction can
17 result in NRC enforcement action, which may include civil penalties. The reciprocity filing must
18 be renewed annually.

19 Specific guidance regarding NRC licensees filing for reciprocity in Agreements States and
20 Agreement State licensees filing for reciprocity with the NRC or another Agreement State
21 are provided in NUREG–1556, Volume 19, “Consolidated Guidance About Materials
22 Licenses: Guidance for Agreement State Licensees About NRC Form 241 “Report of
23 Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or
24 Offshore Waters” and Guidance for NRC Licensees Proposing to Work in Agreement State
25 Jurisdiction (Reciprocity).”

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective radiation safety program management is vital to achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely and that effective management will result in increased safety, security, and compliance.

“Management,” as used in this volume, refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

3.1 Commitments and Responsibilities

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.32(c), 10 CFR 40.31(b), and 10 CFR 70.22(d), each application must be signed by the applicant or licensee or a person duly authorized to act for and on behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on the behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on the behalf of the applicant or licensee. The signature on an application acknowledges the licensee’s commitments and responsibilities for the following:

- radiation safety, security, and control of radioactive materials and compliance with regulations
- completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9, “Completeness and accuracy of information”)
- knowledge about the contents of the license and application
- compliance with current NRC and U.S. Department of Transportation regulations, the licensee’s operating, emergency, and security procedures, and NRC license commitments
- commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities
- commitment to ensure that radiation workers have adequate training
- prevention of discrimination of employees engaged in protected activities and commitment to provide information to employees about employee protection provisions (10 CFR 30.7, 40.7, and 70.7, “Employee protection”)

- 1 • commitment to provide information to employees about deliberate misconduct provisions
2 (10 CFR 30.10, 40.10, and 70.10, “Deliberate misconduct”)
- 3 • commitment to obtain NRC’s prior written consent before transferring control of the
4 license (see Section 9.1, “Timely Notification of Transfer of Control,” of this report)
- 5 • notification of the appropriate NRC regional administrator, in writing, immediately
6 following the filing of petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h),
7 10 CFR 40.41(f), and 10 CFR 70.32(a)(9)], as discussed further in Section 8.2.1,
8 “Notification of Bankruptcy Proceedings,” of this report

9 For information on NRC inspection, investigation, enforcement, and other compliance programs,
10 see the current version of the NRC’s Enforcement Policy and Inspection Procedures available in
11 the NRC’s online library at <http://www.nrc.gov/reading-rm.html>.

12 **3.2 Safety Culture**

13 Individuals and organizations performing regulated activities are expected to establish and
14 maintain a positive safety culture commensurate with the safety and security significance of
15 their activities and the nature and complexity of their organizations and functions. This applies
16 to all licensees; certificate holders; permit holders; authorization holders; holders of quality
17 assurance program approvals; vendors and suppliers of safety-related components; and
18 applicants for a license, certificate, permit, authorization, or quality assurance program approval,
19 subject to NRC authority.

20 “Nuclear safety culture” is defined in NRC’s safety culture policy statement (76 FR 34773;
21 June 14, 2011) as “the core values and behaviors resulting from a collective commitment by
22 leaders and individuals to emphasize safety over competing goals to ensure protection of
23 people and the environment.” Individuals and organizations performing regulated activities bear
24 the primary responsibility for safely handling and securing these materials. Experience has
25 shown that certain personal and organizational traits are present in a positive safety culture. A
26 trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety,
27 particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety,
28 and cost of the effort versus safety). Refer to Table 3-1 for the traits of a positive safety culture
29 from NRC’s safety culture policy statement.

30 Organizations should ensure that personnel in the safety and security sectors have an
31 appreciation for the importance of each, emphasizing the need for integration and balance to
32 achieve both safety and security in their activities. Safety and security activities are closely
33 intertwined. While many safety and security activities complement each other, there may be
34 instances in which safety and security interests create competing goals. It is important that
35 consideration of these activities be integrated so as not to diminish or adversely affect either;
36 thus, mechanisms should be established to identify and resolve these differences. A safety
37 culture that accomplishes this would include all nuclear safety and security issues associated
38 with NRC-regulated activities.

39 The NRC, as the regulatory agency with an independent oversight role, reviews the
40 performance of individuals and organizations to determine compliance with requirements and
41 commitments through its existing inspection and assessment processes. However, NRC’s
42 safety culture policy statement and traits are not incorporated into the regulations. Many of the
43 safety culture traits may be inherent to an organization’s existing radiation safety practices and

1 programs. For instance, manufacturers and distributors develop production and quality
 2 assurance procedures for providing goods to others may correlate with the safety culture trait
 3 specified in Table 3-1 as “Work Processes” (the process of planning and controlling work
 4 activities to ensure that safety is maintained). However, licensees should be aware that this is
 5 just an example and should consider reviewing their radiation safety programs in order to
 6 develop and implement a safety culture commensurate with the nature and complexity of their
 7 organizations and functions.

8 Refer to Appendix R of this NUREG for the NRC’s safety culture policy statement. More
 9 information on NRC activities relating to safety culture can be found at
 10 <http://www.nrc.gov/about-nrc/safety-culture.html>.

Table 3-1. Traits of a Positive Safety Culture		
Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors	Issues with a potential impact on safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance	All individuals take personal responsibility for safety
Work Processes	Continuous Learning	Environment for Raising Concerns
Employees adopt and follow a process of planning and controlling work activities that ensures safety is maintained	Opportunities to learn about ways to ensure safety are sought out and implemented	A safety-conscious work environment is maintained in which personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety	Trust and respect permeate the organization	Individuals avoid complacency and continuously challenge existing conditions and activities to identify discrepancies that might result in error or inappropriate action

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain regulations applicable to licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

The current versions of these parts can be found under the "Basic References" link at the U.S. Nuclear Regulatory Commission (NRC) online library at <http://www.nrc.gov/reading-rm.htm>; for viewing in a browser, the following list includes direct links to the rules:

- [10 CFR Part 2](#) "Agency Rules of Practice and Procedure"
- [10 CFR Part 19](#) "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- [10 CFR Part 20](#) "Standards for Protection Against Radiation"
- [10 CFR Part 21](#) "Reporting of Defects and Noncompliance"
- [10 CFR Part 30](#) "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- [10 CFR Part 31](#) "General Domestic Licenses for Byproduct Material"
- [10 CFR Part 32](#) "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- [10 CFR Part 33](#) "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- [10 CFR Part 37](#) "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- [10 CFR Part 40](#) "Domestic Licensing of Source Material"
- [10 CFR Part 70](#) "Domestic Licensing of Special Nuclear Material"
- [10 CFR Part 71](#) "Packaging and Transportation of Radioactive Material"
- [10 CFR Part 110](#) "Export and Import of Nuclear Equipment and Material"
- [10 CFR Part 170](#) "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"

- 1 • [10 CFR Part 171](#) “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and
2 Materials Licenses, Including Holders of Certificates of
3 Compliance, Registrations, and Quality Assurance Program
4 Approvals and Government Agencies Licensed by the NRC”

5 Copies of these documents may be obtained by calling the Government Publishing Office
6 Customer Contact Center toll-free at 866-512-1800, in Washington, DC; calling
7 202-512-1800; or ordering online at <http://bookstore.gpo.gov>.

8 In addition, 10 CFR Parts 1 through 199 can be found on the NRC’s Web site at
9 <http://www.nrc.gov/reading-rm/doc-collections/> under Regulations (10 CFR).

10 NRC regulations can also be accessed from the “NRC Library” link on the NRC’s public Web
11 site at <http://www.nrc.gov>. Regulations are periodically amended, and the NRC (as well as all
12 other Federal agencies) is required to publish notice of such amendments in the *Federal*
13 *Register*.

14

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix B of this NUREG), Items 1 through 4, 12, and 13, on the form itself. A link to the form is available at <http://www.nrc.gov/reading-rm/doc-collections/forms/>.
- Complete NRC Form 313, Items 5 through 11, on supplementary pages or use Appendix C of this NUREG.
- Provide sufficient detail for the NRC to determine that the equipment, facilities, training, experience, and radiation safety program are adequate to protect health and safety and minimize danger to life and property.
- For each separate sheet other than NRC Form 313 and Appendix C pages, as applicable, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary, personal privacy, security-related, and other sensitive information should be clearly identified according to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public inspections, exemptions, requests for withholding" (see Chapter 6, "Identifying and Protecting Sensitive Information").

5.2 Where to File

Applicants wishing to possess or use licensed material in any State, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2-1 identifies the NRC's four regional offices and their respective areas for licensing purposes and the Agreement States. Note that all materials applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at Federally controlled sites, or Federally recognized Indian Tribal lands, in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, "Agreement States," for additional information.

1 **5.3 Paper Applications**

2 Paper applications received by the NRC are scanned through an optical character reader and
3 converted to an electronic format. To ensure a smooth transfer to an electronic format,
4 applicants should do the following:

- 5 • Submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily
6 into a document scanner.
- 7 • Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura.
- 8 • Use 11-point or larger font.
- 9 • Avoid stylized characters, such as script or italics.
- 10 • Ensure that the print is clear and sharp.
- 11 • Ensure that there is high contrast between the ink and paper (black ink on white paper
12 is best).

Applications must be signed by the applicant, licensee, or a person duly authorized, as required by 10 CFR 30.32(c) (see Section 8.13, "Certification").
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13

14 **5.4 Electronic Applications**

15 Applications may be submitted in electronic form via the NRC's Electronic Information Exchange
16 or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting
17 the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>. The guidance discusses,
18 among other topics, the formats the NRC can accept, the use of electronic signatures, and the
19 treatment of non-public information.

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in the U.S. Nuclear Regulatory Commission (NRC) Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov.

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked, as indicated in the list that follows in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 before the information is submitted to the NRC. Key examples are as follows:

- **Proprietary Information and Trade Secrets:** If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix T of this NUREG provides a checklist for requests for withholding proprietary information from public disclosure.
- **Personally Identifiable Information:** Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "Information Notices," respectively: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.
- **Security-Related Information:** Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information, and the top of every page of a document that contains such information should be clearly marked: "Security Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 22, 2005, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>. Additional

1 information on procedures and any updates is available at [http://www.nrc.gov/reading-](http://www.nrc.gov/reading-
2 rm/sensitive-info.html)

3 The regulations list various forms of information that can be protected from public disclosure.
4 These include

- 5 • trade secrets and commercial or financial information
- 6 • interagency or intra-agency memoranda or letters that would not be available by law to a
7 party other than an agency in litigation with NRC
- 8 • certain records or information compiled for law enforcement purposes
- 9 • geological and geophysical information and data, including maps, or information
10 concerning wells
- 11 • personnel, medical, and other information, the disclosure of which would constitute a
12 clearly unwarranted invasion of personal privacy

13 In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit
14 sensitive information to NRC so that it may be properly protected from disclosure. This
15 regulation is available electronically on the NRC Web site: [http://www.nrc.gov/reading-rm/doc-](http://www.nrc.gov/reading-rm/doc-
16 collections/cfr)

17 Except for personal privacy information, which is not subject to the affidavit requirement, if NRC
18 determines that the application or affidavit is deficient (i.e., does not contain the required
19 information as outlined in 10 CFR 2.390), the applicant will be notified that additional information
20 is needed and that the review will continue when the required information is received.

21 If the request is denied, in whole or in part, NRC will give the applicant the option of withdrawing
22 the information or application, as permitted in 10 CFR 2.390. If the applicant decides not to
23 withdraw the information or application, NRC will notify the applicant in writing that the request
24 for withholding has been denied and that NRC will disregard any references concerning the
25 proprietary status of the information.

26 Any part of a license application or information provided by a licensee or applicant that the NRC
27 determines should be withheld from public disclosure will be handled in accordance with
28 Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and
29 the licensee or applicant will be notified in writing that NRC plans to honor the request.
30 Management Directive 12.6 is available electronically on the NRC Web site:
31 <http://www.nrc.gov/reading-rm/doc-collections/management-directives/>.

Anyone submitting a request to withhold information from public disclosure should thoroughly review 10 CFR 2.390 and be familiar with its requirements and limitations.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, the licensee or applicant should promptly notify the NRC. The licensee or applicant also should understand that NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination adverse to the above, the licensee or applicant will be notified in advance of any public disclosure. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully apprised of the basis for, and the effects of, licensing or rulemaking actions. It is within NRC's discretion to withhold such information from public disclosure.

1

7 APPLICATION AND LICENSE FEES

2 Each application for which a fee is specified must be accompanied by the appropriate fee.
3 Refer to Title 10 of the *Code of Federal Regulations* (10 CFR) 170.31, "Schedule of fees for
4 materials licenses and other regulatory services, including inspections, and import and export
5 licenses," to determine the amount of the fee. The U.S. Nuclear Regulatory Commission (NRC)
6 will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for
7 information on exemptions from these fees. Once the technical review of an application has
8 begun, no fees will be refunded. Application fees will be charged, regardless of the NRC's
9 disposition of an application or the withdrawal of an application.

10 Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees:
11 Materials licensees, holders of certificates of compliance, holders of sealed source and device
12 registrations, holders of quality assurance program approvals, and government agencies
13 licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees
14 and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."
15 Note that in order to pay reduced fees, a licensee that qualifies as a "small entity" must provide
16 proper certification of this status to the NRC each year along with its annual fee payment.

17 Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the
18 Office of the Chief Financial Officer at NRC Headquarters in Rockville, MD, 301-415-7554.
19 Information about fees may also be obtained by calling NRC's toll-free number, 800-368-5642,
20 extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

1 **8 CONTENTS OF AN APPLICATION**

2 The following information applies to the indicated items on NRC Form 313 (Appendix B of
3 this NUREG).

4 All items in the application should be completed in enough detail for the U.S. Nuclear
5 Regulatory Commission (NRC) to determine whether the proposed equipment, facilities, training
6 and experience, and radiation safety program satisfy regulatory requirements and are adequate
7 to protect public health and safety and minimize danger to life and property. Consideration
8 should be given, when developing the application, to the concepts of keeping exposure as low
9 as is reasonably achievable (ALARA), minimizing contamination, and maintaining control of
10 radioactive materials.

11 Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101(b) states: "The licensee shall
12 use, to the extent practical, procedures and engineering controls based upon sound radiation
13 protection principles to achieve occupational doses and doses to members of the public that are
14 as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, "Operating Philosophy for
15 Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable,"
16 discusses the ALARA concept and philosophy. The application should document ALARA
17 considerations, including establishing administrative action levels and monitoring programs.

18 10 CFR 20.1406, "Minimization of contamination," requires applicants for licenses to describe
19 how facility design and procedures for operation will minimize, to the extent practicable,
20 contamination of the facility and the environment; facilitate eventual decommissioning; and
21 minimize, to the extent practicable, the generation of radioactive waste. As with ALARA
22 considerations, applicants should address these concerns for all aspects of their programs.

23 The application should include information on how the licensee will implement the security
24 requirements in 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of
25 material not in storage."

26 All information submitted to the NRC during the licensing process may be incorporated as part
27 of the license and will be subject to review during inspection.

28 **8.1 Item 1: License Action Type**

29 Item 1 of NRC Form 313 states the following:

30 This is an application for (check appropriate item):

Type of Action	License No.
<input type="checkbox"/> A. New License	Not Applicable
<input type="checkbox"/> B. Amendment	XX-XXXXXX-XX
<input type="checkbox"/> C. Renewal	XX-XXXXXX-XX

31 Check box A for a new license request. Note that a pre-licensing visit may be conducted prior
32 to issuance of the license.

33 Check box B for an amendment to an existing license and provide the license number.

34 Check box C for renewal of an existing license, and provide the license number.

1 See “Amendments and Renewals to a License” in Chapter 9 of this report.

2 **8.2 Item 2: Name and Mailing Address of Applicant**

3 List the legal name of the applicant’s corporation or other legal entity with direct control over use
4 of the radioactive material. A division or department within a legal entity may not be a licensee.
5 An individual may be designated as the applicant only if the individual is acting in a private
6 capacity and the use of the radioactive material is not connected with employment in a
7 corporation or other legal entity. Provide the mailing address where correspondence should be
8 sent. A post office box number is an acceptable mailing address.

9 Notify the NRC of any changes in the mailing address. These changes do not require a fee.

10 **Note:** The NRC must be notified and the transfer approved before control of the license is
11 transferred (see Section 9.1, “Timely Notification of Transfer of Control”). The NRC must also
12 be notified when bankruptcy proceedings have been initiated (see Section 8.2.1, “Notification of
13 Bankruptcy Proceedings”).

14 **8.2.1 Notification of Bankruptcy Proceedings**

15 **Regulation:** 10 CFR 30.34(h); 10 CFR 40.41(f)(1); 10 CFR 70.32(a)(9)(i)

16 **Criteria:** Immediately following the filing of a voluntary or involuntary petition for bankruptcy for
17 or against a licensee, the licensee must notify the appropriate NRC regional administrator, in
18 writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

19 **Discussion:** Even though a licensee may have filed for bankruptcy, the licensee remains
20 subject to all applicable NRC regulatory requirements. The NRC must know when licensees are
21 in bankruptcy proceedings in order to determine whether all licensed material is accounted for
22 and adequately controlled and whether there are any public health and safety concerns
23 (e.g., contaminated facility). The NRC shares the results of its determinations with other
24 involved entities (e.g., trustee), so that health and safety issues can be resolved before
25 bankruptcy actions are completed and may request that the U.S. Department of Justice
26 represent its interests in the bankruptcy proceeding.

27 **Response from Applicant:** None is required at the time of application for a new license.
28 Licensees must immediately notify the NRC in writing following the filing of a voluntary or
29 involuntary petition for bankruptcy by or against the licensee.

30 **Reference:** See NUREG–1556, Volume 15, “Consolidated Guidance About Materials Licenses:
31 Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or
32 Special Nuclear Materials Licenses.”

33 **8.3 Item 3: Address(es) Where Licensed Material Will Be Used** 34 **or Possessed**

35 **Regulations:** 10 CFR 30.34(c); 10 CFR 40.41(c); 10 CFR 70.41(a)

36 Specify the street address, city, and state or other descriptive address (e.g., on Highway 10,
37 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each
38 facility. The descriptive address should be sufficient to allow an NRC inspector to find the

1 facility location. A post office box address is not acceptable. In addition, applicants are
2 encouraged to provide global positioning system coordinates, as appropriate.

3 If licensed material is to be possessed or possessed and used at more than one location, give
4 the specific address of each location. Applicants for a broad scope license need not identify
5 each facility at a particular address where licensed material will be possessed or possessed and
6 used. For example, broad scope applicants can specify that licensed material will be possessed
7 or possessed and used on the manufacturing campus of ABC Corporation located on
8 Presidential Avenue in Anytown, State.

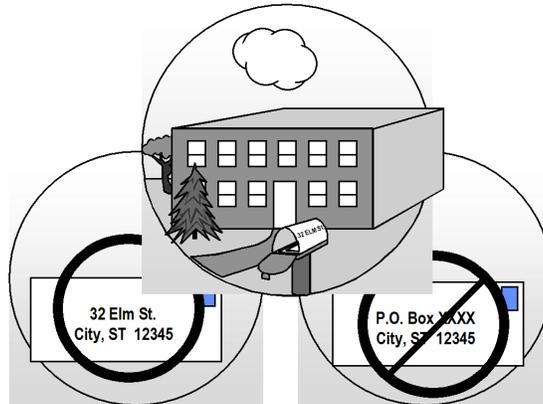


Figure 8-1. Location of Possession or Possession and Use. *An acceptable location of use or possession specifies street address, city, State, and zip code and does not include a post office box number.*

9 Applicants should identify all facilities designed or established for special uses (e.g., panoramic
10 irradiators, interim or long-term waste storage facilities, high-activity laboratories, iodination
11 facilities, alpha laboratories, and incinerators).

12 A license amendment is required before receiving, using, or storing licensed material at an
13 address or location not already listed on the license.

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).

14 If an applicant submits documents that give the exact location of use and storage for any
15 amount of radioactive material, the applicant should mark these documents as “Security Related
16 Information—Withhold under 10 CFR 2.390.” See Chapter 6, “Identifying and Protecting
17 Sensitive Information,” for more details.

18 **Note:** As discussed in Section 8.5.2, “Financial Assurance and Recordkeeping for
19 Decommissioning,” licensees must maintain permanent records that describe where licensed
20 material was used or stored while the license was in effect. This is important for making future
21 determinations about the release of these locations for unrestricted use (e.g., before the license
22 is terminated). Acceptable records are sketches, written descriptions of the specific locations or
23 room numbers where licensed material is used or stored, and any records of leaking radioactive
24 sources or other unusual occurrences involving the possible spread of contamination in or
25 around the licensee’s facilities.

1 **8.4 Item 4: Person To Be Contacted About This Application**

2 Identify the individual who can answer questions about the application, and include a telephone
3 number where the individual may be contacted as well as business cell phone numbers and
4 e-mail addresses. This individual, usually the radiation safety officer (RSO), will serve as the
5 point of contact during the review of the application. If this individual is not a full-time employee
6 of the licensed entity, his or her position and relationship to the licensee should be specified.
7 The NRC should be notified if the person assigned to this function changes or if his or her
8 telephone number, cell phone number, or e-mail address changes. Notification of a contact
9 change is only provided for informational purposes and would not be considered an application
10 for license amendment, unless the notification involves a change in the contact person who is
11 also the RSO.

As indicated on NRC Form 313 (see Appendix B of this NUREG), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C of this NUREG for this purpose and should note that using the suggested wording of responses and committing to use the model procedures in this report will facilitate the NRC's review.

12 **8.5 Item 5: Radioactive Material**

13 **8.5.1 Sealed Sources and Devices or Unsealed Radioactive Material**

14 **Regulations:** 10 CFR 20.2207; 10 CFR 30.6; 10 CFR 30.11; 10 CFR 30.32; 10 CFR 30.33;
15 10 CFR 30.36; 10 CFR 30.37; 10 CFR 30.38; 10 CFR 32.11; 10 CFR 32.14; 10 CFR 32.18;
16 10 CFR 32.21; 10 CFR 32.22; 10 CFR 32.26; 10 CFR 32.30; 10 CFR 32.51; 10 CFR 32.53;
17 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71; 10 CFR 32.72; 10 CFR 32.74; 10 CFR 32.210;
18 10 CFR 37; 10 CFR 40.13; 10 CFR 40.31; 10 CFR 40.32; 10 CFR 40.34; 10 CFR 40.35;
19 10 CFR 40.36; 10 CFR 40.38; 10 CFR 40.41; 10 CFR 40.44; 10 CFR 51.20; 10 CFR 51.21;
20 10 CFR 51.22; 10 CFR 70.39; 10 CFR 70.40; 10 CFR 70.41; 10 CFR 110.9; 10 CFR 110.9a;
21 10 CFR 110.31; 10 CFR 110.32; 10 CFR 150.7.

22 **Criteria:** An application for a license will be approved if the requirements of 10 CFR 30.33,
23 10 CFR 40.32, 10 CFR 51.20, 10 CFR 70.39, 10 CFR 110.31, and/or 10 CFR 110.32 are met.
24 In addition, licensees will be authorized to possess and use only those sealed sources and
25 devices that are specifically approved or registered by NRC or an Agreement State pursuant to
26 10 CFR 32.210 or equivalent Agreement State regulations. Licensees must also protect
27 Category 1 and Category 2 quantities of radioactive material from theft and diversion.

28 **Discussion:**

29 **Materials That Must Be Listed in the Application**

30 Each authorized radionuclide is listed on the NRC license by its element name, chemical and/or
31 physical form, and the maximum possession limit. If a license of broad scope is being sought
32 (under 10 CFR 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"),
33 also refer to NUREG-1556, Vol. 11, "Consolidated Guidance About Materials Licenses:
34 Program-Specific Guidance About Licenses of Broad Scope."

35 The applicant should list each requested radionuclide by its element name and its mass number
36 {e.g., carbon-14 [C-14]} in Item 5. It is necessary to specify whether the material will be
37 acquired and possessed and used in unsealed or sealed form. The name of the specific

1 chemical compound that contains the radionuclide is not required. For volatile radioactive
2 material, however, it is necessary to specify whether the requested radionuclide will be acquired
3 in free (volatile) or bound (non-volatile) form, because additional safety precautions are required
4 when handling and using volatile material. For example, when requesting authorization to
5 possess and use iodine-125 (I-125), the applicant must specify whether the material will be
6 acquired in free form or bound form. If a radionuclide will be acquired in both free and bound
7 forms, then separate possession limits for each form must be requested. The applicant
8 must provide evidence (or information) that demonstrates that the material obtained will be
9 non-volatile. NRC may issue the license with separate or combined possession limits,
10 depending on the reviewer's analysis of the information provided.

11 Applicants requesting an authorization to possess and use volatile radioactive material must
12 provide appropriate facilities, engineering controls, and radiation safety procedures for handling
13 such material.

If you plan to possess radioactive materials in excess of the quantities listed in 10 CFR 30.72 (Schedule C), then you must provide with the application either (i) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 1 rem [0.01 Sv] effective dose equivalent (EDE) or 5 rem [0.05 Sv] to the thyroid or (ii) an emergency response plan for responding to the release, in accordance with the criteria listed in 10 CFR 30.32(i). Refer to Regulatory Guide 3.67 for additional information regarding emergency plans.

14 The anticipated possession limit in millicuries (mCi) [megabecquerels (MBq)] or curies (Ci)
15 [gigabecquerels (GBq)] for each radionuclide must also be specified. Possession limits must
16 cover the total anticipated inventory, including licensed material in storage and waste, and
17 should be commensurate with the applicant's needs and facilities for safe handling. If materials
18 are expected or requested to be returned from customers, then these materials must be
19 factored into the inventory. Applicants should review the requirements for submitting a
20 certification for financial assurance for decommissioning before specifying possession limits of
21 any radionuclide with a half-life greater than 120 days. These requirements are discussed in
22 Section 8.5.2, Financial Assurance and Decommissioning.

23 A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State
24 before authorizing a manufacturer (or distributor) to distribute them. The safety evaluation is
25 documented in a Sealed Source and Device (SSD) registration certificate. Before the
26 formalization of the SSD registration process, some older sources or devices may have been
27 specifically approved on a license. Licensees can continue to possess and use those sources
28 and devices specifically listed on their licenses. Applicants must provide the manufacturer's
29 name and model number, as registered under 10 CFR 32.210 or similar Agreement state
30 regulation, for each requested sealed source and device so that NRC can verify that they have
31 been evaluated in an SSD registration certificate or specifically approved on a license. See also
32 NUREG-1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for
33 Sealed Source and Device Evaluation and Registration."

34 Consult with the proposed manufacturer or distributor to ensure that requested sources and
35 devices are compatible with and conform to the SSD designations registered with NRC or an
36 Agreement State. Licensees may not make any changes to the sealed source, device, or
37 source/device combination that would alter the description or specifications from those indicated
38 in the respective registration certificates, without obtaining NRC's prior permission in a license

1 amendment. To ensure that sources and devices are possessed and used in accordance with
2 the registration certificates, applicants and licensees should request a copy of the certificate
3 from the manufacturer or distributor, review it, and discuss it with the manufacturer or distributor.
4 If the manufacturer and distributor are no longer in service, a copy of the SSD registration
5 certificate may be requested from the NRC or the issuing Agreement State. It is not acceptable
6 to use multiple exempt quantities in a single device, as set forth in 10 CFR 32.19.

7 For sources and devices not registered, as allowed by 10 CFR 32.210(g)(2), the applicant must
8 demonstrate that they have adequate training and experience and facilities and equipment to
9 handle comparable quantities of material in other forms under 10 CFR 30.33(a)(2) and (3) and
10 should propose constraints about unregistered sealed sources and devices, in accordance with
11 10 CFR 30.32(g)(4).

12 Applicant and licensee information on manufacturers, model numbers, and possession limits is
13 sensitive and should be marked accordingly (see Chapter 6, "Identifying and Protecting
14 Sensitive Information").

15 The NRC has jurisdiction over discrete sources of radium (Ra)-226, accelerator-produced
16 radioactive materials, and other discrete sources of naturally occurring radioactive material, as
17 required by the Energy Policy Act of 2005. Applicants must provide the manufacturer's name
18 and model number, as registered under 10 CFR 32.210 or similar Agreement State regulation,
19 for each requested sealed source or device containing Ra-226 or accelerator produced
20 radioactive material. For sources or devices containing naturally occurring or
21 accelerator-produced radioactive material manufactured prior to November 30, 2007, that
22 are not registered with the NRC or Agreement State, the applicant must provide the information
23 required in 10 CFR 30.32(g)(3).

The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material. Category 1 and Category 2 sealed sources must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207. See Section 8.10.10, "Security Program for Category 1 and Category 2 Radioactive Material," of this NUREG for more information on the applicability and requirements of 10 CFR Part 37 and 10 CFR 20.2207.

24 **Response from Applicant:**

- 25 • For unsealed materials
 - 26 – For each radionuclide, provide the element name with mass number, chemical
27 and/or physical form, and maximum requested possession limit.
- 28 • For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85)
 - 29 – Specify whether the material will be free (volatile) or bound (non-volatile) and the
30 requested possession limit for each form.
- 31 • For sealed radioactive materials
 - 32 – Identify each radionuclide (element name and mass number) that will be used, and
33 specify the maximum activity per source.

- 1 – Provide the manufacturer’s (distributor’s) name and model number for each sealed
2 source and device requested.
- 3 – Confirm that each sealed source, device, and source and device combination is
4 registered as an approved sealed source or device by NRC or an Agreement State.
- 5 – Confirm that the sealed source and/or device will be possessed and used, including
6 adherence to the activity per source and maximum activity in each device, as
7 specified in a certificate of registration issued by NRC or by an Agreement State.
- 8 • Identify the largest quantity of each radionuclide to be possessed at one time under the
9 license, including receipts, in-process materials, and waste.
- 10 • In accordance with 10 CFR 30.32(i), applications to possess radioactive materials in
11 unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities
12 listed in 10 CFR 30.72 must include either of the following:
 - 13 – an evaluation showing that the maximum offsite dose caused by a release of
14 radioactive materials would not exceed 0.01 Sv [1 rem] effective dose equivalent or
15 0.05 Sv [5 rem] to the thyroid
 - 16 – an emergency response plan for responding to the release, in accordance with the
17 criteria listed in 10 CFR 30.32(i)(3)

18 **References:** See the Notice of Availability (on the inside front cover of this report) to obtain
19 copies of Regulatory Guide 3.67, “Standard Format and Content for Emergency Plans for Fuel
20 Cycle and Materials Facilities.” Regulatory Guide 3.67 is available on NRC’s Web site at
21 <http://www.nrc.gov>.

22 See also Policy and Guidance Directive 84-14, Revision 1, “Standard Review Plan for
23 Emergency Plans for Fuel Cycle and Materials Licensees.”

24 **8.5.2 Financial Assurance and Recordkeeping for Decommissioning**

25 **Regulations:** 10 CFR 30.32(h); 10 CFR 30.34(b); 10 CFR 30.35; 10 CFR 30.36(e);
26 10 CFR 30.36(g)(4)(v); 10 CFR 30.51(d); 10 CFR 30.51(e); 10 CFR 30.51(f); 10 CFR 40.31(i);
27 10 CFR 40.36; 10 CFR 40.41(b); 10 CFR 40.42(e); 10 CFR 40.42(g)(4)(v); 10 CFR 40.46;
28 10 CFR 40.61(d); 10 CFR 40.61(e); 10 CFR 40.61(f); 10 CFR 70.22(a)(9); 10 CFR 70.25;
29 10 CFR 70.32(a)(3); 10 CFR 70.36; 10 CFR 70.38(e); 10 CFR 70.38(g)(4)(v);
30 10 CFR 70.51(a)(3); 10 CFR 70.51(b)(3).

31 **Criteria:** A licensee authorized to possess licensed material in excess of the limits specified in
32 10 CFR 30.35, 10 CFR 40.36, and/or 10 CFR 70.25—all titled “Financial assurance and
33 recordkeeping for decommissioning”—must submit a decommissioning funding plan (DFP) or
34 provide a certification of financial assurance for decommissioning (FA).

35 Even if no FA is required, all licensees are required to maintain, in an identified location,
36 decommissioning records important to the decommissioning of a facility.

37 Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b),
38 10 CFR 40.46, and/or 10 CFR 70.36, licensees must transfer records important to

1 decommissioning to the new proposed licensee in accordance with 10 CFR 30.35(g), 10 CFR
2 40.36(f) and/or 10 CFR 70.51(b)(3), respectively. Furthermore, before a license is terminated,
3 the licensee must send records important to decommissioning that are required by 10 CFR
4 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g) to the appropriate NRC regional office in
5 accordance with 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a)(3), respectively.

6 **Discussion:** NRC wants to ensure that decommissioning will be carried out with minimum
7 impact on public and occupational health and safety and the environment (53 FR 24018,
8 June 28, 1988). There are two parts to the rule: financial assurance that applies to **SOME**
9 licensees, and recordkeeping, which applies to **ALL** licensees.

10 **Financial Assurance**

11 NRC regulations requiring an FA or a DFP are designed to provide reasonable assurance that
12 the decommissioning of licensed facilities will be accomplished in a safe and timely manner and
13 that licensees will provide adequate funds to cover all costs associated with decommissioning.
14 These requirements, if applicable, specify that a licensee either set aside funds for
15 decommissioning activities or provide a guarantee, through a third party, that funds will be
16 available. Applicants are required to submit an FA or a DFP when the possession of radioactive
17 material of half-life greater than 120 days exceeds certain limits. Criteria for determining
18 whether an applicant is required to submit a DFP or has an option of submitting either a DFP or
19 an FA (or neither) are stated in 10 CFR 30.35, 10 CFR 40.36, and /or 10 CFR 70.25. A DFP
20 contains a site-specific cost estimate and a certification of FA. A Certification of FA includes a
21 certification that the licensee has provided the required FA and an acceptable FA instrument.

22 Acceptable FA includes prepayment options (trusts, escrow accounts, government funds,
23 certificates of deposit, or deposits of government securities); surety, insurance, or other
24 guarantee methods (letters of credit, surety bonds, lines of credit, parent company guarantees,
25 insurance policies); and statements of intent for Government entities. Criteria for parent
26 company guarantees and self-guarantees can be found in 10 CFR 30, Appendix A, Appendix C,
27 Appendix D, and Appendix E. Refer to 10 CFR 30.35(d) for a table of required amounts of
28 financial assurance for decommissioning by quantity of material.

29 NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance—Financial Assurance,
30 Recordkeeping, and Timeliness,” provides guidance acceptable to the NRC staff on the
31 information to be provided for establishing financial assurance for decommissioning, a standard
32 format for presenting the information, and information required to be submitted for a DFP. Note
33 that FA is required for four types of licensed materials: (i) unsealed byproduct material,
34 (ii) sealed byproduct material, (iii) dispersible source material, and (iv) unsealed special nuclear
35 material. The total amount of FA required to be provided is the sum of the FA required for each
36 of these types of materials.

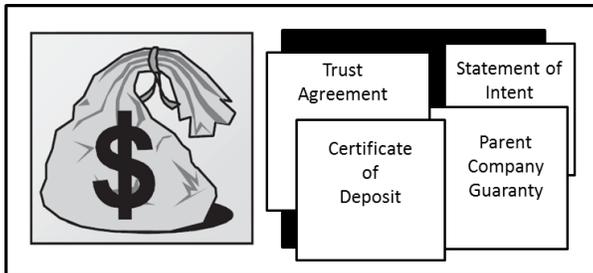
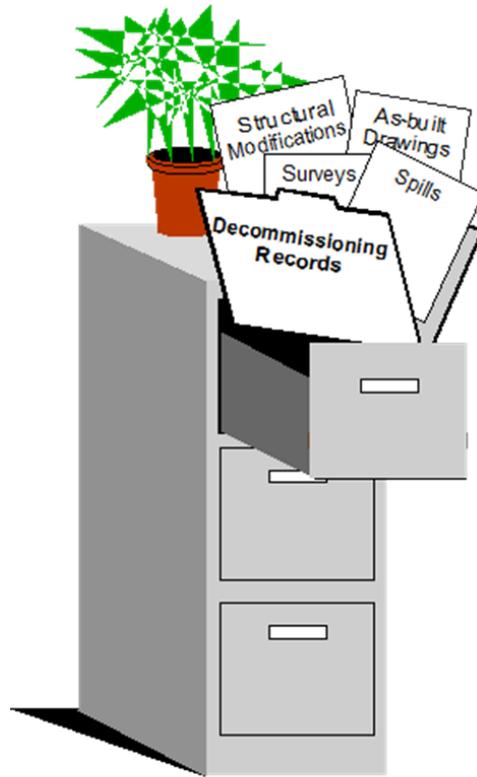


Figure 8-2. Financial Assurance for Decommissioning

1 Most manufacturer licensees do not need to provide *financial assurance* for decommissioning.
2 Large manufacturers may need one of several approved financial mechanisms.

3 Recordkeeping for Decommissioning

4 The requirements for maintaining records important to decommissioning, including the type of
5 information required, are stated in 10 CFR 30.35(g), 10 CFR 40.36(f), and/or 10 CFR 70.25(g).
6 All licensees are required to maintain these records in an identified location until the site is
7 released for unrestricted use. Careful recordkeeping of radionuclides used, including form,
8 amount, and area used, will facilitate area release and license termination. In the event that the
9 licensed activities are transferred to another person or entity, these records must be transferred
10 to the new licensee before the transfer of the licensed activities takes place.



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Figure 8-3. Records Important to Decommissioning. *All possession for manufacturing and distribution licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.*

11

12 In accordance with 10 CFR 30.35(g) and corresponding requirements in Parts 40 and 70,
13 licensees must transfer records important to decommissioning to the new licensee before
14 licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b) and
15 corresponding requirements in Parts 40 and 70.

1 Furthermore, pursuant to 10 CFR 30.51(f), 10 CFR 40.61(f), and/or 10 CFR 70.51(a)(3), prior to
2 license termination, each licensee must forward the records required by 10 CFR 30.35(g),
3 10 CFR 40.36(f) and/or 10 CFR 70.25(g), respectively, to the appropriate NRC regional office.

4 **Response from Applicants:**

- 5 • State the following: “Pursuant to 10 CFR 30.35(g), 10 CFR 40.36(f), and/or
6 10 CFR 70.25(g) and 10 CFR 70.51(b)(3), we will maintain records important to
7 decommissioning and transfer these records to an NRC or Agreement State licensee
8 before licensed activities are transferred or assigned, in accordance with
9 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36. Furthermore, pursuant to
10 10 CFR 30.51(f), 10 CFR 40.61(f), and /or 10 CFR 70.51(a)(3), prior to license
11 termination, we will forward the records required by 10 CFR 30.35(g), 10 CFR 40.36(f),
12 and/or 10 CFR 70.25(g) to the appropriate NRC regional office.”

13 **AND**

- 14 • If financial assurance is required, submit the required documents, as described in
15 NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance—Financial
16 Assurance, Recordkeeping, and Timeliness.”

17 **References:** See the Notice of Availability (on the inside front cover of this report) to obtain
18 copies of NUREG–1757.

19 **8.6 Item 6: Purpose(s) for Which Licensed Material Will Be Used**

20 **Regulations:** 10 CFR 30.4 10 CFR 30.33(a)(1); 10 CFR 30.41; 10 CFR 32.2; 10 CFR 32.11;
21 10 CFR 32.14; 10 CFR 32.18; 10 CFR 32.21; 10 CFR 32.22; 10 CFR 32.26; 10 CFR 32.51;
22 10 CFR 32.53; 10 CFR 32.57; 10 CFR 32.61; 10 CFR 32.71; 10 CFR 32.72; 10 CFR 32.74;
23 10 CFR 32.210; 10 CFR 40.4; 10 CFR 40.32; 10 CFR 51.21; 10 CFR 51.22; 10 CFR 70.4;
24 10 CFR 70.39; 10 CFR 70.42; 10 CFR 110.2; 10 CFR 110.20; 10 CFR 110.42; 10 CFR 110.43;
25 10 CFR 110.50.

26 **Criteria:** Requested radionuclides must be possessed and used for purposes authorized by the
27 Atomic Energy Act of 1954, as amended. Sealed sources and devices containing licensed
28 material must be possessed and used only for the purpose for which they are designed and
29 according to manufacturer’s (distributor’s) instructions and recommendations for possession
30 and use, as specified in the SSD registration certificate.

In order to have a license for distribution of sources and devices containing radioactive materials, the applicant normally must first apply for and receive a sealed source and device registration, in accordance with the procedures in NUREG–1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration.”

31 **Note:** If distributing sealed sources and devices to medical use licenses, also see Appendix S
32 of this NUREG, “Medical Distribution.”

33 **Discussion:** Applicants should clearly specify the purpose for which each radionuclide will be
34 used. The description should be detailed enough to allow NRC to determine the potential for

1 exposure to radiation and radioactive materials to those working with radioactive materials and
2 members of the public.

3 Applicants should pay particular attention to the applicable regulations listed above when
4 applying for a license to manufacture and distribute licensed material (see Figure 8-4).
5 However, this list is not exhaustive, nor does it relieve the applicant from complying with
6 applicable Federal, State, and local requirements.

7 Applicants should clearly specify if the licensed material will be used in animal studies and/or
8 tracer studies as part of manufacturing. Use of licensed material in animals may be in quality
9 control or research studies. Applicants should also state whether the studies will be limited to
10 small animals (e.g., rats, mice) or may also include larger animals (e.g., pigs, dogs, horses).
11 Applicants including animal studies, tracers, or research and development can include the
12 requested licensed materials in this application and should refer to NUREG–1556, Vol. 7,
13 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
14 Academic, Research and Development, and Other Licenses of Limited Scope.” Applicants
15 intending to possess and use licensed materials for medical research involving humans must be
16 authorized to do so pursuant to a license issued under 10 CFR Part 35 and should refer to
17 NUREG–1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific
18 Guidance About Medical Use Licenses.” Applicants intending to become a broad-scope
19 licensee should refer to NUREG–1556, Vol. 11, “Consolidated Guidance for Materials Licenses:
20 Program-Specific Guidance About Licenses of Broad Scope,” for instructions.

21 Licensees who possess and use licensed materials to support the process of manufacturing
22 and/or distribution must have the appropriate possession and uses described in their licenses.
23 An example may be that a manufacturer of depleted uranium counterweights or shields
24 possesses and uses a cesium-137 level gauge to detect blockage in the raw material hopper
25 feed line. The manufacturer would need authorization not only to possess, use, and distribute
26 the uranium for the counterweights and the shields, but also a line authorization to possess and
27 use the level gauging device. If the licensee wishes to calibrate its own radiation survey meters
28 and perform leakage/contamination tests, then separate line authorizations on the same license
29 are needed for the radiation survey instrument calibration source/device and the calibration
30 sources for the detection system for leakage/contamination testing. The licensee should have
31 procedures for these uses.

32 Applicants may use the format given in Table 8-1 below to provide the requested information.

Table 8-1. Sample Format for Providing Information About Requested Radionuclides			
Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Manufacturing—Internal Uses			
Any byproduct material with atomic numbers 1 through 83	Any	Not to exceed 10 curies per radionuclide and 100 curies total	Research and development as defined in 10 CFR 30.4
Hydrogen-3	Unbound/volatile	100 millicuries	Labeling of compounds

Table 8-1. Sample Format for Providing Information About Requested Radionuclides (Continued)

Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Hydrogen-3	Bound/non-volatile	100 millicuries	In vitro studies; studies in small lab animals
Iodine-125	Unbound/volatile	30 millicuries	Protein iodination
Iodine-125	Bound/non-volatile	50 millicuries	In vitro studies; studies in small lab animals; calibration of instruments
Cesium-137	Sealed source, Mfg. name/model number	20 millicuries	Calibration of instruments
Manufacturing and Distribution			
Hydrogen-3	Unbound/volatile	100 millicuries	Labeling of compounds
Iodine-125	Unbound/volatile	30 millicuries	Protein iodination
Any byproduct material with atomic numbers 1 through 83	Any	Not to exceed 10 curies per radionuclide and 100 curies total	For possession, use, and processing for manufacturing of radiochemicals, radiopharmaceuticals, and sealed sources
Any byproduct material with atomic numbers 84 through 94	Any	Not to exceed 50 millicuries per radionuclide and 2 curies total	For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources
Hydrogen-3 Carbon-14 Phosphorus-32 Phosphorus-33 Sulfur-35	Any Any Any Any Any	100,000 curies 500 curies 100 curies 20 curies 400 curies	For storage prior to distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources

Table 8-1. Sample Format for Providing Information About Requested Radionuclides (Continued)

Radionuclide	Chemical/Physical Form	Maximum Possession Limit	Proposed Use
Hydrogen-3 Carbon-14 Phosphorus-32 Phosphorus-33 Sulfur-35	Any Any Any Any Any	100,000 curies 500 curies 100 curies 20 curies 400 curies	For packaging and distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses
Molybdenum-99/Techne-99m	Any	500 curies	For possession, use, and processing for manufacturing of radiochemicals and radiopharmaceuticals
Distribution			
Xenon-133	Prepackaged Units	50 curies	For possession incident to commercial redistribution of unopened containers to authorized recipients
Hydrogen-3 Carbon-14 Phosphorus-32 Phosphorus-33 Sulfur-35	Any Any Any Any Any	100,000 curies 500 curies 100 curies 20 curies 400 curies	Distribution of manufactured radiochemicals, radiopharmaceuticals, and sealed sources

1
2 Applicants requesting a license for distribution-only may need to refer to the information in
3 Appendix D of this NUREG, which describes the different types of distribution licenses
4 (i.e., General “G” Distribution License, Medical “MD” Distribution License, and Exempt “E”
5 Distribution License), in order to determine whether this guidance document should be used for
6 their application. Applicants for medical distribution licenses must refer to 10 CFR 32.72 and
7 32.74, in addition to the guidance specified in Appendices F and U. Some “manufacturers” that
8 are importers of materials and devices from abroad may not require the same extent of
9 information submission and review as a facility that produces an item. However, they are
10 required to have a manufacturer/distributor license as the initial importer and distributor in the
11 U.S. The device distributor may be the sponsor of the “Sealed Source and Device Registry”
12 certificate. The general distribution-only license (“G”) and the exempt distribution-only license
13 (“E”) application requirements are not covered in this document. Applicants for these licenses

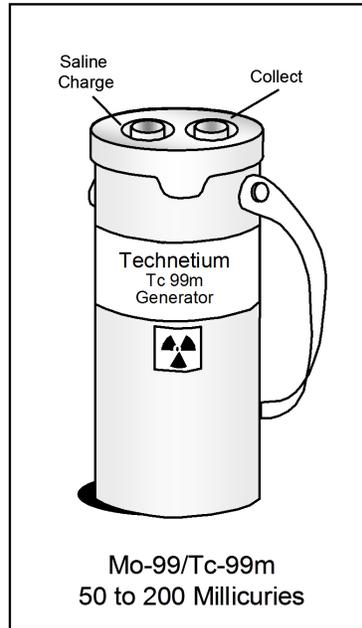


Figure 8-4. Example of a Product Produced Under Possession for Manufacturing and Distribution Authorization. *Other designs of technetium generators can contain up to 4 curies of Mo-99/Tc-99m*

1 are referred to NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses:
 2 Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees,” and
 3 NUREG–1556, Vol. 8, “Consolidated Guidance About Materials Licenses: Program-Specific
 4 Guidance About Exempt Distribution Licenses.”

5 **Response from Applicant:**

- 6 • List the specific use or purpose of each radionuclide that will be possessed and used.
 7 Use of the suggested table format will facilitate review of the application.
- 8 • Identify each device, manufactured article, or material that becomes the product, by
 9 manufacturer and model number.
- 10 • Identify the SSD registration certificate number of each sealed source proposed for
 11 possession and use or incorporation into a manufactured article.
- 12 • Submit information requesting authorization to possess and use any other licensed
 13 materials in support of the manufacturing and distribution license.

14 **Note:** Applicants intending to manufacture sealed sources or devices for medical use should
 15 refer to Appendix S of this NUREG, Item 10.2, for sealed source and device licensing criteria for
 16 evaluation of design and construction.

17 **8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and**
 18 **Their Training and Experience**

19 **Regulations:** 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.22(a)(6); 10 CFR 70.23(a)(2)

1 **Criteria:** Executive management, the RSO (and his/her staff, as necessary), and authorized
2 users work as a team to implement the Radiation Protection Program. Each individual and
3 position plays a critical role within his/her area of responsibility. The roles and responsibilities of
4 executive management, the RSO, the Radiation Safety Office staff, authorized users, and
5 others in restricted areas are discussed in the sections that follow. Refer to the subsequent
6 sections specific to the RSO and Authorized Users described above.

7 **Note:** NUREG–1516, “Management of Radioactive Material Safety Programs at Medical
8 Facilities,” describes the role of executive management and the RSO at medical facilities, and
9 contains information that may be useful to licensees authorized for possession for
10 manufacturing and distribution.

11 **Discussion:** The licensee must be qualified by training and experience to possess and use the
12 material for the purpose requested in a manner that will protect health and minimize danger to
13 life or property before an application for a license is approved.

14 Each program in which radioactive materials are possessed and used under a Commission
15 license will have someone responsible for radiation safety and compliance with the
16 Commission’s regulations. In a small program, the responsibility may be combined with or
17 assigned to (or assumed by) the same individual using radioactive materials; therefore, an
18 authorized user may serve as an RSO. In a medium-sized program, the responsibility may be
19 assigned to an individual on a part-time basis with that person’s primary responsibility being in
20 another area of work. In a large program, the many facets of occupational and environmental
21 radiation safety require that responsibility for the Radiation Safety Program be assigned to a
22 qualified individual on a full-time basis. His or her training and experience must be
23 commensurate with his or her duties and responsibilities. Supporting staff should be provided,
24 as appropriate, for the size and scope of the program. A large program may have some or all of
25 the following characteristics:

- 26 • in-house calibration of radiation survey, monitoring, and measurement instruments
- 27 • possession and use of multiple chemical and physical forms of multiple radionuclides for
28 various purposes
- 29 • program flexibility with regard to the possession and use of radionuclides, their chemical
30 and physical form, and the uses to be made of such radionuclides
- 31 • accurate detection, identification, and measurement of radioactivity in various types of
32 effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for
33 evaluation of these effluents against NRC regulatory requirements and limitations
- 34 • radioactive effluent treatment by filtration, absorption, adsorption, holdup, etc.
- 35 • selection, evaluation, design, fabrication, maintenance, and use of radioactive effluent
36 treatment systems
- 37 • selection, evaluation, and maintenance of radiation measurement and
38 analysis equipment
- 39 • potential for the contamination of facilities, equipment, and personnel accompanied by
40 the need to control such contamination (including airborne contamination),

1 decontaminate personnel and equipment, and evaluate possible internal dose
2 (including determination of the need for bioassays and interpretation of bioassay results)

3 The licensee’s senior management maintains the ultimate responsibility for the safety of
4 licensed activities. NRC holds the licensee responsible for the Radiation Protection Program;
5 therefore, it is essential that strong management controls and oversight exist to ensure that
6 licensed activities are conducted safely. Management responsibility and liability are sometimes
7 underemphasized or not addressed in applications and are often poorly understood by licensee
8 employees and managers. As discussed later in this guide, senior management should
9 delegate to the RSO sufficient authority, organizational freedom, and management prerogative
10 to communicate with and direct personnel regarding NRC regulations and license provisions
11 and to terminate unsafe activities involving byproduct material. Other responsibilities may be
12 delegated to other individuals with adequate training and experience. Such delegations should
13 be clearly communicated to all parties.

14 If a license of broad-scope is being sought (under 10 CFR 33, “Specific Domestic Licenses of
15 Broad Scope for Byproduct Material”), also refer to NUREG–1556, Vol. 11, “Consolidated
16 Guidance About Materials Licenses: Program-Specific Guidance About Licenses of
17 Broad Scope.”

18 **Response from Applicant:** Refer to the subsequent sections specific to the individuals
19 described above. Applicants should submit an organizational chart describing the management
20 structure, reporting paths, and the flow of authority between executive management and
21 the RSO.

22 **8.7.1 Radiation Safety Officer**

23 **Regulations:** 10 CFR 30.33(a)(3); 10 CFR 37; 10 CFR 40.32(b); 10 CFR 70.23(a)(2)

24 **Criteria:** RSOs must have adequate training and specific experience with the types and
25 quantities of licensed material to be authorized on the license.

26 **Discussion:** The person responsible for implementing the radiation protection program
27 including overseeing and ensuring that the licensee’s radioactive material is used and stored
28 safely and securely is the RSO. If the licensee possesses an aggregated Category 1 or
29 Category 2 quantity of radioactive material (such quantities are defined in 10 CFR 37.5), the
30 RSO should be involved with developing and implementing a security program for radioactive
31 material in accordance with 10 CFR 37. The RSO must have adequate training to understand
32 the hazards associated with radioactive material and be familiar with all applicable regulatory
33 requirements. The RSO should have independent authority to stop operations that he or she
34 considers unsafe. He or she should have sufficient time and commitment from management to
35 fulfill certain duties and responsibilities to ensure that radioactive materials are possessed and
36 used in a safe manner, approved radiation safety procedures are being implemented, and the
37 required records of licensed activities are maintained. Typical RSO duties are illustrated in
38 Figure 8-5 and described in Appendix E of this NUREG. The NRC requires the name of the
39 RSO to be listed on the license to ensure that licensee management always has a responsible,
40 qualified person and that the named individual knows of his or her designation as RSO.
41 Appendix E of this NUREG also provides a model Delegation of Authority, which should be used
42 to further emphasize the agreement on duties and responsibilities of the RSO by management
43 and the designated RSO.

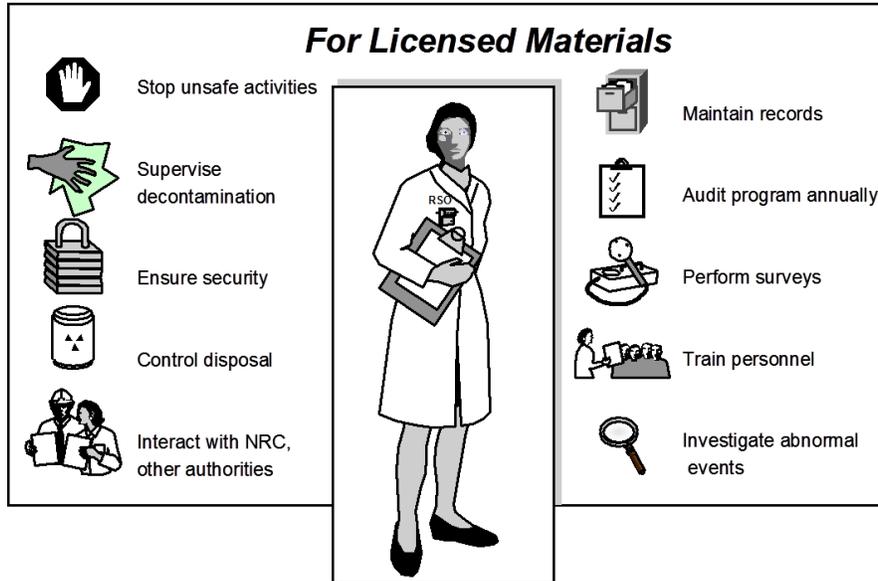


Figure 8-5. Typical Duties and Responsibilities of RSOs

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- 1 The NRC believes that to demonstrate adequate training and experience, the RSO should have,
- 2 at a minimum, (i) a college degree at the bachelor level or equivalent training and experience in
- 3 physical, chemical, biological sciences, or engineering; and (ii) training and experience
- 4 commensurate with the scope of proposed activities.

- 5 Training should include the following subjects:
 - 6 • radiation protection principles
 - 7 • characteristics of ionizing radiation
 - 8 • units of radiation dose and quantities
 - 9 • radiation detection instrumentation
 - 10 • biological hazards of exposure to radiation (appropriate to types and forms of licensed
 - 11 material to be possessed and used)
 - 12 • NRC regulatory requirements and standards
 - 13 • hands-on use of radioactive materials

- 14 Experience should include the following areas:
 - 15 • planning and conducting evaluations, surveys, and measurements similar to those
 - 16 required by the licensee's Radiation Safety Program
 - 17 • using licensed materials that are similar in types, forms, and quantities to those
 - 18 proposed for use under the license
 - 19 • securing and controlling licensed materials

- 1 • monitoring inventory of materials possessed under the license; maintaining records of
2 receipts, transfers, and disposal of licensed materials
- 3 • storing, handling, disposing of and documenting radioactive waste materials
- 4 • planning, conducting and documenting audits and other evaluations of the radiation
5 safety program
- 6 • evaluating and documenting radiation exposures
- 7 • maintaining required records of the radiation safety program and providing required
8 reports
- 9 • other applicable duties and responsibilities as described in Appendix E of this NUREG

10 The amount of training and experience will depend on the type, form, quantity, and proposed
11 use of the licensed material requested. For instance, in addition to a college degree, RSOs at a
12 manufacturing company where workers handle curie quantities of radioactive material should be
13 specialists in the field of radiation protection and may need 40 hours of radiation safety training
14 specific to their job duties, as well as 1 year of experience with similar types, forms, quantities,
15 and uses of radioactive material before the individual is qualified to be RSO. On the other hand,
16 RSOs at “manufacturers” who are importers of timepieces containing tritium that are received in
17 the U.S. as completed products that will be distributed as exempt quantities may only require a
18 few hours of radiation safety training and no prior experience with timepieces containing tritium
19 to be qualified as an RSO. The proposed RSO’s training and experience must be sufficient to
20 identify and control the anticipated radiation hazards. For example, the RSO should have
21 experience planning and conducting evaluations, surveys, and measurements similar to those
22 required by the licensee’s Radiation Safety Program. In addition, the RSO designee should
23 have obtained the above training in a formal course designed for RSOs, presented by an
24 academic institution, commercial radiation safety consulting company, or a professional
25 organization of radiation protection experts.

26 **Response from Applicant:**

27 Provide the following:

- 28 • name of the proposed RSO
- 29 • information demonstrating that the proposed RSO is qualified by training and experience
30 should include, as a minimum:
 - 31 – formal training and/or education in radiation safety (topics covered, duration of
32 training when training was received, identity/location of training provider)
33 (Note: a course outline may be provided)
 - 34 – experience using licensed materials (types, forms, quantities handled, activities
35 performed, duration of experience)
 - 36 – experience performing the duties of a Radiation Safety Officer (activities, duration of
37 experience, scope of program)

Applicants should provide information about the proposed RSO's training and experience relative to the licensed material and uses requested in the application. Do not include personally identifiable information (PII) (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). For further information concerning PII, see Chapter 6, "Identifying and Protecting Sensitive Information." Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal private information. Submittal of unrelated material may slow down the review process.

1 **Note:** It is important to notify the NRC and obtain a license amendment before making changes
2 in the designation of the RSO responsible for the radiation safety program.

3 **8.7.2 Authorized Users**

4 **Regulations:** 10 CFR 20.1101(b); 10 CFR 30.33(a)(3); 10 CFR 40.32(b); 10 CFR 70.23(a)(2);
5 10 CFR 71.5; 10 CFR 110.26; 10 CFR 110.27; 10 CFR 110.28; 10 CFR 110.29; 10 CFR
6 110.30; 10 CFR 110.42; 10 CFR 110.43; 10 CFR 110.44; 49 CFR Parts 170 through 189
7 (appropriate to the mode of transport).

8 **Criteria:** Authorized Users (AUs) must have adequate training and experience with the types
9 and quantities of licensed material that they propose to possess and use.

10 **Discussion:** Applicants must name at least one individual who is qualified to use the requested
11 licensed materials. An AU is a person whose training and experience have been reviewed and
12 approved by NRC, who is normally named on the license, and who uses or directly supervises
13 the use of licensed material. The AU's primary responsibility is to ensure that radioactive
14 materials are used safely and according to regulatory requirements. The AU is also responsible
15 for ensuring that procedures and engineering controls are used to keep occupational doses and
16 doses to members of the public ALARA.

17 AUs must have adequate training and experience to provide reasonable assurance that they will
18 use licensed material safely, including maintaining the security of, and controlling access to,
19 licensed material, and responding appropriately to events or accidents involving licensed
20 material to prevent the spread of contamination.

21 The NRC believes that the AU should have (i) a college degree at the bachelor level or
22 equivalent training and experience in physical, chemical, or biological sciences or in engineering
23 and (ii) training and experience commensurate with the scope of proposed activities. Training
24 should include the following subjects:

- 25 • radiation protection principles
- 26 • characteristics of ionizing radiation
- 27 • units of radiation dose and quantities
- 28 • radiation detection instrumentation
- 29 • biological hazards of exposure to radiation (appropriate to the types and forms of
30 byproduct material that the licensee will use)

1 • hands-on use of radioactive materials

2 The amount of training and experience needed will depend upon the type, form, quantity, and
3 proposed use of the licensed material requested, but it should cover the subjects stated.

4 For instance, in addition to a college degree, authorized users at a manufacturing company
5 where workers handle curie quantities of radioactive material should have 40 hours of radiation
6 safety training and a minimum of 6 months of experience with similar types, forms, quantities,
7 and uses of radioactive material before the individual is qualified to be an authorized user. On
8 the other hand, authorized users at “manufacturers” who are importers of timepieces containing
9 tritium that are received in the U.S. as completed products that will be distributed as exempt
10 quantities may only require a few hours of radiation safety training and no prior experience with
11 timepieces containing tritium to be qualified as an authorized user. In general, AUs must
12 demonstrate training and experience with the type and quantity of material that they propose to
13 use. For example, someone with training and experience only with sealed radioactive sources
14 may not be qualified to use or supervise the use of unsealed licensed material. In addition,
15 someone with experience using only trace quantities may not understand the risks of working
16 with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants
17 should pay particular attention to the type of radiation involved. For example, someone
18 experienced with gamma emitters may not have appropriate experience for high-energy
19 beta emitters.

20 An AU is considered to be supervising the use of radioactive materials when he or she directs
21 personnel in operations involving the licensed material. Although the AU may delegate specific
22 tasks to supervised users (e.g., conducting surveys, keeping records), he/she is responsible for
23 the safe use of radioactive material to ensure that areas are not contaminated.

24 **Response from Applicant:** Provide the following:

- 25 • name of each proposed AU with the types and quantities of licensed material to be
26 possessed or possessed and used
- 27 • information demonstrating that each proposed AU is qualified by training and experience
28 to possess and use the requested licensed materials, including, as a minimum
- 29 – formal training and/or education in radiation safety (topics covered, duration of
30 training when training was received, identity/location of training provider)
31 (Note: a course outline may be provided)
- 32 – experience using licensed materials (types, forms, quantities handled, activities
33 performed, duration of experience)

Applicants should provide information about the proposed AU’s training and experience relative to the licensed material requested in the application. Do not include PII (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). For further information concerning PII, see Chapter 6, “Identifying and Protecting Sensitive Information.” Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, etc. Submittal of unrelated material may slow the review process.

1 **Note:** Applicants for broad scope programs should refer to NUREG–1556, Vol. 11,
2 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses
3 of Broad Scope.” Broad-scope programs may be permitted to name authorized users without
4 amending the license.

5 **8.8 Item 8: Training for Individuals Working in or Frequenting** 6 **Restricted Areas**

7 **Regulations:** 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 20.1801; 10 CFR 20.1802;
8 10 CFR 30.7; 10 CFR 30.9; 10 CFR 30.10; 10 CFR 30.33(a)(3); 10 CFR 30.34(e);
9 10 CFR 37.43; 10 CFR 40.32(b); 10 CFR 40.41(e); 10 CFR 70.23(a)(2); 10 CFR 70.32(b)

10 **Criteria:** Individuals whose assigned duties involve exposure to radiation and/or radioactive
11 material (from both licensed and unlicensed sources), and in the course of their employment are
12 likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv)
13 [100 mrem], whether from all external sources, all internal sources, or any combination, must
14 receive instruction commensurate with their duties and responsibilities, as required by
15 10 CFR 19.12. Any licensee that possesses an aggregated Category 1 or Category 2 quantity
16 of radioactive material must implement a training program for those individuals implementing the
17 security program.

18 **Discussion:** Before beginning work with licensed material, most individuals must receive
19 radiation safety training commensurate with their assigned duties and specific to the licensee’s
20 Radiation Safety Program. Each individual should also receive periodic (for example, annual)
21 refresher training. Training should also be performed whenever there is a significant change in
22 hazards, duties, procedures, regulations, or terms of the license.

23 Licensees should not assume that safety instruction has been adequately covered by prior
24 employment or academic training. Site-specific training should be provided for all individuals.
25 Particular attention should be given to persons performing work with radioactive materials that
26 may require special procedures, such as working in hot cells. Ancillary personnel (e.g., clerical,
27 housekeeping, security) whose duties may require them to work in the vicinity of radioactive
28 material (whether escorted or not) need to be informed about radiation hazards and the
29 appropriate precautions. The licensee should assess each individual’s involvement with
30 licensed material and cover each applicable subject appropriately.

31 Training may be in the form of lecture, demonstrations, videotape, online, or self-study, and
32 should emphasize practical subjects important to the safe possession and use of licensed
33 material. If training is not conducted by an instructor, a method should be adopted whereby a
34 trainee can ask questions and discuss topics relating to occupational radiation exposure. The
35 guidance in Appendix F of this NUREG, Radiation Safety Training Topics, may be used to
36 develop a training program. The program should consider all topics pertinent for each group of
37 workers, as well as the method and frequency of training. The licensee should determine
38 whether the training succeeded in conveying the desired information and adjust the training
39 program as necessary. This assessment may be performed by a test or observation of the
40 individual in the performance of assigned duties. Remedial training for missed test questions or
41 other areas of apparent weakness should be conducted or additional formal training planned to
42 cover deficient areas.

1 The person conducting the training should be a qualified individual (e.g., a person who meets
2 the qualifications for RSO or authorized user on the license and is familiar with the
3 licensee's program).

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must implement a training program in accordance with 10 CFR 37.43, "General security program requirements," to ensure that those individuals who may have a responsibility to implement portions of the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC for review and approval.

4 **Response from Applicant:** Submit a description of the radiation safety training program,
5 including topics covered, groups of workers, assessment of training, qualifications of instructors,
6 and the method and frequency of training.

7 **8.9 Item 9: Facilities and Equipment**

8 **Regulations:** 10 CFR 20.1101(b); 10 CFR 20.1406; 10 CFR 30.33(a)(2); 10 CFR 30.35(g);
9 10 CFR Part 37; 10 CFR 37.49; 10 CFR 37.53; 10 CFR 40.27(b); 10 CFR 40.28(b);
10 10 CFR 40.31(h); 10 CFR 40.32(c); 10 CFR 40.34(a); 10 CFR 51.20(b); 10 CFR 70.23(a)(3);
11 10 CFR 70.39(a).

12 **Criteria:** Facilities and equipment must be adequate to protect health and minimize danger to
13 life or property and provide physical protection of Category 1 and Category 2 quantities of
14 radioactive material. They must minimize the possibility of contamination and keep exposures
15 to workers and the public ALARA. Applicants must describe how facility design and procedures
16 for operation will minimize, to the extent practicable, contamination of the facility and the
17 environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the
18 generation of radioactive waste.

19 **Discussion:** Applicants must demonstrate that their facilities and equipment provide sufficient
20 engineering controls and barriers to protect the health and safety of the public and its
21 employees, keep exposures to radiation and radioactive materials ALARA, and minimize the
22 danger to life and property from the uses of the types and quantities of radioactive materials to
23 be used.

24 Applicants may delay completing facilities and acquiring equipment until after the application
25 review is completed, in case changes are required as a result of the application review. This
26 also ensures the adequacy of the facilities and equipment before the applicant makes a
27 significant financial commitment. In all cases, the applicant may not possess or use licensed
28 material until after the facilities are approved, equipment is procured, and the license is issued.

1 Applicants may delay completing facilities and acquiring equipment until after the application
2 review is completed, in case changes are required as a result of the application review.

3 This also ensures the adequacy of the facilities and equipment before the applicant makes a
4 significant financial commitment. In all cases, the applicant may not possess or use licensed
5 material until after the facilities are approved, equipment is procured, and the license is issued.

6 Applicants are reminded that records important to decommissioning as described in
7 10 CFR 30.35(g) and corresponding regulations in Parts 40 and 70 include the following:

- 8 • as-built drawings and modifications of structures and equipment in restricted areas
- 9 • as-built drawings and modifications of locations of possible inaccessible contamination
10 such as buried pipes that may be subject to contamination
- 11 • records of spills and unusual occurrences that may result in contamination of the facility
12 or site

13 These records are required to be maintained in an identifiable location. Facilities are required to
14 meet NRC criteria prior to release. Therefore, careful facility design is important to prevent
15 contamination, or facilitate decontamination, reducing the costs needed for decommissioning.
16 For further information, see Section 8.5.2, Financial Assurance and Recordkeeping for
17 Decommissioning.

18 For additional guidance regarding facilities and equipment, refer to Appendix G of this NUREG,
19 Facilities and Equipment.

20 When designing facilities and developing procedures for their safe use, applicants should think
21 ahead and consider how to minimize radioactive contamination during operation,
22 decontamination and decommissioning efforts, and radioactive waste generation. When
23 submitting new applications, applicants should consider the following:

- 24 • implementation of and adherence to good health physics practices in operations
- 25 • minimization of areas, to the extent practicable, where licensed materials are used
26 and stored
- 27 • maximization of the frequency of surveys, within reason, to minimize spread of
28 contamination in the event of a spill
- 29 • choice of isotope to be used, whenever practical, in consideration of half-life and
30 chemical composition
- 31 • appropriate filtration of effluent streams
- 32 • use of nonporous materials for such areas as counter tops and flooring
- 33 • ventilation stacks and ductwork with minimal lengths and minimal abrupt changes
34 in direction
- 35 • use of appropriate plumbing materials with minimal pipe lengths and traps

- 1 • minimization of the number of disposal sites (sinks) where liquid waste is disposed

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must,

- implement the physical protection requirements in 10 CFR Part 37 for material in use and storage, at both permanent and temporary jobsites; and
- in accordance with 10 CFR 37.49 and 10 CFR 37.53, be able to monitor and immediately detect and assess any unauthorized entries into security zones, including those surrounding mobile devices.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, “Implementation Guidance for 10 CFR Part 37, ‘Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.’” Additional information regarding best practices for the protection of risk-significant radioactive material is available in NUREG–2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material.”

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC for review and approval.

2 **Response from Applicant:**

- 3 • Describe the facilities and equipment to be made available at each location where
4 radioactive material will be possessed or possessed and used (see Appendix G of this
5 NUREG for topics to consider). This information should be from the point of view of
6 performance criteria. For example, state the purpose of your filtration equipment and the
7 associated acceptance criteria to accomplish this purpose (such as the ventilation flow
8 rate you are trying to maintain).
- 9 • Include a description of the area(s) assigned for the receipt, shipping, storage,
10 preparation, security, and measurement of radioactive materials.
- 11 • Submit a diagram showing the locations of shielding, the proximity of radiation sources
12 to unrestricted areas, and other items related to radiation safety (see Figures 8-6).
- 13 • When applicable to facilities where radioactive materials may become airborne, the
14 diagrams should contain schematic descriptions of the ventilation systems, with pertinent
15 airflow rates, pressures, filtration equipment, and monitoring systems.
- 16 • Diagrams should be drawn to a specified scale, or dimensions should be indicated.
- 17 • For facilities where it is anticipated that more than one laboratory or room may be used,
18 a generic laboratory or room diagram may be submitted.
- 19 • If radioactive materials will be used with animals, include a description of the
20 animal-handling housing facilities. NUREG–1556, Vol. 7 may also be used as guidance.
- 21 Diagrams of facilities should be marked: “Security Related Information—Withhold under
22 10 CFR 2.390.”

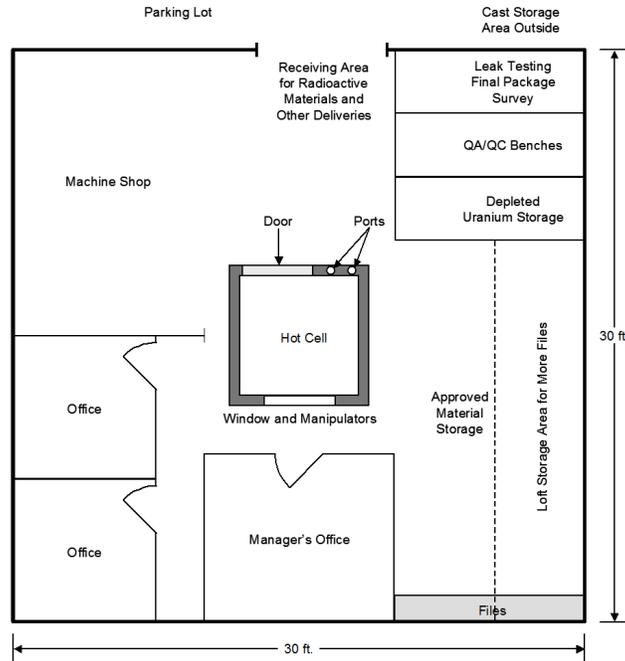


Figure 8-6. Diagram Showing Information Related to Radiation Safety. *This diagram is an example only and does not contain actual security-related information.*

1 **8.10 Item 10: Radiation Safety Program**

2 **8.10.1 Audit and Review of Program**

3 **Regulations:** 10 CFR 20.1101; 10 CFR 20.2102, 20.2110, 10 CFR 21.21(a); 10 CFR 37.33;
4 10 CFR 37.55

5 **Criteria:** Licensees must review the content and implementation of their radiation safety
6 programs at least annually to ensure the program

- 7 • is commensurate with the scope and extent of licensed activities
- 8 • is compliant with NRC and DOT regulations (as applicable), and the terms and
9 conditions of the license
- 10 • maintains occupational doses and doses to members of the public ALARA
11 (10 CFR 20.1101)
- 12 • is documented

13 Records of audits and other reviews of program content are maintained for 3 years after the
14 record is made.

15 Licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material
16 must annually review their access authorization program and security program.

17 **Discussion:** Appendix H of this NUREG contains a suggested audit program that is specific to
18 possession licenses for manufacturing and distribution and is acceptable to NRC. Since all

1 areas indicated in Appendix H may not be applicable to every licensee and all items may not
2 need to be addressed during each audit, licensees may wish to develop a program-specific
3 audit checklist.

4 The NRC encourages licensee management to conduct performance-based reviews by
5 observing work in progress, interviewing staff, and spot-checking required records. As part of
6 the audit program, licenses should consider including unannounced audits of users to observe
7 whether radiation safety procedures are being followed.

8 It is essential that once problems are identified, comprehensive corrective actions are taken in a
9 timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development
10 and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this
11 subject. The NRC routinely reviews licensee's records to verify whether appropriate corrective
12 actions were implemented in a timely manner to address recurrence. It is in the best interest of
13 the licensee to identify potential violations of regulatory requirements and take necessary steps
14 to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee
15 for these violations if prompt and effective corrective actions are implemented. The NRC's
16 Enforcement Policy may be found online at [http://www.nrc.gov/about-](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html)
17 [nrc/regulatory/enforcement/enforce-pol.html](http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html), and the Enforcement Manual may be found online
18 at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>. For examples of the
19 NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's
20 enforcement documents at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

21 With regard to audit records, 10 CFR 20.2102 requires, in part, that licensees maintain records
22 of "audits and other reviews of program content and implementation" for 3 years after the record
23 is made. The NRC has found audit records that contain the following information to be
24 acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the
25 auditor(s), areas audited, audit findings, corrective actions, and followup.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or
Category 2 quantity of radioactive material must,

- in accordance with 10 CFR 37.33, review its access authorization programs at least annually to confirm compliance with the requirements of Subpart B of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified; and
- in accordance with 10 CFR 37.55, review its security program at least annually to confirm compliance with the requirements of Subpart C of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.'" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC for review and approval.

1 **Response from Applicant:** The applicant is not required to, and should not, submit its audit
2 program to the NRC for review as part of a license application. However, this matter may be
3 reviewed during NRC inspections.

4 **References:**

5 • Inspection Procedure 87126, "Industrial/Academic/Research Programs,"
6 September 2005

7 • Inspection Procedure 87125, "Materials Processor/Manufacturer Programs,"
8 September 2005

9 • Information Notice 96-28, "Suggested Guidance Relating to Development and
10 Implementation of Corrective Action," dated May 1, 1996

11 **8.10.2 Radiation Monitoring Instruments**

12 **Regulations:** 10 CFR 20.1501; 10 CFR 20.2103(a); 10 CFR 30.33(a)(2)

13 **Criteria:** Licensees must possess, or have access to, radiation monitoring instruments that are
14 necessary to protect health and minimize danger to life or property. Instruments used for
15 quantitative radiation measurements must be calibrated periodically for the radiation measured.

16 **Discussion:** Licensees should possess, or have access to, calibrated radiation
17 detection/measurement instruments or licensed services to perform, as necessary,
18 the following:

- 19 • package surveys
- 20 • measure personnel and facility contamination
- 21 • test for sealed source leaks
- 22 • take and measure air samples
- 23 • take bioassay measurements
- 24 • take effluent release measurements
- 25 • perform dose rate surveys

26 For the purposes of this document, radiation monitoring instruments are defined as any device
27 used to measure the radiological conditions at a licensed facility. Some of the instruments that
28 may be used to perform the above functions include:

- 29 • portable or stationary count rate meters
- 30 • portable or stationary dose rate or exposure rate meters
- 31 • single or multichannel analyzers
- 32 • liquid scintillation counters
- 33 • gamma counters
- 34 • proportional counters
- 35 • solid state detectors
- 36 • neutron detectors

37 Other equipment and instrumentation associated with the radiation hazard assessment also
38 must be calibrated periodically, in accordance with 10 CFR 20.1501(c). This includes

1 equipment used to collect radiological samples to perform assessments of airborne hazards and
2 other radiological hazards that cannot be directly assessed, such as

- 3 • rotameters
- 4 • anemometers
- 5 • other devices that measure air pump flow rates, volumes, and time
- 6 • liquid volume collection/measurement devices

7 The choice of instrument should be appropriate for the type of radiation to be measured, and for
8 the type of measurement to be taken (e.g., count rate, dose rate). Applications should include
9 descriptions of the instrumentation available for use and the instrumentation that applicants
10 intend to purchase prior to starting licensed activities. The description should include the type of
11 instrument and probe, and the instrument's intended purpose.

12 NRC requires that radiation survey instruments used for quantitative measurements be
13 calibrated periodically. Calibrations requiring the use of radioactive sources should be
14 performed by the instrument manufacturer or a person specifically authorized by NRC or an
15 Agreement State, unless the applicant specifically requests this authorization. Radiation survey
16 instruments should be calibrated at least annually (every 12 months), unless another frequency
17 is specified by regulation or license condition. Applicants seeking authorization to perform
18 radiation survey instrument calibrations must submit procedures for review. The licensee may
19 wish to review available industry standards for calibration of instruments, such as
20 American National Standards Institute (ANSI) N323A-1997, "Radiation Protection
21 Instrumentation Test and Calibration, Portable Survey Instruments." Appendix I of this NUREG
22 provides radiation monitoring instrument specifications and a model radiation survey instrument
23 calibration program. Applicants should be aware that calibrations often require possession and
24 use of a calibration source or device. Regardless of whether an applicant is authorized to
25 calibrate radiation survey meters or contracts with an authorized firm to perform calibrations, the
26 licensee must retain records of the calibration of instruments and equipment used for
27 quantitative radiation measurements for 3 years after the record is made, in accordance with 10
28 CFR 20.2103(a).

29 Some instruments may only need to be checked periodically for operability and response to
30 radiation rather than receive full calibration. For example, G-M detection instruments used to
31 identify contamination in laboratories may only need to be checked for ability to detect low-level
32 contamination. However, such instruments cannot be used for quantitative measurement of
33 surface contamination or radiation levels without a calibration with appropriate radioactive
34 sources, as described in Appendix I of this NUREG.

35 **Response from Applicant:**

36 **For Radiation Monitoring Instruments**

37 Describe the instrumentation that will be used to perform required surveys.

38 **AND**

39 State that: "We will use instruments that meet the radiation monitoring instrument specifications
40 published in Appendix I in NUREG-1556, Volume 12, Revision 1, 'Program-Specific Guidance
41 About Possession Licenses for Manufacturing and Distribution.' We reserve the right to
42 upgrade our radiation survey instruments as necessary."

1 **For Instrument Calibration**

2 State that: "Instruments will be calibrated before first use, at least annually thereafter, and after
3 any repair, by a vendor that the NRC or an Agreement State has licensed to perform
4 instrument calibration."

5 **OR**

6 State that: "We will implement the model radiation survey instrument calibration program
7 published in Appendix I in NUREG-1556, Volume 12, Revision 1, 'Program-Specific Guidance
8 About Possession Licenses for Manufacturing and Distribution.'"

9 **OR**

10 Submit equivalent procedures for instrument calibrations.

11 **Note:** Alternative responses will be reviewed using the criteria listed above.

12 **8.10.3 Material Receipt and Accountability**

13 **Regulations:** 10 CFR 20.2207; 10 CFR 30.34(e); 10 CFR 30.35(g); 10 CFR 30.41;
14 10 CFR 30.51; 10 CFR 20.1501(a); 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906;
15 10 CFR 20.2001; 10 CFR 20.2108; 10 CFR 20.2201; 10 CFR 20.2207; 10 CFR 31.11;
16 10 CFR 37.75; 10 CFR 37.77

17 **Criteria:** Licensees must do the following:

- 18 • develop, implement, and maintain written procedures for safely opening packages
- 19 • develop, implement, and maintain procedures to ensure security and accountability of
20 licensed material
- 21 • maintain records of receipt, transfer, and disposal of licensed material
- 22 • update transactions in the NSTS, including an annual inventory reconciliation,
23 if applicable
- 24 • preplan, coordinate, and provide advance notification of shipment of Category 1
25 quantities of radioactive material, and coordinate shipment of Category 2 quantities of
26 radioactive material
- 27 • conduct physical inventories at intervals not to exceed 6 months (or some other interval
28 justified by the applicant and approved by the NRC) to account for all sealed sources in
29 accordance with license condition

30 **Discussion:** To ensure that only trained, experienced, and authorized individuals use or
31 supervise the use of licensed material, the RSO should know who has requested an order of
32 licensed material and the types and amounts of licensed materials requested. Control
33 procedures should also be established for the procurement of licensed materials that may be
34 obtained outside the normal channels (e.g., through the loan or other transfer of materials

1 without purchase or through surplus). A model procedure for Ordering and Receiving
2 Radioactive Material is included in Appendix L of this NUREG.

3 Licensed material is considered to become part of the licensee's inventory at the time that it is
4 received by the licensee, be it during normal working hours or after hours when delivered by the
5 carrier, in accordance with procedures established by the licensee. If through some error, the
6 licensee receives material it is unauthorized to possess or receives quantities of material that
7 would result in the total inventory being in excess of license possession limits, the licensee
8 should place the package in secure storage and arrange for the return of these materials in a
9 timely manner. If return of the materials is not possible, the licensee should contact the NRC
10 regional office and request issuance of an expedited license amendment. The materials must
11 not be used until the amendment is granted.

12 Licensees should make arrangements to receive radioactive packages when they are delivered
13 or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee
14 can pick up the package expeditiously. Licensees are required to develop, implement, and
15 maintain written procedures for safely opening packages, in accordance with 10 CFR 20.1906,
16 "Procedures for Receiving and Opening Packages." Some packages may require special
17 procedures that take into consideration the type, quantity, or half-life of the nuclide being
18 delivered. Model procedure for safely opening packages containing licensed materials is
19 included in Appendix L of this NUREG.

20 In many limited-scope radiation safety programs, the RSO or his/her staff usually receives the
21 incoming package directly from the carrier and performs all verification, surveying, opening, and
22 documentation for inventory. The package is then delivered to the AU, or the AU retrieves the
23 package from the RSO. If the package is transported over public roads by the licensee, it must
24 be repackaged and transported, in accordance with DOT regulations.

25 If the package of licensed material is delivered to the licensed facility's receiving department,
26 individuals working in that department should be trained to do the following:

- 27 • Identify the package as radioactive by labeling and shipping papers.
- 28 • Segregate the package from other incoming items in a secured area until released by
29 the RSO.
- 30 • Notify the RSO.

31 When notified by the receiving unit that a package of licensed material has arrived, the RSO or
32 his/her staff should retrieve the package and follow the safe-opening procedures.

33 NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages
34 containing licensed material. These requirements are described in Table 8-2, below.

Package	Contents	Survey Type	Survey Time*
Damaged	Licensed Material	Radiation Level and Radioactive Contamination [§20.1906(b)(3)]	As soon as practicable, but not later than 3 hours after receipt of package

35

Package	Contents	Survey Type	Survey Time*
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Greater Than Type A	Radiation Level (§20.1906(b)(2)) and Radioactive Contamination [§20.1906(b)(1)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Greater Than Type A	Radiation Level [§20.1906(b)(2)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Not Gas Nor Special Form Less Than or Equal to Type A	Radioactive Contamination [§20.1906(b)(1)]	As soon as practicable, but not later than 3 hours after receipt of package
Labeled (White I, Yellow II, Yellow III)	Gas or Special Form Less Than or Equal to Type A	None [§20.1906(b)(1)]	None
Not Labeled	Licensed Material	None [§20.1906(b)]	None†

*Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next work day to perform the required surveys.
†Excepted Packages and limited-quantity packages received by many laboratories are required to have the appropriate identification number from the Hazardous Materials Table in 49 CFR 172.101 (i.e., the “UN number”) on the outside of the box, identifying it as containing radioactive materials. It is good health physics practices to perform an incoming survey on these packages, even though transportation regulations do not require it.

1 The licensee is required to immediately notify the final delivery carrier and the NRC Operations
2 Center by telephone at 310-816-5100, pursuant to 10 CFR 20.1906(d), when removable
3 radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or external radiation
4 levels exceed the limits of 10 CFR 71.47. The limits in 10 CFR 71.87(i) refer to
5 49 CFR 173.443, Table 9; for packages that are not transported by exclusive use shipment
6 (i.e., most packages), the relevant limits will be for “Non-fixed external radioactive contamination
7 limits for packages” for beta/gamma emitters and low-toxicity alpha emitters, 240 dpm per cm²,
8 and for all other alpha emitters, 24 dpm/cm². The limits in 10 CFR 71.47 that are applicable to
9 packages that are not transported by exclusive-use shipment (i.e., most packages) are 2 mSv/h
10 [200 mrem/h] at any point on the external surface of the package and the transport index does
11 not exceed 10.

12 As illustrated in Figure 8-7, licensed materials must be tracked from “receipt to disposal” in order
13 to ensure accountability and to ensure that possession limits listed on the license are
14 not exceeded.

15 10 CFR 20.1801 and 20.1802 require licensees to secure radioactive materials from
16 unauthorized removal or access while in storage and to control and maintain constant
17 surveillance over licensed material that is not in storage. Applicants for limited-scope licenses
18 must establish policies and procedures to ensure compliance with security requirements. It is
19 recognized that loss, theft, or misplacement of licensed material can occur; however, licensees
20 must have in place an accountability and control system for promptly detecting losses of
21 licensed material.

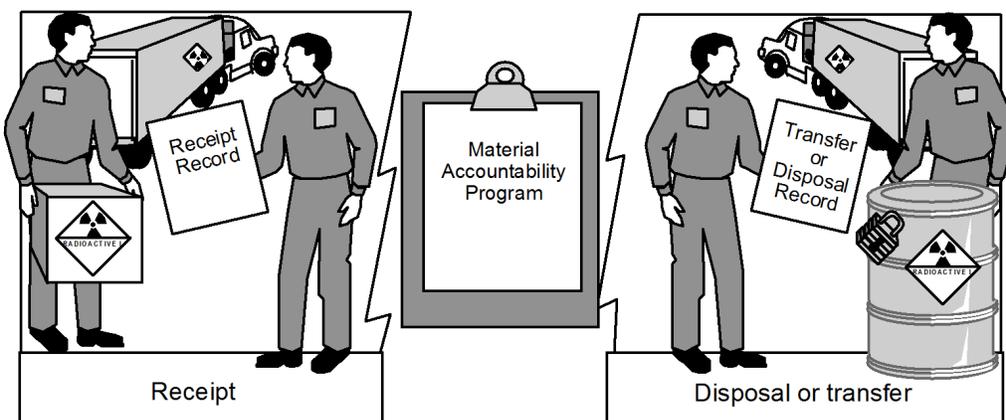


Figure 8-7. Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal of licensed material.

1 Inventory and Accountability of Radioactive Materials

2 Licensees who use and/or possess sealed sources are required by license condition to perform
 3 inventories of all sealed sources, including those that are in storage, every 6 months. Licensees
 4 are also required to conduct leak tests of sealed sources at 6-month intervals (or at longer
 5 intervals as specified in the SSD registration certificate). Since leak tests require an individual
 6 to locate and work with the sealed source, records of leak tests may be used as part of an
 7 inventory and accountability program.

8 With regard to unsealed licensed material, licensees may use various methods (e.g., computer
 9 programs, manual ledgers, log books) to account for the inventory of unsealed materials from
 10 the time of receipt, through the use and storage of the unsealed materials, to removal from
 11 inventory through transfer, disposal, and/or radioactive decay. These methods help to ensure
 12 that possession limits are not exceeded. Individual AUs should be able to account for all
 13 materials in their possession, whether the material is in solid, liquid, or gas form, and whether it
 14 is possessed in a stock vial or dispersed in samples or placed into waste containers in the AU's
 15 laboratory. The licensee should be able to account for the location of all materials possessed,
 16 whether the material is located in a secured laboratory cabinet, a locked sample container in a
 17 refrigerator or freezer, or in appropriate waste containers awaiting disposal. The RSO should
 18 perform periodic update of the total inventory of all unsealed materials possessed under the
 19 license. Depending on how often unsealed materials are received and used, the periodic
 20 update may be weekly, monthly, quarterly, or at less frequent intervals.

21 NRC regulations applicable to transfers are stated in 10 CFR 30.41. Sample policy transfer
 22 statements are included in Appendix L of this NUREG. Transfer of licensed materials within the
 23 facility may require special procedures to ensure proper control. Licensees must consider
 24 potential contamination of laboratory equipment or components, such as refrigerators and
 25 freezers, and carefully control the removal of these items for maintenance, repair, or disposal.

Licensees who also possess Radioactive Materials Under a General License or an Exemption

In addition to radionuclides that are specifically listed on their license, licensees frequently possess radioactive material under a general license or that was distributed to them as an exempt quantity or item. 10 CFR Part 31 provides information regarding devices that may be possessed under a general license. Any person who acquires, receives, possesses, uses, or transfers a device under a general license must do so in accordance with the provisions of the general license. A specific licensee may also possess material under a general license. A specific license does not automatically remove general licensee status nor automatically “move” licensed material from the general license to the specific license. The NRC recognizes that multiple authorizations can create some confusion; therefore, a specific licensee always has the option of receiving and possessing radioactive materials that “qualify” for a general license, by adding these to its specific license as described in 10 CFR 31.5(c)(8)(iii) or other applicable regulations. Persons who wish to convert items from a general license to a specific license should discuss the process with the NRC.

Some facilities may have separate laboratories or locations that use material for in-vitro assay that may be possessed under the general license in 10 CFR 31.11. Each location is a separate general license from the other. The multiple locations are not considered to operate under a single general license and are not considered part of the specific license. In accordance with 10 CFR 31.11(c)(1), the possession limit of 7.4 MBq [200 microcuries], only applies to a total amount of iodine-125 (I-125), iodine-131 (I-131), selenium-75 (Se-75), and/or iron-59 (Fe-59) used and/or stored in one location.

Similarly, radioactive material received by a specific licensee under an exemption from the requirements for a license is not subject to the terms and conditions of the specific license. NRC does not require that licensees possess or control these types of devices under the provisions of their specific license.

- 1 Receipt, inventory, transfer, and disposal records must be maintained for the times specified in
- 2 Table 8-3. Typically, these records contain the following types of information:
 - 3 • radionuclide and the activity (in units of becquerels or curies) of byproduct material in
 - 4 each sealed source
 - 5 • manufacturer’s or distributor’s name, model number, and serial number (if appropriate)
 - 6 of each device containing byproduct material
 - 7 • location of each sealed source and device
 - 8 • for inventories, the date of the inventory, and name and signature of the individual
 - 9 conducting the inventory
 - 10 • for materials transferred or disposed of, the date of the transfer or disposal, the name
 - 11 and license number of the recipient, and a description of the affected radioactive
 - 12 material (e.g., radionuclide, activity, manufacturer’s or distributor’s name and model
 - 13 number, serial number)
- 14 Manufacturers/distributors must also make reports to regulatory agencies for exempt and
- 15 general licensed devices distributed so that these can be accounted for and registered in

1 some cases. Please refer to NUREG–1556, Vol. No. 8, “Consolidated Guidance About
 2 Materials Licenses: Program-Specific Guidance About Exempt Distribution Licenses,” and
 3 NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses: Program-Specific
 4 Guidance About Licenses Authorizing Distribution to General Licensees.”

Table 8-3. Record Maintenance

Type of Record	How Long Record Must Be Maintained
Receipt	For as long as the material is possessed and for 3 years following transfer or disposal of the material
Inventory	For 5 years from the date of the inventory in accordance with license conditions
Transfer	For 3 years after each transfer unless a specific requirement dictates otherwise
Disposal	Until NRC terminates the license
Important to Decommissioning*	Until the site is released for unrestricted use

*See Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning,” for more details.

5 Information about locations where licensed material is used or stored are among the records
 6 important to decommissioning and required by 10 CFR 30.35(g). See also Section 8.5.2,
 “Financial Assurance and Record Keeping for Decommissioning.”

The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction Report (NSTTR) to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays enough to no longer be of concern.

In addition to general security requirements for shipment and transfer of a Category 1 or Category 2 quantity of radioactive material, in accordance with 10 CFR 37.75 and 37.77, any licensee that ships Category 1 quantities of radioactive material must preplan and coordinate shipment, and must provide advanced notification of shipments. Under 10 CFR 37.75, any licensee that ships Category 2 quantities of radioactive material must coordinate the shipment of such material. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, “Implementation Guidance for 10 CFR Part 37, ‘Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.’” Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, “Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material.”

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC for review and approval.

7 **Response from Applicant:**

- 8 • State that: “We will comply with the NSTS reporting requirement, as described in
 9 10 CFR 20.2207.”

10 **AND**

- 1 • State that: “We will develop, implement, and maintain procedures for ensuring
2 accountability of license materials at all times.”

3 **AND**

- 4 • Provide either of the following:
- 5 – State that: “Physical inventories will be conducted at intervals not to exceed
6 6 months, to account for all sealed sources and devices received and possessed
7 under the license. Records of inventory will be maintained for a period of 5 years
8 from the date of each inventory and will include the radionuclides, quantities,
9 manufacturer’s name and model numbers, and the date of the inventory.”

10 **OR**

- 11 – Provide a description of the procedures for ensuring that no sealed sources have
12 been lost, stolen, or misplaced.

13 **Notes:**

- 14 • No response is needed from applicants for package opening procedures. Package
15 opening procedures will be reviewed during NRC inspections.
- 16 • Alternative responses will be evaluated using the criteria listed above.

17 **Reference:**

- 18 • NUREG–1516, “Management of Radioactive Material Safety Programs at
19 Medical Facilities”
- 20 • NUREG–1556, Vol. No. 8, “Consolidated Guidance About Materials Licenses:
21 Program-Specific Guidance About Exempt Distribution Licenses”
- 22 • NUREG–1556, Vol. 16, “Consolidated Guidance About Materials Licenses:
23 Program-Specific Guidance About Licenses Authorizing Distribution to
24 General Licensees”
- 25 • NCRP Report No. 114, “Maintaining Radiation Protection Records” (1992)
- 26 • NCRP Report No. 105, “Radiation Protection For Medical and Allied Health
27 Personnel” (1989)
- 28 • NCRP 127, “Operational Radiation Safety Program” (1998)

29 **8.10.4 Occupational Dose**

30 **Regulations:** 10 CFR 19.13, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203,
31 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502,
32 10 CFR 20.1703, 10 CFR 20.2104, 10 CFR 20.2105, 10 CFR 20.2106, 10 CFR 20.2206,
33 10 CFR 20, Appendix B

1 **Criteria:** Licensees must evaluate the potential occupational exposure of all workers and
2 monitor occupational exposure.

3 The use of individual monitoring devices for external dose is required, pursuant to
4 10 CFR 20.1502(a), for

5 • adults who are likely to receive an annual dose in excess of any of the following
6 (each evaluated separately)

- 7 – 5 mSv [0.5 rem] deep-dose equivalent
- 8 – 15 mSv [1.5 rems] lens (of the eye) dose equivalent
- 9 – 50 mSv [5 rems] shallow-dose equivalent to the skin
- 10 – 50 mSv [5 rems] shallow-dose equivalent to any extremity

11 • minors who are likely to receive an annual dose in excess of any of the following (each
12 evaluated separately)

- 13 – 1.0 mSv [0.1 rem] deep-dose equivalent
- 14 – 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent
- 15 – 5 mSv [0.5 rem] shallow-dose equivalent to the skin
- 16 – 5 mSv [0.5 rem] shallow-dose equivalent to any extremity

17 • declared pregnant women who are likely to receive a dose from radiation sources
18 external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem]
19 deep-dose equivalent

20 • individuals entering a high or very high radiation area

21 Internal exposure monitoring is required pursuant to 10 CFR 20.1502(b), for the following:

22 – adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable
23 Annual Limit on Intake (ALI) for ingestion and inhalation

24 – minors likely to receive, in 1 year, a committed effective dose equivalent in excess of
25 1.0 mSv [0.1 rem] and declared pregnant women likely to receive, during the entire
26 pregnancy, a committed effective dose equivalent in excess of 1 mSv [0.1 rem]

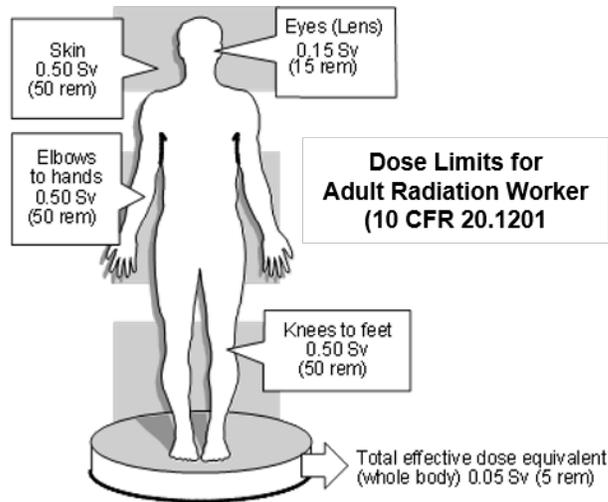


Figure 8-8. Annual Dose Limits for Adult Radiation Workers

1 **Discussion:**

Total effective dose equivalent (TEDE) equals the effective dose equivalent (for external exposures) plus the committed effective dose equivalent (for internal exposures).

2 If an adult radiation worker is likely to receive in 1 year a dose greater than 10 percent of any
 3 applicable limit (See Figure 8-8 for annual dose limits), monitoring for occupational exposure is
 4 required. Monitoring is required for minors and declared pregnant females as shown in the
 5 criteria section. The licensee should perform an evaluation of the dose the individual is likely to
 6 receive prior to allowing the individual to receive the dose. This evaluation need not be made
 7 for every individual; evaluations can be made for employees with similar job functions or
 8 work areas.

9 If this prospective evaluation shows that an adult individual's dose is not likely to exceed
 10 10 percent of any applicable limit, there are no recordkeeping or reporting requirements in
 11 regard to the individual's exposure. For individuals who have received doses at other facilities
 12 in the current year, the previous dose need not be considered in this prospective evaluation.
 13 Only dose that could be received at the facility performing the evaluation need be considered
 14 when determining the need for monitoring, and therefore, recordkeeping and reporting
 15 requirements. If it was determined that monitoring was not required and a subsequent
 16 evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when
 17 monitoring was not provided should be estimated, recorded, and reported. These estimates can
 18 be based on any combination of work location radiation monitoring or survey results, monitoring
 19 results of individuals in similar work situations, or other estimates to produce a "best estimate" of
 20 the actual dose received.

21 Licensees should use NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5,
 22 "Occupational Dose Record for a Monitoring Period," to record individual dose. If monitoring is
 23 not required to demonstrate compliance with all limits but is required relative to one or more
 24 specific limits, the licensee should enter "N/A," for "Not Applicable" in the blocks on
 25 NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity
 26 or skin doses). Where monitoring was provided but not measurable, the licensee should enter
 27 "ND," for "Not Detectable."

1 If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an
 2 applicable limit, then monitoring and reporting of the results of monitoring performed—
 3 regardless of the actual dose received—is required. If air sampling or bioassay is required,
 4 discussion of air sampling or bioassay should provide enough detail so that the NRC staff is
 5 assured that appropriate steps will be taken to manage and monitor such exposure. Licensees
 6 are required to provide individual radiation exposure data to each worker annually and as
 7 otherwise described in 10 CFR 19.13.

8 Licensees should also perform prospective evaluations of the doses that may be received by
 9 occupationally exposed minors and declared pregnant women. As with individual adult workers,
 10 licensees must supply and require the use of individual monitoring devices to monitor external
 11 exposures and monitor the occupational intake of radioactive material when the results of
 12 prospective dose evaluations exceed the doses specified in 10 CFR 20.1502.

13 When personnel dosimeters that require processing to determine the radiation dose are used to
 14 comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a),
 15 licensees must use dosimeters supplied by a NVLAP-approved processor. The exchange
 16 frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their
 17 NVLAP-approved processor for its recommendations for exchange frequency and proper use of
 18 the dosimeter.

19 For guidance about methodologies for determination of internal occupational dose and
 20 summation of occupational dose, refer to Table 8-4.

Table 8-4. Guidance on Personnel Monitoring and Bioassay	
Regulatory Guide 8.7, Revision 2	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20, Revision 1	Applications of Bioassay for I-125 and I-131
Regulatory Guide 8.21, Revision 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23, Revision 1	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.32	Criteria for Establishing a Tritium Bioassay Program
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Doses
Regulatory Guide 8.35, Revision 1	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Facilities

Table 8-4. Guidance on Personnel Monitoring and Bioassay	
ANSI N13.30- 2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

1

2 **Additional Reference for Further Reading:**

- 3 • U.S. Department of Energy (DOE) G 441.1

4 **Response from Applicant:** Provide one of the following statements:

5 “We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored
6 individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.”

7

OR

8 “We will monitor individuals in accordance with the criteria in the section titled, ‘Radiation Safety
9 Program–Occupational Dose’ in NUREG–1556, Vol. 12, Rev. 1, ‘Consolidated Guidance About
10 Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing
11 and Distribution.’”

12

OR, IN LIEU OF THESE STATEMENTS,

13 provide a description of an alternative method for demonstrating compliance with the referenced
14 regulations.

15 **Reference:** The NIST maintains a directory of laboratories that are NVLAP-approved at
16 <http://ts.nist.gov/standards/scopes/dosim.htm>.

17 **Note:**

- 18 • Alternative responses will be evaluated using the criteria listed above.
- 19 • Some licensees choose to provide personnel dosimetry to their workers for reasons
20 other than compliance with NRC requirements (e.g., to respond to worker requests).

21 **8.10.5 Public Dose**

22 **Regulations:** 10 CFR 20.1101(d); 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801;
23 10 CFR 20.1802; 10 CFR 20.2107

24 **Criteria:** Licensees must ensure that licensed material will be used, transported, stored, and
25 disposed of in such a way that members of the public will not receive more than 1 mSv
26 [100 mrem] in a year and that the dose in any unrestricted area will not exceed 0.02 mSv
27 [2 mrem] in any 1 hour from licensed operations. In addition, there is a constraint on the
28 licensee’s air emissions of radioactive material to the environment at a TEDE in excess of
29 10 millirem [0.1 mSv] per year to individual members of the public.

1 **Discussion:** Public dose is defined in 10 CFR Part 20 as “the dose received by a member of
2 the public from exposure to radiation or to radioactive material released by a licensee, or to any
3 other source of radiation under the control of a licensee.” Public dose excludes occupational
4 doses received from background radiation and medical procedures. Whether the dose to an
5 individual is an occupational dose or a public dose depends on the individual’s assigned duties.
6 It does not depend on the area (restricted, controlled, or unrestricted) where the individual is
7 when he or she receives the dose.

8 There are both external exposure components and internal exposure components of public
9 dose. The licensee should review all possible internal and external exposure pathways and
10 decide which are applicable to its operations.

11 For guidance about accepted methodologies for determining dose to members of the public,
12 please refer to Appendix K of this NUREG, Guidance for Demonstrating That Individual
13 Members of the Public Will Not Receive Doses Exceeding the Allowable Limits.

14 Figure 8-9 shows the steps to calculate the annual dose to an individual member of the public.

15 There are many possible internal dose pathways that contribute to the TEDE. The TEDE can,
16 however, be broken down into three major dose pathway groups:

- 17 • airborne radioactive material
- 18 • waterborne radioactive material
- 19 • external radioactive exposure

20 The licensee should review these major pathways and decide which are applicable to
21 its operations.

22 Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b).
23 The extent and frequency of monitoring will depend upon each licensee’s needs. For
24 additional guidance regarding monitoring of effluents, refer to Section 8.10.7, Radiation Safety
25 Program—Surveys and Leak Tests.

26 The regulations in 10 CFR 20.2107, “Records of dose to individual members of the public,”
27 requires that licensees maintain records sufficient to demonstrate compliance with the dose
28 limits for members of the public until the Commission terminates the license.

Calculating the Annual Dose to an Individual Member of the Public

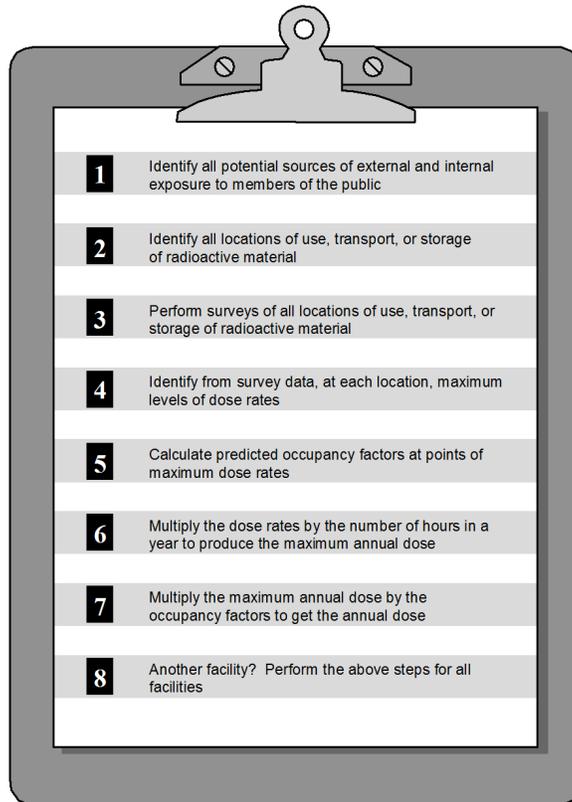


Figure 8-9. Calculating Public Dose. Steps to calculate the annual dose to an individual member of the public (see Appendix K of this NUREG for more information about occupancy factors).

1 **Response from Applicant:**

2 No response is required from the applicant, but records and written materials documenting
3 compliance will be examined during inspection. During NRC inspections, licensees must be
4 able to demonstrate, by measurement or calculation, that the total effective dose equivalent to
5 the individual likely to receive the highest dose from the licensed operation does not exceed the
6 annual limit for members of the public.

7 See Appendix K of this NUREG for examples of methods to demonstrate compliance.

8 **8.10.6 Safe Use of Radionuclides and Emergency Procedures**

9 **Regulations:** 10 CFR 19.11(a)(3); 10 CFR 20.110; 10 CFR 20.1406; 10 CFR 20.1801;
10 10 CFR 20.1802; 10 CFR 20.1902 – 1905; 10 CFR 20.2201 – 2203; 10 CFR 21.21;
11 10 CFR 30.32(i); 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR 30.72; 10 CFR Part 32;
12 10 CFR Part 40; 10 CFR 37 (Subpart B); 10 CFR 37.21(a); 10 CFR 37.45; 10 CFR 37.49;
13 10 CFR 37.53; 10 CFR Part 70

14

1 **Criteria:** Licensees are required to do all of the following:

- 2 • Keep radiation doses to workers and members of the public ALARA.
- 3 • Ensure security of licensed material.
- 4 • Make the required notifications of events to NRC.

5 **Discussion:** Licensees are responsible for the security and safe possession and use of all
6 licensed material from the time it arrives at their facility until it is used, transferred, and/or
7 disposed. Licensees should develop written procedures to ensure safe possession and use of
8 licensed material, and the procedures should also include operational and administrative
9 guidelines. The written procedures should provide reasonable assurance that only
10 appropriately trained personnel will handle and use licensed material without undue hazard to
11 workers or members of the public.

12 Licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material
13 must also establish, implement, and maintain its access authorization program; coordinate, to
14 the extent practicable, with local law enforcement authorities, for responding to threats to the
15 licensee's facility; and be able to monitor and immediately detect and assess any unauthorized
16 entries into security zones.

17 **General Safety and Manufacturing Process Procedures**

18 The written procedures should include the following elements:

- 19 • contamination controls
- 20 • waste disposal practices
- 21 • personnel and area monitoring (including limits)
- 22 • use of protective clothing and equipment
- 23 • recordkeeping requirements
- 24 • reporting requirements
- 25 • responsibilities

26 These procedures should include policies for:

- 27 • frequency of personnel monitoring
- 28 • use of appropriate shielding (see Figure 8-10)
- 29 • frequent change of gloves to minimize exposure to the individual and to avoid spread of
30 contamination in work areas

31 Applicants should also develop product and radionuclide-specific procedures, based on the
32 respective hazards associated with the products and radionuclides. General safety guidelines
33 are described in Appendix L of this NUREG, General Topics for Safe Possession and Use of
34 Radioactive Materials and Model Emergency Procedures. Applicants should use these
35 guidelines to develop procedures for the safe use of radionuclides.

36

- 1 Licensees should determine if they have areas that require posting, in accordance with
- 2 10 CFR 20.1902, unless they meet the exemptions listed in 10 CFR 20.1903. Also, containers
- 3 of licensed material (including radioactive waste) must be labeled in accordance with
- 4 10 CFR 20.1904, unless they meet the exemptions in 10 CFR 20.1905.

Working Behind a Shield

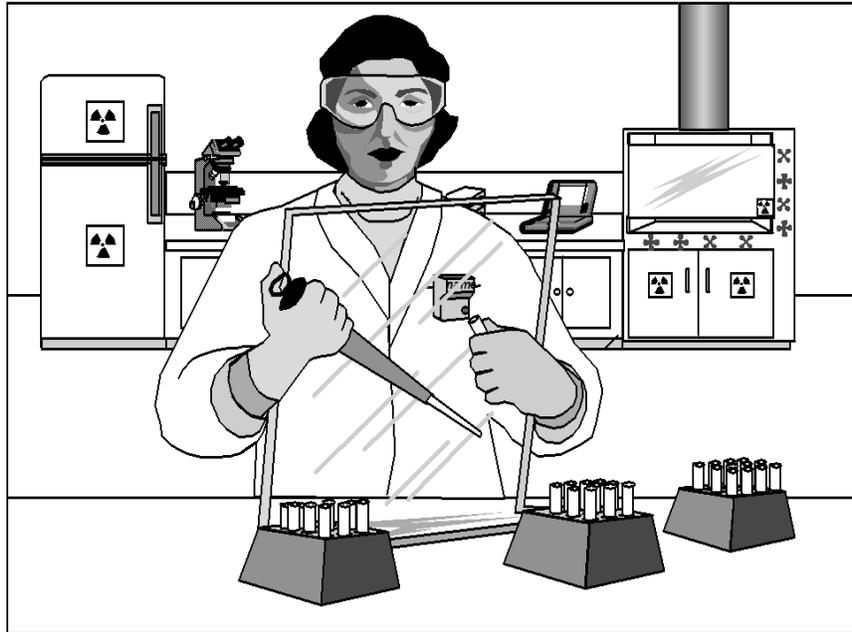


Figure 8-10. Use of Appropriate Shielding. *This worker is using high-density plastic shielding, which is appropriate for radionuclides that emit beta radiation.*

5 Security Procedures

- 6 All licensed materials that are stored in controlled or unrestricted areas must be secured from
- 7 unauthorized access or removal. When any licensed materials are in use in controlled or
- 8 unrestricted areas, they must be under constant surveillance so that the radiation worker can
- 9 prevent others from becoming contaminated by or exposed to the material and to prevent
- 10 persons from removing the material from the area. Acceptable methods for securing material
- 11 will vary from one facility to another. Some alternatives used by licensees include (i) storage
- 12 and use of licensed materials only in restricted areas; (ii) limiting access to an entire facility or
- 13 building or portion of the building only to radiation workers; (iii) providing storage areas that can
- 14 be locked to prevent access to the material; and (iv) implementing procedures that require a
- 15 radiation worker to be within "line of sight" of the materials whenever licensed materials are in
- 16 use. Applicants should develop procedures that clearly state acceptable methods to secure
- 17 licensed material at their facility. Particular attention may need to be paid to security procedures
- 18 at facilities that may have unusual needs due to the activities performed, such as hot cells,
- 19 animal care facilities, and waste processing facilities.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must,

- in accordance with 10 CFR 37.21(a), establish, implement, and maintain its access authorization program in accordance with the requirements of 10 CFR 37, Subpart B;
- in accordance with 10 CFR 37.45, attempt to coordinate with their local law enforcement agency (LLEA) for responding to threats to a licensee's facility; and
- in accordance with 10 CFR 37.49 and 37.53, be able to monitor and immediately detect and assess any unauthorized entries into security zones, including those surrounding mobile devices.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC for review and approval.

1 Emergency Procedures

2 Accidents and emergencies can happen during any operation with radionuclides, including their
3 transportation, use, production processes, transfer, and disposal. Such incidents can result in
4 contamination or release of material to the environment and unintended radiation exposure to
5 workers and members of the public. In addition, loss or theft of licensed material, sabotage,
6 fires, floods, etc., can adversely affect the safety of personnel and members of the public.
7 Therefore, it is necessary to develop written procedures to minimize, as much as possible, the
8 effect of these incidents on personnel, members of the public, and the environment. Applicants
9 that plan to possess quantities of material in excess of the applicable amounts listed in
10 10 CFR 30.72 Schedule C may also be required to submit an "Emergency Response Plan for
11 Responding to a Release." Applicants who need to submit an "Emergency Response Plan"
12 may refer to Regulatory Guide DG-3005, "Standard Format and Content for Emergency Plan for
13 Fuels Cycle and Materials Facilities" for assistance in preparing an emergency plan.

14 Applicants should establish written procedures to handle events ranging from a minor spill to a
15 major accident that may require intervention by outside emergency response personnel. These
16 procedures should include provisions for immediate response, after-hours notification, handling
17 of each type of emergency, equipment, and the appropriate roles of users and the radiation
18 safety staff. Except for minor spills or releases of radioactivity that can be controlled and
19 cleaned up by the user, the licensee's staff should have a clear understanding of their limitations
20 in an emergency, along with step-by-step instructions and clear guidelines for whom to contact.
21 Typical notification and reporting requirements are described in Appendix M of this NUREG.
22 Applicants should use these guidelines to develop procedures for notification and reporting of
23 accidents and emergencies.

24 Licensees should have a sufficient number of appropriate and calibrated radiation survey
25 instruments readily available. Emergency spill kits should be strategically placed in well-marked
26 locations for use by all users and the radiation safety staff. All equipment should be inspected

1 periodically for proper operation, and replenished as necessary. Appendix L of this NUREG
2 includes model emergency procedures. Applicants may adopt these procedures or develop
3 their own, incorporating the safety features included in these model procedures.

4 **Collection of Bioassay Samples**

5 In the event of an emergency where an individual became contaminated and radioactive
6 material was taken into the body through skin absorption or other means, or is suspected of
7 having ingested or inhaled radioactive material, an estimate of the amount of material taken into
8 the body may be required. Frequently, this estimate is made by performing bioassay of the
9 individual. Bioassays may be performed through direct methods, such as whole body counting
10 or thyroid counting, where the radioactive material in the body can be directly measured using
11 appropriate instruments. Bioassays may also be performed through indirect means by sampling
12 urine or other excreta from the body and calculating the intake from the amount of material
13 detected in the samples, the time between suspected intake and sample collection, and
14 knowledge of the rate of excretion of the compound and/or radionuclide from the body. While
15 there are many ways to perform the calculations, including using computer models, the method
16 of calculation is only as good as the quality of the samples and analyses performed. Because a
17 dose estimate may be required, bioassay procedures for a suspected intake may differ from
18 those in a routine bioassay screening program, and your radiation safety program should
19 include procedures and equipment for appropriate sample collection in an emergency. The
20 following items should be considered in developing your procedures:

- 21 • type of bioassay that must be performed (e.g., direct or indirect)
- 22 • number of samples or data points to be collected
- 23 • frequency of sampling (e.g., only once, hourly, daily, weekly)
- 24 • size of the sample to be collected (e.g., 24-hour urine collection)
- 25 • ease/difficulty of sample collection
- 26 • need for written instructions to be provided to the sample collector, who may be the
27 contaminated individual

28 **Response from Applicant:**

29 The applicant should provide the following statements:

30 “Procedures for safe use, security of materials, and emergencies will be developed and
31 documented before receipt of licensed material. Operating and emergency procedures will be
32 implemented and maintained.”

33 **AND**

34 “Procedures will be revised only if (i) the changes are reviewed and approved by the licensee
35 management and the RSO in writing; (ii) the licensee staff is provided training in the revised
36 procedures prior to implementation; (iii) the changes are in compliance with NRC regulations
37 and the license; and (iv) the changes do not degrade the effectiveness of the program.”

1

AND

2 If an “Emergency Response Plan” is required for your license, pursuant to 10 CFR 30.32(i),
3 submit it as a separate part of the application.

4 **8.10.7 Surveys and Leak Tests**

5 **Regulations:** 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR 30.53; 10 CFR 32.59;
6 10 CFR 40.6310; 10 CFR 70.56

7 **Criteria:** Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological
8 hazards in their workplace. NRC requires testing to determine whether there is any radioactive
9 leakage from sealed sources. Licensees must maintain records of leak test results in
10 accordance with license conditions or, if applicable, NRC regulations.

11 **Discussion:** Surveys are evaluations of radiological conditions and potential hazards
12 (see Figure 8-11). These evaluations may be measurements (e.g., radiation levels measured
13 with radiation survey instruments or results of wipe tests for contamination), calculations, or a
14 combination of measurements and calculations. The selection and proper use of appropriate
15 instruments is one of the most important factors in ensuring that surveys accurately assess the
16 radiological conditions. In order to meet regulatory requirements for surveying, measurements
17 of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, and
18 gamma) and compared to the appropriate limits.

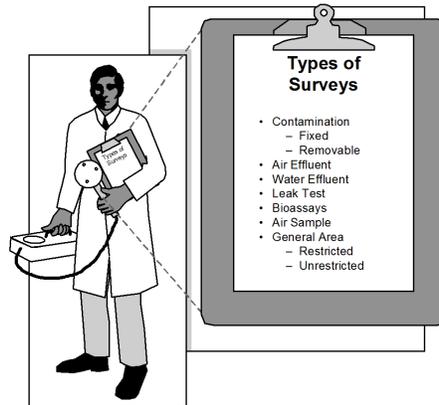
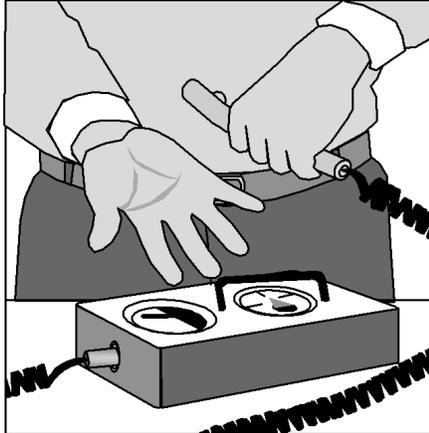


Figure 8-11. Types of Surveys. *There are many different types of surveys performed by manufacturer and distribution licensees.*

19 Radiation surveys are used to detect and evaluate contamination of:

- 20 • facilities
- 21 • equipment
- 22 • personnel (during use, possession, transfer, or disposal of licensed material)
- 23 (see Figure 8-12)
- 24 • restricted and unrestricted areas
- 25 • products produced

Surveying arm and hand using survey meter and gamma probe.



Surveying feet and legs using survey meter and gamma probe.

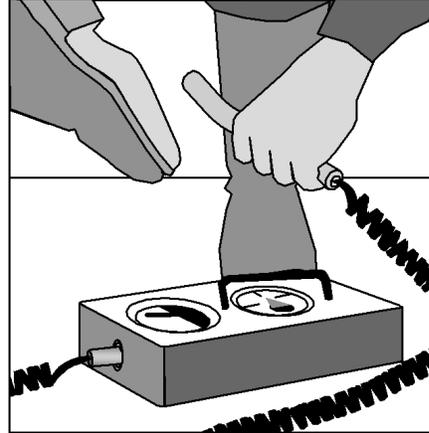


Figure 8-12. Personnel Surveys. Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the area of use.

1 Surveys are also used to plan work in areas where licensed material or radiation exists and to
2 evaluate doses to workers and individual members of the public.

3 As required by 10 CFR 20.1501, surveys will be performed when it is reasonable, under the
4 circumstances, to evaluate a radiological hazard and when necessary for the licensee to comply
5 with the regulations. Many different types of surveys may need to be performed because of the
6 particular use of licensed materials. The most important surveys are as follows:

7 • surveys for radioactive contamination that could be present on surfaces of floors, walls,
8 laboratory furniture, production line and equipment

9 • measurements of radioactive material concentrations in air for areas where radioactive
10 materials are handled or processed in unsealed form, where operations could expose
11 workers to the inhalation of radioactive material, or where licensed material is, or could
12 be, released to unrestricted areas

13 • measurements of radioactive material concentrations in water released to the
14 environment or to the sanitary sewer

15 • bioassays to determine the kinds, quantities, or concentration, and in some cases, the
16 location of radioactive material in the human body [bioassay can be made by direct
17 measurement (*in vivo* counting) or by analysis and evaluation of material excreted or
18 removed from the human body]

19 • surveys of external radiation exposure levels in both restricted and unrestricted areas

20 The frequency of routine surveys depends on the nature, quantity, and use of radioactive
21 materials, as well as the specific protective facilities, equipment, and procedures designed to
22 protect the worker from external and internal exposure. Also, the frequency of the survey
23 depends on the type of survey, such as those listed above (see Appendix N of this NUREG,
24 Radiation Safety Survey Topics).

1 Not all instruments can measure a given type of radiation. The presence of other radiation may
2 interfere with a detector's ability to measure the radiation of interest. Correct use of radiation
3 detection and measurements is an important aspect of any radiation safety program.

4 Regulations in 10 CFR Part 20 do not specify limits for surface contamination. Each applicant
5 should propose and justify the removable surface contamination limits that will be allowed
6 before decontamination will be performed in each work area. Contamination checks are
7 required before distributing fabricated sources. Appendix N of this NUREG contains
8 contamination limits that are acceptable to NRC.

9 **Sealed Source and Plated Foil Leak Tests**

10 Sealed sources and devices approved by the NRC or an Agreement State and located and
11 used according to their SSD registration certificates usually pose little risk of contamination.
12 Leak tests performed, as specified in the SSD registration certificate, should identify defective
13 sources. Leaking sources must be withdrawn immediately from use and decontaminated,
14 repaired, or disposed of according to NRC requirements. These steps minimize the spread of
15 contamination and reduce radioactive waste associated with decontamination efforts. Other
16 efforts to minimize radioactive waste do not apply to programs using only sealed sources and
17 devices that have not leaked.

18 When issued, a license will require performance of leak tests of sealed and plated foil sources
19 at intervals, as approved by NRC or an Agreement State and specified by the SSD registration
20 certificate. The measurement of the leak test sample is a quantitative analysis requiring that
21 instrumentation used to analyze the sample be capable of detecting 185 Bq [0.005 μ Ci] of the
22 radionuclide contained in the sealed or plated foil source.

23 Manufacturers, distributors, consultants, and other organizations may be authorized by NRC or
24 an Agreement State either to perform the entire leak test sequence on behalf of licensees or
25 provide leak test kits to licensees. In the latter case, the licensee takes the leak test sample
26 according to the manufacturer's and/or the kit supplier's instructions and returns it to the leak
27 test service provider for where contaminating would accumulate if the sealed source were
28 leaking. The NRC or an Agreement State may, in a license condition, specifically authorize
29 manufacturers and distributors to conduct the entire leak test sequence themselves.

30 Leak tests are not required if:

- 31 • Sources contain only H-3.
- 32 • Sources contain only byproduct material with a half-life of less than 30 days.
- 33 • Sources contain only a radioactive gas.
- 34 • Sources contain 3.7 MBq [100 μ Ci] or less of beta-emitting or gamma-emitting material
35 or 370 kBq [10 μ Ci] or less of alpha emitting material.
- 36 • Sources are stored and not being used (but must be leak tested before use or transfer,
37 or if stored more than 10 years).

38 For more information regarding leak tests, see Appendix O of this NUREG, Model Leak
39 Test Program.

1 **Service Licenses**

2 If a licensee wants to perform leak tests for its customers, it must obtain a service license. This
3 may also be accomplished by amending an existing license. For more information regarding
4 service license applications, see NUREG–1556, Vol. 18, “Consolidated Guidance About
5 Materials Licenses: Program-Specific Guidance About Service Provider Licenses.”

6 **Response from Applicant:** Do one of the following:

- 7 • State: “We will survey our facility and maintain contamination levels in accordance
8 with the survey frequencies and contamination levels published in Appendix N to
9 NUREG–1556, Vol. 12, Rev. 1.” If applicable, state, “We will perform contamination
10 checks on all fabricated sealed sources prior to distribution. Also, leak tests will be
11 performed at the intervals approved by NRC or an Agreement State and specified in the
12 SSD registration certificate. Leak tests will be performed by an organization authorized
13 by NRC or an Agreement State to provide leak testing services to other licensees or by
14 using a leak test kit supplied by an organization authorized by NRC or an Agreement
15 State, to provide leak test kits to other licensees and according to the sealed source or
16 plated foil manufacturer’s (distributor’s) and kit supplier’s instructions.”

17 **OR**

- 18 • State: “We will survey our facility and maintain contamination levels in accordance
19 with the survey frequencies and contamination levels published in Appendix N to
20 NUREG–1556, Vol. 12, Rev. 1.” If applicable, state, “We will perform contamination
21 checks on all fabricated sealed sources prior to distribution. Also, leak tests will be
22 performed at the intervals approved by NRC or an Agreement State and specified in the
23 SSD registration certificate. We will follow the model procedures in Appendix O of
24 NUREG–1556, Vol. 12, Rev. 1, ‘Consolidated Guidance about Material Licenses:
25 Program-Specific Guidance about Possession Licenses for Manufacturing and
26 Distribution.”

27 **OR**

- 28 • Submit a description of alternative equipment and/or procedures to evaluate radiological
29 hazards at your facility, in accordance with 10 CFR 20.1501, and for determining
30 whether there is radioactive leakage from sealed sources or plated foils. If applicable,
31 state, “We will perform contamination checks on all fabricated sealed sources prior to
32 distribution. Also, leak tests will be performed at the intervals approved by NRC or an
33 Agreement State and specified in the SSD registration certificate.”

34 **Notes:**

- 35 • Alternative responses will be reviewed using the criteria listed above.
- 36 • If a sealed source or plated foil is added to an existing license, that license might already
37 authorize the licensee to perform the entire leak test sequence. In this case, the
38 licensee may perform the leak testing on the sealed source or plated foil according to the
39 procedures previously approved on its license.

1 **Reference:** See the Notice of Availability (on inside front cover of this report) to obtain a copy
2 of NUREG–1556, Vol. 18, “Program-Specific Guidance About Service Provider Licenses.”

3 **8.10.8 Maintenance**

4 **Regulations:** 10 CFR 20.1101; 10 CFR 30.34(e)

5 **Criteria:** Maintenance of devices and facilities that use radioactive materials is necessary.
6 Maintenance should be planned and carried out as frequently as needed, using ALARA
7 principles. Individuals performing maintenance should be trained in the procedures they
8 implement. Procedures should be written to account for the skills of the implementing
9 personnel. Ordinarily, individuals handling unshielded materials should have up to 40 hours of
10 classroom and on-the-job training in radiation safety. Instructors should be more extensively
11 qualified than the staff they teach.

12 **Discussion:** Maintenance of equipment and facilities is necessary in order to produce a quality
13 product safely and efficiently and to ensure a safe environment for staff and the public.
14 Manufacturing a product incorporating radioactive materials is an additional hazard, requiring
15 attention to detail when incorporating maintenance information into procedures. Licensee staff
16 should ensure that materials in the process stream are properly shielded/located/protected to
17 minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards
18 and the procedures to minimize their exposure to radioactive materials that are possessed and
19 used to control the manufacturing process. As examples (i) a radionuclide hot cell should have
20 its contents moved or shielded before any maintenance requiring entry is begun, and the staff
21 should survey the hot cell working area prior to entry; and (ii) a maintenance procedure should
22 direct the shutdown and lockout of applicable process control gauges before beginning work in
23 the area, which may be in the direct beam of the gauge, whether inside the process vessel or
24 outside the vessel. Maintenance procedures should be prepared with the use of engineering
25 controls first, using ALARA principles and administrative controls, as needed.

26 **Response from Applicant:** No response is required in the application process. The results of
27 actions taken in the maintenance and repair of facilities and equipment process will be reviewed
28 during inspection.

29 **8.10.9 Transportation**

30 **Regulations:** 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 37 (Subpart D);
31 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38;
32 10 CFR 71.47; 10 CFR 71.87, Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178

33 **Criteria:** Applicants who will transport or ship licensed material, including radioactive waste,
34 must develop, implement, and maintain safety programs for transport of radioactive material to
35 ensure compliance with NRC and U.S. Department of Transportation (DOT) regulations.
36 Licensees must also preplan, coordinate, and provide advance notification of the shipment of
37 Category 1 quantities of radioactive material and coordinate the shipment of Category 2
38 quantities of radioactive material.

39 **Discussion:** Licensed material, including radioactive waste, must be packaged and transported
40 in accordance with NRC and DOT requirements if the transportation involves common carriers
41 or the use of public highways. Licensees should develop and maintain their own radiation

1 safety procedures for transporting licensed material within their own facilities if it does not
2 involve the use of public highways.

3 Packages shipped by licensees frequently meet the “Limited Quantity” criteria, as described in
4 49 CFR 173.421 and, therefore, may be subject to other less restrictive DOT requirements
5 (e.g., 49 CFR 173.422 and 173.424; also see Appendix P of this NUREG for more information)
6 than packages requiring a DOT White I, Yellow II, or Yellow III label. Under DOT regulations,
7 each person (shipper or carrier) involved in the transportation of radioactive materials is
8 considered a “hazardous materials employee” who must receive appropriate training for the jobs
9 they perform related to transportation every 3 years. Jobs related to transportation include
10 activities such as packaging radioactive materials, loading and securing the package on a
11 vehicle, or preparing paperwork for shipping the material.

12 Licensees should consider the safety of all individuals who may handle or may come into
13 contact with the packages containing licensed material. Therefore, the primary considerations
14 in packaging licensed material should be to ensure that the package integrity is not
15 compromised during transport and that radiation levels (including removable contamination
16 levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, but
17 are also ALARA.

All domestic shipping papers and labels must be in SI units only or must be in SI units first,
with English units in parenthesis.

18 Licensees shipping radioactive waste for disposal must prepare appropriate documentation, as
19 specified in 10 CFR 20, Appendix E.

20 The general license in 10 CFR 71.17 provides the authorization used by most licensees to
21 transport, or offer for transport, packages of radioactive material and specifies certain
22 conditions. Transporting licensed materials originating at some facilities involves quantities of
23 radioactive material that require a Type B package. The manufacturer (or service licensee) who
24 is subject to the provisions of 10 CFR 71.17 or 10 CFR 71.19, as appropriate, is responsible for
25 proper packaging of the radioactive materials and compliance with NRC and DOT regulations.
26 Licensees who use another manufacturer’s Type B package must ensure that the other
27 manufacturer (or service licensee):

- 28 • is authorized to possess the licensed material at temporary jobsites (i.e., at the
29 facility location)
- 30 • actually takes possession of the licensed material under its license
- 31 • uses an approved Type B package
- 32 • is registered with NRC as a user of the Type B package
- 33 • has an NRC-approved QA plan

For each shipment, it must be clear who possesses the licensed material and is responsible
for proper packaging of the radioactive materials and compliance with NRC and DOT
regulations.

1 If a licensee plans to make shipments of licensed materials in Type B packages on its own, the
2 licensee must be registered as a user of the package and have an NRC-approved quality
3 assurance (QA) plan, two of the requirements under the 10 CFR 71.17 general license. For
4 information about QA plans, see Revision 2 of Regulatory Guide 7.10, "Establishing Quality
5 Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated
6 March 2005. For further information about registering as a user of a package or submitting a
7 QA program for review, contact the NRC's Office of Nuclear Material Safety and Safeguards,
8 Division of Spent Fuel Storage and Transportation, by calling the NRC's toll free number,
9 800-368-5642. For information about any associated fees, contact the NRC's Office of the
10 Chief Financial Officer, by calling the NRC's toll free number, 800-368-5642, and asking for
11 extension 415-7554.

12 During an inspection, NRC uses the provisions of 10 CFR 71.5 and a "Memorandum of
13 Understanding with DOT on the Transportation of Radioactive Material," signed June 6, 1979, to
14 examine and enforce various DOT requirements listed in Appendix P of this NUREG.

In accordance with 10 CFR Part 37, any licensee transferring a Category 1 or Category 2 quantity of radioactive material must implement the physical protection in the transit requirements in 10 CFR Part 37, Subpart D. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG-2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.'" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC for review and approval.

15 **Response from Applicant:** No response is needed from applicants during the licensing phase.
16 However, before making shipments of licensed materials on its own in Type B packages, a
17 licensee needs to have registered with NRC as a user of the package and obtained NRC's
18 approval of its QA program. Transportation issues will be reviewed during inspection.

19 **References:** "A Review of Department of Transportation Regulations for Transportation of
20 Radioactive Materials (1998 revision)" can be obtained by calling DOT's Office of Hazardous
21 Safety Administration Training Office, at 202-366-4900. Publications, guidance and training
22 materials can be found at the DOT Web site <http://phmsa.dot.gov/hazmat/training/publications>

23 **8.10.10 Security Program for Category 1 and Category 2 Radioactive Material**

24 **Regulations:** 10 CFR Part 37; 10 CFR 20.2207

25 **Criteria:** Licensees must ensure the security of Category 1 and Category 2
26 radioactive material.

27 **Note:** The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated
28 Category 1 or Category 2 quantity of radioactive material, as specified in Appendix A to
29 10 CFR Part 37. The requirements in 10 CFR 20.2207 for submitting National Source Tracking
30 Transaction Reports (NSTTR) are applicable to those licensees that manufacture, transfer,
31 receive, disassemble, or dispose of sealed sources containing a quantity equal to or greater

1 than the Category 1 or Category 2 levels of radioactive material listed in Appendix E to 10 CFR
2 Part 20.

3 **Discussion:**

4 Requirements in 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities
5 of Radioactive Material”

6 In accordance with 10 CFR Part 37, licensees authorized to possess Category 1 or Category 2
7 quantities of radioactive material must establish, implement, and maintain a security program to
8 ensure physical protection of the radioactive material.

9 Table 1 of Appendix A, “Category 1 and Category 2 Radioactive Materials,” to 10 CFR Part 37,
10 lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant
11 should refer to this table to determine whether its proposed activities would be subject to the
12 10 CFR Part 37 requirements.

13 Licensees authorized to hold Category 1 or Category 2 quantities of radioactive material must
14 establish access authorization programs in accordance with 10 CFR Part 37, Subpart B. Before
15 giving individuals unescorted access to such quantities of radioactive material, licensees must
16 conduct prior background investigations of these individuals in accordance with 10 CFR 37.25.

17 In accordance with 10 CFR 37.41(b), licensees must establish a security program designed to
18 monitor and, without delay, detect, assess, and respond to any actual or attempted efforts to
19 gain unauthorized access to Category 1 or Category 2 quantities of radioactive material.

20 Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or
21 Category 2 quantities of radioactive materials in transit. These requirements apply to licensees
22 delivering such material to a carrier for transport, as well as cases in which licensees are
23 transporting such material. Please note that the Subpart D requirements applicable to the
24 transport of Category 1 quantities of radioactive material are more stringent than those
25 applicable to Category 2 quantities.

Applicants and licensees are required to implement the 10 CFR Part 37 security requirements before they take possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

In accordance with 10 CFR 37.41(a)(3), any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been made subject to the provisions of 10 CFR Part 37, Subpart C shall notify the NRC regional office specified in 10 CFR 30.6 in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

26 For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155,
27 “Implementation Guidance for 10 CFR Part 37, “Physical Protection of Category 1 and
28 Category 2 Quantities of Radioactive Material.”” Additional information regarding best practices
29 for protection of risk-significant radioactive material is available in NUREG–2166, “Physical
30 Security Best Practices for the Protection of Risk-Significant Radioactive Material.”

31

1 Requirements in 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources"

2 The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers,
3 receives, disassembles, or disposes of a nationally tracked source shall complete and submit an
4 NSTTR to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that
5 tracks high-risk radioactive sources from the time they are manufactured or imported through
6 the time of their disposal or export, or until the source activity decays enough to no longer be
7 of concern.

8 **Response from Applicant:** No response is required from an applicant or licensee.

9 **8.11 Item 11: Waste Management**

10 **Regulations:** 10 CFR 20.1904; 10 CFR 20.2001; 10 CFR 20.2002; 10 CFR 20.2003;
11 10 CFR 20.2004; 10 CFR 20.2005; 10 CFR 20.2006; 10 CFR 20.2007; 10 CFR 20.2108;
12 10 CFR 30.51; 10 CFR 61.52

13 **Criteria:** Radioactive waste must be disposed of in accordance with regulatory requirements
14 and license conditions. Appropriate records of waste disposal must be maintained.

15 **Discussion:** Radioactive waste is normally generated when conducting licensed activities.
16 Such waste may include used or unused radioactive material, unusable items contaminated with
17 radioactive material (e.g., absorbent paper, gloves). Licensees may not receive radioactive
18 waste from other licensees for processing, storage, or disposal, unless the NRC specifically
19 authorized them to do so.

20 All radioactive waste must be stored in appropriate containers until its disposal. The integrity of
21 the waste containers must be assured. Radioactive waste containers must be appropriately
22 labeled. All radioactive waste must be secured against unauthorized access or removal.

23 Licensees may implement procedures to reduce the volume of radioactive waste for final
24 disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures
25 include volume reduction by segregating, consolidating, compacting, or allowing certain
26 short-lived radioactive waste to be stored until it has decayed. Waste compaction or other
27 treatments can reduce the volume of radioactive waste, but such processes may pose
28 additional radiological hazards (e.g., airborne radioactivity) to workers and members of the
29 public. The program should include adequate safety procedures to protect workers, members
30 of the public, and the environment.

31 NRC requires licensees to dispose of radioactive waste generated at their facilities through one
32 or more of the following methods:

- 33 • decay-in-storage (DIS)
- 34 • release into sanitary sewerage
- 35 • transfer to an authorized recipient
- 36 • disposal of waste as if it were not radioactive (specific wastes)
- 37 • obtaining prior approval of NRC of any alternate method
- 38 • release in effluents to unrestricted areas, other than into sanitary sewerage
- 39 • incineration

1 Licensees may choose one or more of these methods to dispose of their radioactive waste. The
2 NRC has observed that most of the possession licenses for manufacturing and distribution store
3 or dispose of radioactive waste through a combination of the first four methods because of the
4 types and amounts of licensed materials these facilities use. Applicants that want to dispose of
5 radioactive waste by incineration should refer to Policy and Guidance Directive PG 8-10,
6 "Disposal of Incinerator Ash as Ordinary Waste," issued January 1997. Applicants should note
7 that compliance with NRC regulations does not relieve them of their responsibility to comply with
8 any other applicable Federal, State, or local regulations. Furthermore, some of the radioactive
9 waste may also include additional hazards (e.g., biohazard or chemical hazard). Such waste is
10 called "mixed waste," and its storage and disposal must also comply with all other applicable
11 Federal, State, and local regulatory requirements.

12 Applicants should describe their program for management and disposal of radioactive waste.
13 The program should include procedures for handling of waste, safe and secure storage,
14 characterization, minimization, and disposal of radioactive waste. Appropriate training should
15 be provided to waste handlers. Regulations require that licensees maintain all appropriate
16 records of disposal of radioactive waste. The U.S. Environmental Protection Agency issued
17 guidance for developing a comprehensive program to reduce hazardous waste that, in many
18 instances, may also include radioactive waste. The NRC transmitted these guidelines to
19 licensees in IN 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on
20 the Elements of a Waste Minimization Program," dated March 25, 1994.

21 Licensees that do not have access to a radioactive waste facility may have to store waste for
22 long periods of time. The NRC has developed guidance for such extended interim storage of
23 waste, discussed below.

24 **Disposal by Decay-in-Storage**

25 The NRC has concluded that materials with half-lives of less than or equal to 120 days are
26 appropriate for DIS. The holding time of the waste should be based on the radionuclide(s),
27 half-life, and the activity present when the waste was placed into storage. Such waste may be
28 disposed of as ordinary trash if radiation surveys (performed in a low background area and
29 without any interposed shielding) of the waste at the end of the holding period indicate that
30 radiation levels are indistinguishable from background. In accordance with 10 CFR 20.1904(b),
31 all radiation labels must be defaced or removed from containers and packages before disposal
32 as ordinary trash. If the decayed waste is compacted, all labels visible in the compacted mass
33 must also be defaced or removed.

34 Applicants should ensure that adequate space and facilities are available for the storage of such
35 waste. Licensees can minimize the need for storage space, if the waste is segregated
36 according to physical half-life. Waste-containing radionuclides of physical half-lives within a
37 certain range may be stored in one container and allowed to decay in the container.
38 Procedures for management of such waste should include methods of segregation, surveys
39 before disposal, and maintenance of records of disposal. Records should include the date
40 when the waste was put in storage for decay, date of disposal, and results of final survey before
41 disposal as ordinary trash. Appendix Q of this NUREG provides a model procedure for disposal
42 of radioactive waste by DIS, which incorporates the above guidelines.

43

1 **Release Into Sanitary Sewerage**

2 10 CFR 20.2003 authorizes disposal of radioactive waste by release into a public sanitary
3 sewerage system if each of the following conditions is met:

- 4 • Material is readily soluble (or is readily dispersible biological material) in water.
- 5 • The quantity of licensed material that the licensee releases into the sewer each month
6 averaged over the monthly volume of water released into the sewer does not exceed the
7 concentration specified in Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and
8 Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent
9 Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20.
- 10 • If more than one radionuclide is released, the sum of the ratios of the average monthly
11 discharge of a radionuclide to the corresponding limit in Table 3 of Appendix B to
12 10 CFR Part 20 cannot exceed unity.
- 13 • Total quantity of licensed material released into the sanitary sewerage system in a year
14 does not exceed 185 GBq [5 Ci] of H-3, 37 GBq [1 Ci] of C-14, and 37 GBq [1 Ci] of all
15 other radionuclides combined.

16 Licensees are responsible for demonstrating that licensed materials discharged into the public
17 sewerage system are readily soluble in water. NRC IN 94-07, "Solubility Criteria for Liquid
18 Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated
19 January 28, 1994, provides acceptable criteria for evaluating solubility of wastes released to the
20 sewer. Careful consideration should be given to the possibility of reconcentration of
21 radionuclides released into the sewer. NRC alerted licensees to the potentially significant
22 problem of reconcentration of radionuclides released to sanitary sewerage systems in IN 84-94,
23 "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems
24 Permitted under 10 CFR 20.303 (now 10 CFR 20.2003)," dated December 21, 1984.

25 Applicants should provide procedures that will ensure that all releases of radioactive waste into
26 the sanitary sewerage meet the criteria stated in 10 CFR 20.2003 and do not exceed the
27 monthly and annual limits specified in regulations. Licensees are required to maintain accurate
28 records of all releases of licensed material into the sanitary sewerage. Appendix Q of this
29 NUREG provides a model program for disposal of radioactive waste through sanitary sewer.

The regulations at 10 CFR 20.2003 are not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas under 10 CFR 20.1301, "Dose Limits for Individual Members of the Public." However, if licensed material is released to a private sewerage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described in Section 8.11, "Waste Management," of this document.

30 **Release into Air and Water**

31 Release of radioactive material into air and water must conform to the requirements in
32 10 CFR 20.1302(b)(2) (See Figure 8-13). The applicant should describe the monitoring and

1 control mechanisms in place to ensure compliance with the requirements. Applicants are
2 reminded of the “constraint” on air emissions of radioactive material required by
3 10 CFR 20.1101(d), which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for
4 release of gaseous effluents by a factor of ten. Applicants considering release of radioactive
5 material into air and water should review Regulatory Guide 8.37, “ALARA Levels for Effluents
6 From Materials Facilities,” dated July 1993, which deals with the application of ALARA in
7 controlling gaseous and liquid effluents and references documents with acceptable methods of
8 effluent monitoring. Regulatory Guide 4-20, “Constraint on Releases of Airborne Radioactive
9 Materials to the Environment for Licensees Other than Power Reactors,” dated April 2012, also
10 contains useful information.

11 **Transfer to an Authorized Recipient**

12 Licensees may transfer radioactive waste to an authorized recipient for disposal. The licensee
13 is responsible for verifying that the intended recipient is authorized to receive the radioactive
14 waste before making any shipment. The waste must be packaged in approved containers for
15 shipment, and each container must identify the radionuclides and the amounts contained in the
16 waste. Additionally, packages must comply with the requirements of the particular burial site’s
17 license and State requirements. Each shipment must comply with all applicable NRC and
18 DOT requirements.

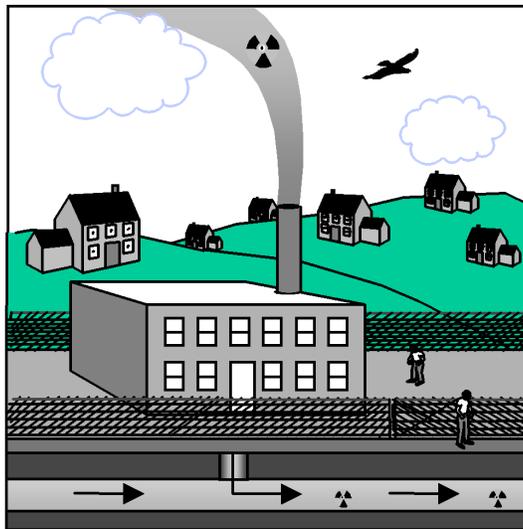


Figure 8-13. Air and Water Effluents from a Manufacturing Facility. *Also note the fence, creating a “controlled area.”*

19 In some cases, the waste handling contractor may provide guidance to the licensee for
20 packaging and transportation requirements; however, the licensee is ultimately responsible for
21 ensuring compliance with all applicable regulatory requirements.

22 The shipper must provide all information required in NRC’s Uniform Low-Level Radioactive
23 Waste Manifest, and transfer this recorded manifest information to the intended recipient, in
24 accordance with Appendix G to 10 CFR Part 20. Each shipping manifest must include a
25 certification by the waste generator, as specified in Section II of the appendix. Each person
26 involved in the transfer for disposal and disposal of waste, including waste generator, waste
27 collector, waste processor, and disposal facility operator, must comply with requirements
28 specified in Section III of Appendix G.

1 **Disposal of Specific Waste As If It Were Not Radioactive**

2 The following radioactive wastes may be disposed of as non-radioactive waste, pursuant to
3 10 CFR 20.2005, "Disposal of specific wastes:"

- 4 • liquid scintillation media (including vials and other items contaminated with liquid
5 scintillation media) containing no more than 1.85 kBq [0.05 µCi] of H-3 or C-14 per gram
6 of the medium
- 7 • animal carcasses or animal tissue containing no more than 1.85 kBq [0.05 µCi] of H-3 or
8 C-14 per gram averaged over the weight of the entire animal

9 Applicants should have procedures to ensure that the above limits are not exceeded and that
10 animal tissue or carcasses containing licensed material are disposed of in a way that will not
11 permit their use either as food for humans or animals. Applicants must maintain accurate
12 records of these disposals.

13 **Alternate Methods**

14 Applicants may also request alternate methods under 10 CFR 20.2002, "Method for obtaining
15 approval of proposed disposal procedures," for the disposal of radioactive waste generated at
16 their facilities. Such requests must describe the waste containing licensed material, including
17 the physical and chemical properties that may be important to assess risks associated with the
18 waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant
19 must submit its analysis and evaluation of pertinent information on the nature of the
20 environment, the nature and location of other affected facilities, and procedures to ensure that
21 radiation doses are maintained ALARA and within regulatory limits. An applicant cannot make
22 such disposals until the NRC has reviewed and approved the request.

23 **Extended Interim Storage**

24 Some licensees do not have an LLW disposal facility available to them and, therefore, must use
25 on-site interim storage until such time that a facility becomes available. Licensees should
26 exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site
27 extended interim storage of radioactive waste only as a last resort. The protection of workers
28 and the public is enhanced by disposal rather than storage of waste. Licensees may also find it
29 more economical to dispose of radioactive waste than to store it on site because, as the
30 available capacity decreases, the cost of disposal of radioactive waste may continue to
31 increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and
32 for no longer than is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level
33 Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990, provides
34 guidance to licensees for requesting an amendment to authorize extended interim storage of
35 LLW. This information was updated by NRC Regulatory Issue Summary (RIS) 2008-12,
36 "Considerations For Extended Interim Storage Of Low-Level Radioactive Waste By Fuel Cycle
37 And Materials Licensees." In addition, the NRC issued Regulatory Issue Summary 2011-09,
38 "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste,"
39 which refers to other helpful guidance documents.

40 **Note:** Before licensed activities are transferred or assigned in accordance with
41 10 CFR 30.34(b), 10 CFR 40.46, and/or 10 CFR 70.36, if licensees are authorized to possess
42 byproduct material with a half-life greater than 120 days in an unsealed form, source material in

1 an unsealed form, and/or special nuclear material, the licensees must, in accordance with 10
2 CFR 30.51(e), 10 CFR 40.61(e), and/or 10 CFR 70.51(b)(1)&(2), respectively, transfer the
3 following records to the new licensee:

- 4 • records of disposal of licensed material made under:
 - 5
 - 6 – 10 CFR 20.2002, “Method for obtaining approval of proposed disposal procedures“
 - 7 – 10 CFR 20.2003, “Disposal by release into sanitary sewerage”
 - 8 – 10 CFR 20.2004, “Treatment or disposal by incineration
 - 9 – 10 CFR 20.2005, “Disposal of specific wastes”
- 10
- 11 • records required by 20.2103(b)(4) of the results of measurements and calculations used
12 to evaluate the release of radioactive effluents to the environment
13

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

14

15 **Response from Applicant:**

16 State that: “We will use the model waste procedures and guidelines published in Appendix Q
17 to NUREG–1556, Vol. 12, Rev. 1, ‘Consolidated Guidance About Materials Licenses:
18 Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.’”

19

OR

20 If the applicant wishes to use only selected model procedures and guidelines, state that, “We
21 will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage]
22 model waste procedures that are published in Appendix Q to NUREG–1556, Vol. 12, Rev 1.,
23 ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
24 Possession Licenses for Manufacturing and Distribution.’”

25

AND

26 If the applicant wishes to compact or incinerate radioactive waste, provide the requested
27 information concerning these activities in Appendix Q to NUREG–1556, Vol. 12, Rev. 1,
28 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
29 Possession Licenses for Manufacturing and Distribution.”

30

AND/OR

31 If access to a radioactive waste burial site is unavailable, the applicant should request
32 authorization for extended interim storage of waste. Applicant should use the references listed
33 below for guidance and submit the required information with the application.

34 **Note:** Applicants do not need to provide information to the NRC if they plan to dispose of LLW
35 via transfer to an authorized recipient or to dispose of liquid scintillation media or animals
36 containing low levels of H-3 or C-14, as authorized by 10 CFR 20.2005.

1 Alternative responses will be reviewed using the criteria listed above.

2 **References:**

- 3 • Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste
4 Minimization Program," dated March 1994
- 5 • Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary
6 Sewerage Under the Revised 10 CFR 20," dated January 1994
- 7 • Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into
8 Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003),"
9 dated December 1984
- 10 • Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by
11 Fuel Cycle and Materials Licensees," dated February 1990
- 12 • Regulatory Issue Summary 2008-12, "Considerations For Extended Interim Storage Of
13 Low-Level Radioactive Waste By Fuel Cycle And Materials Licensees"
- 14 • Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended
15 Storage Of Low-Level Radioactive Waste"
- 16 • Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary
17 Waste," January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and
18 Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.
- 19 • NRC Regulatory Issue Summary 2004-17, Revision 1, Revised Decay-In-Storage
20 Provisions For The Storage Of Radioactive Waste Containing Byproduct Material,
21 September 2005
- 22 • State and Tribal Communication Letter FSME 12-025 dated March 13, 2012
23 "Clarification of the Authorization for Alternative Disposal of Material Issued Under
24 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No.
25 ML12065A038)
- 26 • Division of Waste Management and Environmental Protection, Environmental and
27 Performance Assessment Directorate, Operating Procedures, EPPAD 3.5 (Draft for
28 Interim Use), "Review, Approval, and Documentation of Low-Activity Waste Disposals in
29 Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a)," dated August 2009
- 30 • DRAFT Regulatory Issue Summary 2016-XX, "Requests to Dispose of Very Low-Level
31 Radioactive Waste Pursuant to 10 CFR 20.2002," XXXX 2016

32 Information Notices and Regulatory Issue Summaries are available at <http://www.nrc.gov>.

33

34

1 **8.12 Item 12: License Fees**

2 On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of
3 the fee enclosed with the application.

4 Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to
5 the Office of the Chief Financial Officer at NRC Headquarters in Rockville, MD,
6 301-415-7554. Information about fees may also be obtained by calling NRC's toll-free number,
7 800-368-5642, extension 415-7554. The e-mail address for fees questions is
8 Fees.Resource@nrc.gov.

9 **8.13 Item 13: Certification**

10 A representative of the corporation or legal entity filing the application should sign and date
11 NRC Form 313. The representative signing the application must be authorized to make binding
12 commitments and to sign official documents on behalf of the applicant. As discussed previously
13 in Chapter 3, "Management Responsibility," signing the application acknowledges
14 management's commitment to and responsibility for the radiation safety program. The NRC will
15 return all unsigned applications for proper signature.

16 **Notes:**

- 17 • It is a criminal offense to knowingly and willfully make a false statement or
18 representation on applications or correspondence (18 U.S.C. 1001).
- 19 • When an application references commitments, those items will be incorporated into the
20 license and, therefore, become binding regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [see Title 10 of *Code of Federal Regulations* (10 CFR) 2.109(a), 10 CFR 30.36(a)].

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an U.S. Nuclear Regulatory Commission (NRC) Form 313 or a letter requesting amendment or renewal.
- Provide the license number and docket number.
- For renewals, provide a complete and up-to-date application, including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.1 Timely Notification of Transfer of Control

Regulation: 10 CFR 30.34(b); 10 CFR 40.41(b); 10 CFR 70.32(a)(3)

Criteria: Licensees must provide all supporting information and obtain the NRC's prior, *written consent* before transferring control of the license, also referred to as a "change of ownership" and/or "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior NRC written consent to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are capable, competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.
- The transferee has the financial resources to decommission the license, if necessary.
- Public health and safety are not compromised by the use of such materials.

- 1 • Adequate financial assurance is provided for compliance with the applicable NRC
2 requirements, if required.

3 For further information, see RIS 2014-08, Revision 1, "Regulatory Requirements for Transfer of
4 Control (Change of Ownership) of Specific Materials Licenses," dated May 5, 2016, which can
5 be found on the NRC's Generic Communications Web page under "Regulatory Issue
6 Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

7 **Response from Applicant:** No response is required from an applicant for a new license.
8 However, current licensees should refer to NUREG-1556, Volume 15, "Consolidated Guidance
9 About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving
10 Byproduct, Source, or Special Nuclear Materials Licenses," for more information about transfer
11 of control (i.e., ownership).

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10 APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31; 10 CFR 20.2301; 10 CFR 30.11; 10 CFR 40.14; 10 CFR 70.17

Criteria: Licensees may request exemptions from U.S. Nuclear Regulatory Commission (NRC) regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest. Licensees may also use existing specific exemptions outlined in Title 10 of the *Code of Federal Regulations* (10 CFR) regulations if they meet the established criteria.

Discussion: Various sections of the NRC’s regulations address requests for exemptions (e.g., 10 CFR 19.31, “Application for exemptions”; 10 CFR 20.2301, “Applications for exemptions”; 10 CFR 30.11, “Specific exemptions”; 10 CFR 40.14, “Specific exemptions”; 10 CFR 70.11, “Specific exemptions”). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations or apply to large classes of licensees and are generally limited to unique situations. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.
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11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 10 CFR 30.36(d), 10 CFR 30.36(g), 10 CFR 30.36(h), 10 CFR 30.36(j), 10 CFR 30.51(f), 10 CFR 40.36(f), 10 CFR 40.42, 10 CFR 40.42(d), 10 CFR 40.42(g), 10 CFR 40.42(h), 10 CFR 40.42(j), 10 CFR 40.46, 10 CFR 70.36, 10 CFR 70.38, 10 CFR 70.38(d), 10 CFR 70.38(g), 10 CFR 70.38(h), 10 CFR 70.38(j), 10 CFR 70.51(b)(3)

Criteria: The licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
 - expiration of its license
 - a decision to permanently cease principal activities¹ at the entire site
 - for licensees subject to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36, a decision to permanently cease principal activities¹ in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
 - for licensees subject to 10 CFR 40.42 or 10 CFR 70.38, a decision to permanently cease principal activities¹ in any separate building or outdoor area
 - no principal activities¹ under the license have been conducted for a period of 24 months
 - no principal activities¹ have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by 10 CFR 30.36(g), 10 CFR 40.42(g), and/or 10 CFR 70.38(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j), 10 CFR 40.42(h) and (j), and/or 10 CFR 70.38(h) and (j).
- Submit to the appropriate NRC regional office a completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information), and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final survey and leak test results).

¹Principal activities' are activities which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

- 1 • Before a license is terminated, send records important to decommissioning that are
2 required by 10 CFR 30.35(g), 10 CFR 40.36(f) and/or 10 CFR 70.25(g) to the
3 appropriate NRC regional office in accordance with 10 CFR 30.51(f), 10 CFR 40.61(f),
4 and/or 10 CFR 70.51(a)(3), respectively.
5
- 6 • Before a license is terminated, send records of disposal of licensed material made under
7 10 CFR 20.2002, 10 CFR 20.2003, 20.2004, 20.2005, and the results of measurements
8 and calculations used to evaluate the release of radioactive effluents to the environment
9 to the appropriate NRC regional office in accordance with 10 CFR 30.51(d), 10 CFR
10 40.61(d), and/or 10 CFR 70.51(a)(1)&(2), if authorized to possess byproduct material
11 with a half-life greater than 120 days in an unsealed form, source material in an
12 unsealed form, and/or special nuclear material, respectively.
13

14 **Discussion:** To comply with the above criteria, before a licensee can decide whether it must
15 notify the NRC under 10 CFR 30.36(d), 10 CFR 40.42(d), and/or 10 CFR 70.38(d), the licensee
16 must determine whether residual radioactivity is present and, if so, whether the levels make the
17 building or outdoor area unsuitable for release, according to NRC requirements. A licensee's
18 determination that a facility is not contaminated is subject to verification by NRC inspection.

19 The permanent cessation of principal activities¹ in an individual room or laboratory may require
20 the licensee to notify the NRC if no other licensed activities are being performed in the building.

21 For further information, see Regulatory Issue Summary (RIS) 2015-19, "Decommissioning
22 Timeliness Rule Implementation and Associated Regulatory Relief," dated December 21, 2015,
23 which can be found on the NRC's Generic Communications Web page under "Regulatory Issue
24 Summaries": <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/>.

25 For guidance on the disposition of licensed material, see Section 8.11 "Waste Management."
26 For guidance on decommissioning records, see Section 8.5.2, "Financial Assurance and
27 Recordkeeping for Decommissioning."

28 NUREG-1757, "Consolidated Decommissioning Guidance," contains the current regulatory
29 guidance concerning decommissioning of facilities and termination of licenses. Licensees that
30 have large facilities to decommission should review NUREG-1575, "Multi-Agency Radiation
31 Survey and Site Investigation Manual (MARSSIM)." The computer code "DandD" offers an
32 acceptable method for calculating screening values to demonstrate compliance with the
33 unrestricted dose limits. Supplemental information on the implementation of the final rule on
34 radiological criteria for license termination was published in the *Federal Register* (63 FR 64132)
35 on November 18, 1998.

36 Supplemental information on the implementation of the final rule on radiological criteria for
37 license termination also was published in the *Federal Register* on December 7, 1999,
38 (64 FR 68395) which addresses screening values in soils for the most common radionuclides,
39 and in the *Federal Register* on June 13, 2000, (65 FR 37186) for screening values for building
40 surfaces and soils contaminated with radionuclides not addressed in the prior *Federal*
41 *Register* notices.

42

1 **Response from Applicant:** The applicant is not required to submit a response to the NRC
2 during the initial application. The licensee's obligations in this matter begin when the license
3 expires or at the time the licensee ceases operations, whichever is earlier. These obligations
4 are to undertake the necessary decommissioning activities, to submit NRC Form 314 or
5 equivalent information, and to perform any other actions summarized in "Criteria" above.

6 **Reference:** NRC Form 314 is available at <http://www.nrc.gov/reading-rm/doc-collections/forms/>

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APPENDIX A

LIST OF DOCUMENTS CONSIDERED IN DEVELOPMENT OF THIS NUREG

List of Documents Considered in Development of this NUREG

This Appendix incorporates and updates the guidance previously found in the Regulatory Guides (RG) 10.2 and 10.7. In addition, it references other RGs, Policy and Guidance Directives (P&GD), Information Notices (IN), Inspection Procedure (IP), Technical Assistance Requests (TAR) and other guidance documents used in its preparation. The guidance incorporated and referenced is listed in Table A–1.

Table A–1. List of Documents Considered in Development of this NUREG		
Document Identification	Title	Date
RG 3.67, Rev. 1	Regulatory Guide 3.67, Rev. 1, “Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities,” ADAMS No. ML103360487	April 2011
RG 4.20	Regulatory Guide 4.20, “Constraint on Release of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors”	April 2012
RG 4.22	Regulatory Guide 4.22, “Decommissioning Planning During Operations,” ADAMS No. ML12158A361	December 2012
RG 8.7, Rev. 2	Regulatory Guide 8.7, Rev. 2, “Instructions for Recording and Reporting Occupational Radiation Exposure Data”	11/2005
RG 8.9, Rev. 1	Regulatory Guide, Rev. 1, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program”	July 1993
RG 8.10	Regulatory Guide 8.10, “Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable,” ADAMS No. ML003739563	May 1977
RG 8.20 and DG-8050	Regulatory Guide 8.20, “Applications of Bioassay for I-125 and I-131” (Note: DG-8050, “Proposed Revision 2 of Regulatory Guide 8.20, dated September 1979, Applications of Bioassay for I-125 and I-131,” ADAMS Accession No. ML102800439)	September 1979 September 2011
RG 8.21, Rev. 1	Regulatory Guide 8.21, Rev. 1, “Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants”	October 1979
RG 8.23	Regulatory Guide 8.23, “Radiation Safety Surveys at Medical Institutions”	January 1981
RG 8.25	Regulatory Guide 8.25, “Air Sampling in the Workplace”	June 1992
RG 8.32	Regulatory Guide 8.32, “Criteria for Establishing a Tritium Bioassay Program”	July 1988

Table A-1. List of Documents Considered in Development of this NUREG		
Document Identification	Title	Date
RG 8.34	Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Doses"	July 1992
RG 8.35, Rev. 1	Regulatory Guide 8.35, Rev. 1, "Planned Special Exposures"	August 2010
RG 8.36	Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus"	7/1992
RG 8.37	Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities"	July 1993
NUREG-1140	NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report," ADAMS Accession No. ML062020791.	January 1988
NUREG-1400	NUREG-1400, "Air Sampling in the Workplace"	September 1993
NUREG-1516	NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities"	May 1997
NUREG-1549	NUREG-1549, "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination," ADAMS Accession No. ML993250291	July 1998,
NUREG-1575	NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," Revision 1	August 2000
NUREG-1575, Supplement 1	NUREG-1575, Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)"	January 2009
NUREG-1748	NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs" ADAMS No. ML032450279	August 2003
NUREG-1757, Volume 1	NUREG-1757, Volume 1, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees," Revision 2 ADAMS No. ML070390074	September 2006
NUREG-1757, Volume 2	NUREG-1757, Volume 2, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria," Revision 1 ADAMS No. ML070390081	September 2006

Table A-1. List of Documents Considered in Development of this NUREG

Document Identification	Title	Date
NUREG-1757, Volume 3	NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," Revision 1 ADAMS No. ML12048A683	February 2012
NUREG-2155	NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material""	February 2013
NUREG-2166	NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material"	May 2014
NUREG/CR-4884	NUREG/CR-4884, "Interpretation of Bioassay Measurements"	July 1987
NUREG/CR-5512, Volume 2	NUREG/CR-5512, Volume 2, "Residual Radioactive Contamination from Decommissioning User's Manual DandD Version 2.1," ADAMS Accession No. ML010940257	April 2001
NUREG/CR-5512, Volume 3	NUREG/CR-5512, Volume 3, "Residual Radioactive Contamination from Decommissioning, Parameter Analysis, Draft Report for Comment," ADAMS Accession No. ML082460902	October 1999
IN 84-94	Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 [now 10 CFR 20.2003]," ADAMS No. ML082321340	December 1984
IN 89-25, Rev. 1	Information Notice 89-25 (Revision 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities"	December 1994
IN 90-09	Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licenses"	February 1990
IN 94-07	Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20"	January 1994
IN 94-23	Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Programs"	March 1994
IN 96-28	Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," ADAMS No. ML090080059	May 1996

Table A-1. List of Documents Considered in Development of this NUREG

Document Identification	Title	Date
IN 97-30	Information Notice 97-30, "Control of Licensed Material During Reorganizations, Employee-Management Disagreements and Financial Crises"	June 1997
IN 99-33	Information Notice 99-33, "Management of Wastes Contaminated with Radioactive Materials"	December 1999
IN 2000-10	Information Notice 2000-10, "Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits"	July 2000
IN 2000-16	Information Notice 2000-16, "Potential Hazards Due to Volatilization of Radionuclides"	October 2000
IN 2001-01	Information Notice 2001-01, "The Importance of Accurate Inventory Controls To Prevent the Unauthorized Possession of Radioactive Material"	March 2001
IN 2003-12	Information Notice 2003-12, "Problems Involved in Monitoring Dose to the Hands Resulting from the Handling of Radiopharmaceuticals"	August 2003
IN 2009-07	Information Notice 2009-07, "Withholding of Proprietary Information from Public Disclosure"	March 2009
IN 2009-30	Information Notice 2009-30, "Findings from the NRC Initiative To Assess Materials Licensees' Compliance with the NRC Decommissioning Requirements"	November 2009
RIS 2004-17, Rev. 1	Regulatory Issue Summary 2004-17, Rev. 1, "Revised Decay-In-Storage Provisions For The Storage Of Radioactive Waste Containing Byproduct Material"	September 2005
RIS 2005-31	Regulatory Issue Summary 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material" ADAMS No. ML053480073	December 2005
RIS 2007-04	Regulatory Issue Summary 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission" ADAMS No. ML063470597	March 2007
RIS 2008-12	Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," ADAMS No. ML073330725	May 2008

Table A-1. List of Documents Considered in Development of this NUREG		
Document Identification	Title	Date
RIS 2011-09	Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste" ADAMS No. ML111520042	August 2011
RIS 2014-08, Rev. 1	Regulatory Issue Summary 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of specific Materials Licenses"	5/5/2016
RIS 2015-19	Regulatory Issue Summary 2015-19, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief"	12/21/2015
RIS 2016-XX	DRAFT Regulatory Issue Summary 2016-XX, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002," ADAMS Accession No. ML16007A488	XXXXXX 2016
Administrative Letter 96-05	NRC Administrative Letter 96-05, 'Compliance with the Rule "Timeliness in Decommissioning of Material Facilities,"' ADAMS Accession No. ML031200667	November 1996
Administrative Letter 96-05 (Rev. 1)	NRC Administrative Letter 96-05 (Rev. 1), 'Compliance with the Rule "Timeliness in Decommissioning of Material Facilities,"' ADAMS Accession No. ML081570203)	July 1998
PG 8-10	Policy and Guidance Directive PG 8-10 technical basis, "Generic Dose Assessment for Disposal of Incinerator Ash in a Landfill," ADAMS Accession No. ML003752866	September 1994
PG 8-10	Technical Justification Addendum for PG 8-10: "Generic Dose Assessment for Disposal in a Landfill of Incinerator Ash Containing: S-35, Ca-45, Fe-59, P-32, and Tc-99m, Using RESRAD and NUREG\1500 Methodology," ADAMS Accession No. ML003744988	March 1996
IP 87103	Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing"	November 2000
IP 87125	Inspection Procedure 87125, "Materials Processor/Manufacturer Programs"	September 2005
IP 87126	NRC Inspection Manual, Inspection Procedure 87126, "Industrial/Academic/Research Program," ADAMS No. ML052730315	September 2005

Table A-1. List of Documents Considered in Development of this NUREG		
Document Identification	Title	Date
Memo	Staff Memorandum dated March 19, 2004, "Updated Guidance on Review of Environmental Assessments," ADAMS Accession No. ML040790751	March 2004
Memo	Staff Memorandum dated October 20, 2009, "Updated Guidance for Distinguishing Between 'Simple' and 'Complex' Environmental Assessment," ADAMS Accession No. ML092321078	October 2009
SP-96-022	"All Agreement States Letter," SP-96-022, dated February 16, 1996	February 1996
State and Tribal Communication Letter FSME 12-025	State and Tribal Communication Letter FSME 12-025 dated March 13, 2012, "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR," ADAMS Accession No. ML12065A038	March 2012
EPPAD 3.5 (Draft for Interim Use)	Division of Waste Management and Environmental Protection, Environmental and Performance Assessment Directorate, Operating Procedures, EPPAD 3.5, "Review, Approval, and Documentation of Low-Activity Waste Disposals in Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a)," ADAMS Accession No. ML092460058	August 2009
ANSI N323AB-2013	ANSI N323AB-2013, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments"	2013
ANSI N13.1-2011	ANSI N13.1-2011, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities"	2011
ANSI N13.30-2011	ANSI N13.30-2011, "Performance Criteria for Radiobioassay"	2011
ANSI N42.18-2004	ANSI N42.18-2004, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents"	2004
NCRP Commentary No. 3	NCRP Commentary No. 3, "Screening Techniques for Determining Compliance with Environmental Standards"	published in January 1989, and the addendum published October 1989

Table A-1. List of Documents Considered in Development of this NUREG

Document Identification	Title	Date
NCRP Report No. 105	NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel"	1989
NCRP Report No. 114	NRCRP Report No. 114, "Maintaining Radiation Protection Records"	1992
DOE G 441.1-1C, Admin Chg 1	U.S. Department of Energy, DOE G 441.1-1C, Admin Chg 1, "Radiation Protection Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection"	July 8, 2011
63 FR 67132-34	<i>Federal Register</i> : "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination"	November 18, 1998
64 FR 68395-96	<i>Federal Register</i> : "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination"	December 7, 1999
65 FR 37186	<i>Federal Register</i> : "Use of Screening Values to Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination"	<i>June 13, 2000</i>

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APPENDIX B

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U.S. NUCLEAR REGULATORY COMMISSION FORM 313

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U.S. Nuclear Regulatory Commission Form 313

Please use the most current version of this form, which may be found at:
<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf>

NRC FORM 313 <small>(06-2016)</small> <small>10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40</small>	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES: 06/30/2019		
 APPLICATION FOR MATERIALS LICENSE		Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.			
INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.					
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: MATERIALS SAFETY LICENSING BRANCH DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352			
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,		ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,			
SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713		SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511			
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.					
1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i> <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____		2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include ZIP code)</i>			
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION BUSINESS TELEPHONE NUMBER _____ BUSINESS CELLULAR TELEPHONE NUMBER _____ BUSINESS EMAIL ADDRESS _____			
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.					
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.		6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.			
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.		7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.			
10. RADIATION SAFETY PROGRAM.		9. FACILITIES AND EQUIPMENT.			
12. LICENSE FEES <i>(Fees required only for new applications, with few exceptions*)</i> <small>(See 10 CFR 170 and Section 170.31)</small> *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.		FEE CATEGORY <input style="width: 50px;" type="text"/>	AMOUNT ENCLOSED \$ <input style="width: 50px;" type="text"/>		
13. CERTIFICATION. <i>(Must be completed by applicant)</i> THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.					
CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE		SIGNATURE	DATE		
FOR NRC USE ONLY					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$	DATE	
APPROVED BY				DATE	

NRC FORM 313 (06-2016)

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APPENDIX C

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**SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN
ITEMS 5 THROUGH 11 OF U.S. NUCLEAR REGULATORY COMMISSION
FORM 313**

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1 **Suggested Format for Providing Information Requested in**
 2 **Items 5 through 11 of U.S. Nuclear Regulatory Commission Form 313**

3 The table below is designed to help applicants develop their applications. It may also be used
 4 as a License Reviewer Checklist for applications for Manufacturing and Distribution licenses. A
 5 box in a column () indicates that the licensee may agree to use a model procedure, or if not
 6 using a model procedure, the licensee is then expected to describe its program or submit its
 7 procedures for the particular item.

8 For broad scope usage applications, refer to NUREG–1556, Vol. 11, “Consolidated Guidance
 9 About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope,”
 10 issued April 1999.

Table C–1. License Reviewer Checklist			
ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
5.	<p>RADIOACTIVE MATERIAL</p> <p>Unsealed or Sealed Sources, or Both</p> <p>For unsealed materials, do the following:</p> <ul style="list-style-type: none"> • For each radionuclide, provide the element name with mass number, chemical and/or physical form, and maximum requested possession limit. • For potentially volatile materials (e.g., I-125, I-131, H-3, Kr-85), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form. <p>For sealed radioactive materials, do the following:</p> <ul style="list-style-type: none"> • Identify each radionuclide (element name and mass number) that will be used, and specify the maximum activity per source. • Provide the manufacturer’s (distributor’s) name and model number for each sealed source and device requested. • Confirm that each sealed source, device, and source and device combination is registered as an approved sealed source or device by NRC or an Agreement State. 	N/A	<input type="checkbox"/>
		N/A	<input type="checkbox"/>

Table C–1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
5.	<p>RADIOACTIVE MATERIAL <i>(Continued)</i></p> <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • If financial assurance is required, submit the required documents, as described in NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance—Financial Assurance, Recordkeeping, and Timeliness.” 	N/A	<input type="checkbox"/>
6.	<p>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE POSSESSED AND USED</p> <ul style="list-style-type: none"> • List the specific use or purpose of each radionuclide that will be possessed and used. Use of the suggested table format will facilitate review of the application. • Identify each device, manufactured article, or material that becomes the product, by manufacturer and model number. • Identify the SSD registration certificate number of each sealed source proposed for possession and use or incorporation into a manufactured article. • Submit information requesting authorization to possess and use any other licensed materials in support of the manufacturing and distribution license. 	N/A	<input type="checkbox"/>
7.	<p>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p>RSO</p> <p>Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.</p> <p>Information should include, as a minimum:</p> <ul style="list-style-type: none"> • formal training and/or education in radiation safety (topics covered, duration of training when training was received, identity/location of training provider) (Note: a course outline may be provided.) • experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience) 	N/A	<input type="checkbox"/>

Table C-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
7.	<p>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</p> <p><i>RSO (Continued)</i></p> <ul style="list-style-type: none"> • experience performing the duties of a Radiation Safety Officer (activities, duration of experience, scope of program) 		
	<p>Authorized Users</p> <p>Provide the name of each proposed AU with the types and quantities of licensed material to be possessed or possessed and used. Also provide information demonstrating that each proposed AU is qualified by training and experience to possess and use the requested licensed materials.</p> <p>Information should include, as a minimum:</p> <ul style="list-style-type: none"> • formal training and/or education in radiation safety (topics covered, duration of training when training was received, identity/location of training provider) (Note: a course outline may be provided.) • experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience) 	N/A	<input type="checkbox"/>
8.	<p>TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p> <p>Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.</p>	N/A	<input type="checkbox"/>
9.	<p>FACILITIES AND EQUIPMENT</p> <p>Describe the facilities and equipment to be made available at each location where radioactive material will be possessed or possessed and used (see Appendix G of this NUREG for topics to consider). This information should be from the point of view of performance criteria. For example, state the purpose of your filtration equipment and the associated acceptance criteria to accomplish this</p>	N/A	<input type="checkbox"/>

Table C–1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
	purpose (such as the ventilation flow rate you are trying to maintain).		
9.	<p>FACILITIES AND EQUIPMENT (Continued)</p> <p>Include a description of the area(s) assigned for the receipt, shipping, storage, preparation, security, and measurement of radioactive materials.</p> <p>Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.</p> <ul style="list-style-type: none"> • When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. • Diagrams should be drawn to a specified scale, or dimensions should be indicated. • For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. <p>If radioactive materials will be used with animals, include a description of the animal-handling housing facilities. NUREG–1556, Vol. 7 may also be used as guidance.</p>	<p>N/A</p> <p>N/A</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
10.	<p>RADIATION SAFETY PROGRAM</p> <p>Audit Program</p> <p>The applicant is not required to, and should not, submit its audit program to the NRC for review as part of a license application. However, this matter may be reviewed during NRC inspections.</p> <p>Radiation Monitoring Instruments</p> <p>Describe the instrumentation that will be used to perform required surveys.</p> <p style="text-align: center;">AND</p> <p>State that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix I in NUREG–1556, Volume 12, Rev.1,</p>	<p>N/A</p> <p>N/A</p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p>

Table C–1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
	‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing		
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>and Distribution.’ We reserve the right to upgrade our radiation survey instruments as necessary.”</p> <p>For Instrument Calibration</p> <p>State that: “Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.”</p> <p style="text-align: center;">OR</p> <p>State that: “We will implement the model radiation survey instrument calibration program published in Appendix I in NUREG–1556, Volume 12, Rev. 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.’”</p> <p style="text-align: center;">OR</p> <p>Submit equivalent procedures for instrument calibrations.</p> <p>Material Receipt and Accountability</p> <p>State that: “We will comply with the NSTS reporting requirement, as described in 10 CFR 20.2207.”</p> <p style="text-align: center;">AND</p> <p>State that: “We will develop, implement, and maintain procedures for ensuring accountability of license materials at all times.”</p> <p style="text-align: center;">AND</p> <p>Provide either of the following</p> <ul style="list-style-type: none"> • a statement that: “Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of 	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>	<p>N/A</p> <p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p>

Table C–1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
	inventory will be maintained for a period of 5 years from the date of each inventory and will include the radionuclides, quantities, manufacturer’s name and model numbers, and the date of the inventory.”		
10.	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • a description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced <p>Occupational Dose</p> <p>The applicant should provide one of the following statements:</p> <p>“We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.”</p> <p style="text-align: center;">OR</p> <p>“We will monitor individuals in accordance with the criteria in the section titled, ‘Radiation Safety Program–Occupational Dose’ in NUREG–1556, Vol. 12, Rev. 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.’”</p> <p style="text-align: center;">OR, IN LIEU OF THESE STATEMENTS,</p> <p>provide a description of an alternative method for demonstrating compliance with the referenced regulations.</p> <p>Public Dose</p> <p>No response is required from the applicant; however, the NRC will examine records and written materials documenting compliance during inspection.</p> <p>Safe Use of Radionuclides and Emergency Procedures</p> <p>The applicant should provide the following statements: “Procedures for safe use, security of materials, and emergencies will be developed and documented before receipt of licensed material. Operating and emergency</p>	<p>N/A</p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p>N/A</p> <p>N/A</p> <p>N/A</p>

Table C-1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
	<p>procedures will be implemented and maintained.”</p> <p style="text-align: center;">AND</p>		
<p>10.</p>	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>“Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing; (ii) the licensee staff is provided training in the revised procedures prior to implementation; (iii) the changes are in compliance with NRC regulations and the license; and (iv) the changes do not degrade the effectiveness of the program.”</p> <p style="text-align: center;">AND</p> <p>If an “Emergency Response Plan” is required for your license pursuant to 10 CFR 30.32(i), submit it as a separate part of the application.</p> <p>Surveys and Leak Tests</p> <p>The applicant should provide one of the following statements:</p> <p>“We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix N to NUREG-1556, Vol. 12, Rev. 1, ‘Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.’”</p> <p>If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or by using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions.”</p> <p style="text-align: center;">OR</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p>	<p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p>

Table C–1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
	<p>“We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix N to NUREG–1556, Vol. 12, Rev. 1, ‘Consolidated Guidance about Material Licenses: Program-Specific Guidance about</p>	<input type="checkbox"/>	N/A
<p>10.</p>	<p>RADIATION SAFETY PROGRAM (Continued)</p> <p>Possession Licenses for Manufacturing and Distribution.” If applicable, state, “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate. We will follow the model procedures in Appendix O of NUREG–1556, Vol. 12, Rev. 1, ‘Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.”</p> <p style="text-align: center;">OR</p> <p>Submit a description of alternative equipment and/or procedures to evaluate radiological hazards at your facility, in accordance with 10 CFR 20.1501 and for determining whether there is radioactive leakage from sealed sources or plated foils. If applicable, state: “We will perform contamination checks on all fabricated sealed sources prior to distribution. Also, leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD registration certificate.”</p> <p>Maintenance</p> <p>No response is required in the application process. The results of actions taken in the maintenance and repair of facilities and equipment process will be reviewed during inspection.</p> <p>Transportation</p> <p>No response is needed from applicants during the licensing phase; however, the NRC will examine records and written materials that document compliance.</p> <p>Security Program For Category 1 and 2 Material</p> <p>No response is required from an applicant or licensee.</p>	<p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p>

Table C–1. License Reviewer Checklist (Continued)

ITEM NO.	SUGGESTED RESPONSE	AGREE TO USE	DESCRIPTION ATTACHED
11.	<p>WASTE MANAGEMENT</p> <p>The applicant should provide one of the following statements:</p>		
11.	<p>WASTE MANAGEMENT (Continued)</p> <ul style="list-style-type: none"> • “We will use the model waste procedures and guidelines published in Appendix Q to NUREG–1556, Volume 12, Rev. 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.’” <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • “We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures and guidelines that are published in Appendix Q to NUREG–1556, Volume 12, Rev. 1, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.’” <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • If the applicant wishes to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix Q to NUREG–1556, Vol. 12, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution.” <p style="text-align: center;">AND/OR</p> <ul style="list-style-type: none"> • If access to a radioactive waste burial site is unavailable, the applicant should request authorization for extended interim storage of waste. Applicant should use the references listed below for guidance and submit the required information with the application. 	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p>	<p style="text-align: center;">N/A</p> <p style="text-align: center;">N/A</p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>

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APPENDIX D

2

LICENSE TYPES—GUIDANCE

License Types–Guidance

The following codes are used for each byproduct material license.

XX (State code)-XXXXX (institution code – a unique identifier for each licensee)-XX (sequential number of license for that licensee). Letters that follow the license number on distribution licenses include E, G, and MD. No letters indicates a possession license.

Manufacturer’s Possession License XX-XXXXX-XX

This specific license is issued to a manufacturer to possess, use, manufacture, etc., licensed material for distribution (includes importers that may not manufacture but want a location for distribution) and for use by the licensee in process controls. It can include distribution to other specific licensees who are also specifically authorized to receive the materials pursuant to their specific license. The manufacturer’s possession license contains conditions that prohibit distribution pursuant to 10 CFR 32.72 and 32.74 and prohibit distribution to general licensees and to persons exempt from licensing.

General Distribution License XX-XXXXX-XXG

This specific license is issued to manufacturers and/or distributors to distribute approved materials to persons who are generally licensed to possess and use the materials. This license does not authorize the possession of byproduct, source, or special nuclear material.

The most common products distributed to general licensees are

- 10 CFR 32.51/51a/52–Certain measuring, gauging, or controlling devices, including fixed gauges (e.g., density, thickness), and may include multi-curie sources, gas chromatograph ECDs, X-ray fluorescence or other analytical devices, curie-quantity tritium light sources for exit signs, and similar devices. For possession and use by persons authorized by a General License pursuant to 10 CFR 31.5.
- 10 CFR 32.71 – Kits for *in vitro* clinical or laboratory testing (e.g., microcurie quantities of H-3, C-14, Fe-55, I-125). For possession and use by persons authorized by a General License pursuant to 10 CFR 31.11.

Exempt Distribution License XX-XXXXX-XXE

Specific license to distribute approved materials to persons who are not required to have any license in order to possess or use the material. Exempt Distribution is authorized by a specific license issued by NRC Headquarters in Washington, D.C. This license does not authorize the possession of byproduct, source, or special nuclear material.

Medical Distribution License (XX-XXXXX-XXMD)

10 CFR 32.72 and 32.74

Sources/devices for medical use pursuant to 10 CFR 35.65 400/500 /600/1000 for radiopharmaceuticals for medical use pursuant to 10 CFR 35.100/200/300/1000 (This license does not authorize the possession of byproduct, source, or special nuclear material.)

1 Manufacturers of medical devices may wish to plan for return shipments of licensed materials.
2 Manufacturers of sealed source devices such as eye applicators or bone densitometers may
3 wish to provide a return at the end of useful life service. Radiopharmaceutical manufacturers
4 may wish to receive spent generator assemblies from their customers and dispose of them by
5 decay-in-storage. The manufacturer should prepare return shipping procedures for customers
6 to use. The shipper is responsible for the proper preparation for shipment. Many licensees
7 request assistance from manufacturers about shipments, and the license applicant should
8 provide instructions to facilitate their customer. These instructions may be included with this
9 license application. Returned materials are possessed pursuant to the manufacturer's
10 possession license.

11

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APPENDIX E

2

RADIATION SAFETY OFFICER DUTIES AND RESPONSIBILITIES

Radiation Safety Officer Duties and Responsibilities

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety and compliance with NRC and the conditions of the license. Typically, the RSO's duties and responsibilities include the following:

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license.
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301.
- Ensure security of radioactive material, and for licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, develop and implement a security program for radioactive material in accordance with 10 CFR Part 37.
- Post documents as required by 10 CFR Parts 19.11 and 21.6.
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are ALARA.
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed or possessed and used.
- Act as liaison with NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Distribute and process personnel radiation-monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, and regulations.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.

- 1 • Oversee the storage of radioactive material not in current use, including waste.
- 2 • Perform or arrange for leak tests on all sealed sources and calibration of radiation
3 survey instruments.
- 4 • Maintain an inventory of all radionuclides possessed under the license, and limit the
5 quantity to the amounts authorized by the license.
- 6 • Immediately terminate any unsafe condition or activity that is found to be a threat to
7 public health and safety or property.
- 8 • Supervise decontamination and recovery operations.
- 9 • Maintain other records not specifically designated above (e.g., records of
10 receipts; transfers; and surveys, as required by 10 CFR 30.51 and 10 CFR 20,
11 Subpart L, "Records").
- 12 • Hold periodic meetings with and provide reports to licensee management.
- 13 • Ensure that all users are properly trained.
- 14 • Perform periodic audits of the Radiation Safety Program to ensure that the licensee is
15 complying with (i) all applicable NRC regulations; (ii) the terms and conditions of the
16 license (e.g., leak tests; inventories; possession or possession and use limited to
17 trained, approved users); (iii) the content and implementation of the Radiation Safety
18 Program to achieve occupational doses and doses to members of the public that are
19 ALARA, in accordance with 10 CFR 20.1101; and (iv) the requirement that all records be
20 properly maintained.
- 21 • Ensure that the results of audits, identification of deficiencies, and recommendations for
22 change are documented (and maintained for at least 3 years) and provided to
23 management for review, and ensure that prompt action is taken to correct deficiencies.
- 24 • Ensure that the audit results and corrective actions are communicated to all personnel
25 who possess or possess and use licensed material.
- 26 • Ensure that all incidents, accidents, and personnel exposure to radiation in excess of
27 ALARA or Part 20 limits are investigated and reported to NRC and other appropriate
28 authorities, if required, within the required time limits.
- 29 • Maintain an understanding of, and up-to-date copies of, NRC regulations, the license,
30 and revised licensee procedures, and ensure that the license is amended whenever
31 there are changes in licensed activities, responsible individuals, or information or
32 commitments provided to NRC during the licensing process.

33

1 **Model Delegation of Authority**

2 Memo To: Radiation Safety Officer

3 From: Chief Executive Officer

4 Subject: Delegation of Authority

5

6 You, _____, have been appointed radiation safety officer and
7 are responsible for ensuring the safe and secure use of radiation. You are responsible for
8 managing the Radiation Safety Program; identifying radiation protection problems; initiating,
9 recommending, or providing corrective actions; verifying implementation of corrective actions;
10 stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated
11 the authority necessary to meet those responsibilities, including prohibiting the use of byproduct
12 material by employees who do not meet the necessary requirements and shutting down
13 operations, when justified, to maintain radiation safety. You are required to notify management if
14 staff does not cooperate and does not address radiation safety issues. In addition, you are free
15 to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that
16 you will spend _____ hours per week conducting radiation protection activities.

17

18 _____
19 Signature of Management Representative
20 Date

21

22 I accept the above responsibilities.

23

24 _____
25 Signature of Radiation Safety Officer

_____ Date

26

27

28 cc: Affected department heads

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APPENDIX F

2

RADIATION SAFETY TRAINING

Radiation Safety Training

This appendix is intended only as a guide for developing a training program. Individuals working with radionuclides may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be accomplished by providing a simple hand-out, whereas others may require extensive training, including an exam to assess retention of the topics presented.

The licensee should determine whether the training succeeded in conveying the desired information, and adjust the training program as necessary. This assessment may be performed by a test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

Frequency of Training

- A. before assuming duties with or when in the vicinity of radioactive materials
- B. whenever there is a significant change in duties, regulations, or the terms of the license
- C. annually (refresher training)

General Information

- A. radiation safety
 - 1. radiation vs. contamination
 - 2. internal vs. external exposure
 - 3. biological effects of radiation
 - 4. ALARA concept
 - 5. use of time, distance, and shielding to minimize exposure
 - 6. contact dose rates and dose rates at a distance from high activity sources
 - 7. dose reduction responsibilities
- B. regulatory requirements
 - 1. RSO
 - 2. material control and accountability
 - 3. personnel dosimetry
 - 4. Radiation Safety Program audits

- 1 5. transfer and disposal
- 2 6. recordkeeping
- 3 7. surveys
- 4 8. postings
- 5 9. labeling of containers
- 6 10. handling and reporting of incidents or events
- 7 11. licensing and inspection by NRC
- 8 12. need for complete and accurate information
- 9 13. employee protection
- 10 14. deliberate misconduct

11 **Licensee-Specific Program Elements**

- 12 A. authorized users and supervised users
- 13 B. worker-specific manufacturing process tasks
- 14 C. shipping
- 15 D. ordering and receiving radionuclides
- 16 E. applicable regulations and license conditions
- 17 F. areas where radioactive material is used or stored
- 18 G. potential hazards associated with radioactive material in each area where the individuals
19 will work
- 20 H. appropriate radiation safety procedures
- 21 I. licensee's in-house work rules (for instructions on laboratory safety and uses of
22 radionuclides, see Appendix L of this NUREG)
- 23 J. each individual's obligation to report unsafe conditions to the RSO
- 24 K. appropriate response to spills, emergencies, or other unsafe conditions
- 25 L. worker's right to be informed of occupational radiation exposure and bioassay results,
26 if applicable
- 27 M. locations where the licensee has posted or made available notices, copies of pertinent
28 regulations, and copies of pertinent licenses and license conditions (including applications
29 and applicable correspondence), as required by 10 CFR Part 19

- 1 N. security of materials
- 2 1. receiving materials
- 3 2. using materials
- 4 3. storing materials
- 5 4. possessing Category 1 or 2 materials and then 10 CFR Part 37 security training.
- 6 O. emergency procedures
- 7 1. RSO name and telephone number
- 8 2. immediate steps to prevent or control spread of contamination
- 9 3. clean-up instructions, decontamination
- 10 P. survey program
- 11 1. radiation survey instrument accessibility
- 12 2. who is responsible
- 13 3. types, contamination, and areas
- 14 4. frequency
- 15 5. levels of contamination
- 16 6. personnel, hands, shoes
- 17 7. records
- 18 Q. radioactive waste
- 19 1. liquid
- 20 2. solids
- 21 3. sanitary sewer
- 22 4. burial (transfer to low-level waste repository)
- 23 5. storage
- 24 6. decay-in-storage
- 25 7. waste storage surveys
- 26 8. records

- 1 R. dosimetry
- 2 1. whole body
- 3 2. extremities
- 4 3. lost or replacement badges and dose assessment
- 5 4. bioassay procedures
- 6 5. records
- 7 S. Instrumentation
- 8 1. radiation survey meters – use, calibration frequency, use of check sources
- 9 2. analytical instruments – gas flow counters, liquid scintillation counters
- 10 T. Procedures for receiving packages containing radioactive materials
- 11 1. normal
- 12 2. off-duty
- 13 3. notification of user and RSO
- 14 4. exposure levels
- 15 5. possession limit
- 16 6. receipt of damaged packages
- 17 U. Procedures for opening and examining packages
- 18 1. leakage and contamination
- 19 2. monitoring packages
- 20 3. monitoring packing materials
- 21 4. gloves
- 22 5. transferring material to users
- 23 V. Animal experiments
- 24 1. description of facilities
- 25 2. procedures to be performed with animals
- 26 3. safety instructions, including handling of animals, waste, carcasses, and cleaning and
- 27 decontamination of cages

- 1 W. Sealed sources
- 2 1. leak-test requirements
- 3 2. inventory requirements
- 4 3. exempt quantities
- 5 4. records
- 6 X. NRC/State/Licensee audit findings
- 7 Y. Other topics
- 8 Z. Question and answer period

9 **For Laboratory Safety and Use of Radionuclides**

- 10 A. Control procedures for obtaining permission to possess or possess and use radioactive
11 materials at the facility; give limitations on quantity to be handled per user, or allowed per
12 experiment, etc.
- 13 B. Protective clothing and what laboratory apparel to wear and what equipment to use.
- 14 C. Limitations and conditions relative to handling unsealed licensed material and what
15 laboratory equipment to use when working with such material. For example, discuss which
16 licensed materials and what procedures should be confined to radiochemical fume hoods or
17 glove boxes. Explain what shielding or remote handling equipment is to be used when beta
18 and/or gamma-emitting licensed materials are handled.
- 19 D. Routine survey and monitoring procedures to be followed for contamination control. Include
20 where and how contaminated articles and glassware are to be handled and stored.
- 21 E. Emergency procedures concerning spills, fires, release of material, and/or accidental
22 contamination of personnel.
- 23 F. Decontamination procedures to use and whom to contact in case of an emergency.
- 24 G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors,
25 if applicable.
- 26 H. Requirements for storage, labeling of containers, and identification of areas where licensed
27 materials are possessed or possessed and used.
- 28 I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and
29 exposure results.
- 30 J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and
31 procedures to use for waste storage. If the program involves experiments with animals,
32 procedures for cleaning animal quarters and handling animal excreta and carcasses
33 for disposal.

- 1 K. Records to be maintained on possession, use, and disposal of licensed materials.
- 2 L. Prohibition of pipetting by mouth.
- 3 M. Prohibition of eating, smoking, drinking, and application of cosmetics in areas where
- 4 licensed materials are possessed or possessed and used.

1

APPENDIX G

2

FACILITIES AND EQUIPMENT

3

Facilities and Equipment

The applicant should consider the following list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each topic in its application.

- Restricted areas are defined as areas where the licensee is to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted and unrestricted areas and the location of all pertinent safety-related equipment. Bench-top or open work areas may be used for sealed sources, small quantities of solid materials in a form not likely to become airborne or dispersed, and small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.

- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems, such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems. Ventilation systems for these facilities should be designed so that airborne radioactive material work areas are at negative pressure compared to non-radioactive work areas.

Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, unsealed volatile licensed materials, and processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR Part 20, Appendix B.

Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.

For the most efficient operation of hoods and glove boxes, minimize storage of materials and equipment inside the work areas.

- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down to prevent the spread of radioactivity. If appropriate, supply and exhaust fans can be interlocked such that if exhaust fans shut down, the shutdown of supply fans is also triggered, this interlock system is to prevent laboratory

- 1 and work areas from becoming positively pressurized with respect to the surrounding
2 parts of the facility.
- 3 • Sink faucets should be designed, where possible, for operation by foot, knee, or elbow
4 rather than by hand.
 - 5 • Plumbing and ductwork should be designed to avoid radioactive contamination build-up.
6 This build-up of contamination can create external radiation exposure hazards and
7 problems for decommissioning.
 - 8 • To reduce radiation exposure from gamma-emitting radioactive materials, shielding
9 consisting of lead or other high-density material in the form of bricks, panels, L-shields,
10 storage containers, or other shapes may be used on bench tops, in fume hoods, or in
11 glove boxes.
 - 12 • To reduce the exposure from high-energy beta-emitting materials, shielding of low-
13 atomic-number material, such as high-density plastic, may be used. In operations using
14 large quantities (i.e., multi-millicurie quantities) of high-energy beta-emitting
15 radionuclides and/or longer exposure times, it may be necessary to also reduce the
16 bremsstrahlung by adding shielding containing high-atomic-number material such as
17 lead. These shields generally are low-atomic-number materials closest to the source,
18 enclosed by high-atomic-number material.
 - 19 • Shielded shipping containers are used frequently for continued storage after receipt
20 of materials.
 - 21 • Remote handling tools, such as forceps or extension handles, should be used to provide
22 distance in the handling of radioactive materials (ALARA). In addition, shielded handling
23 devices, such as shielded syringes, can be used to protect workers from materials that
24 cannot be handled remotely. Pipetting should be done using appropriate devices.
25 Pipetting by mouth should be strictly forbidden.
 - 26 • Designated areas should be provided for coats and personal belongings, to
27 avoid contamination.
 - 28 • Areas with background radiation levels should be designated for personnel dosimetry
29 storage when not in use.
 - 30 • Areas of use should be well-lighted to avoid spills and other accidents that could result in
31 contamination buildup.
 - 32 • Observation of activities conducted behind shielding with remote tools (or with extended
33 arms and hands, within limits consistent with permissible occupational exposures) can
34 be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through
35 transparent plastic beta shields, or by remote video monitoring.
 - 36 • The combination of containment, shielding, and handling devices proposed for any use
37 of radioactive materials should be appropriate to the type and quantity of materials to be
38 used and to the type and duration of operations to be conducted.

- 1 • If respiratory protective equipment will be used to limit inhalation of airborne licensed
2 material, follow the provisions of 10 CFR Part 20, Subpart H, "Respiratory protection and
3 controls to restrict internal exposure in restricted areas."

- 4 • A particular sink should be designated for disposal of liquid radioactive waste to the
5 sanitary sewerage system. In some cases, depending on the number of users and
6 distance between areas of use, more than one sink may need to be designated.

- 7 • Labeled waste containers should be used. These containers may be shielded as
8 necessary and placed near the waste-generating areas and away from areas that
9 personnel frequently occupy. Additionally, these containers should be effectively
10 enclosed to prevent airborne contamination from radioactive materials deposited. If
11 radioactive waste materials are volatile, the containers should be stored in
12 ventilated areas.

- 13 • If compaction of waste is performed, ensure that the facilities are adequate for the
14 ventilation of the area where the waste is compacted. In addition, also ensure that air
15 sampling for internal exposures is available, if needed per 10 CFR 20.1204.

- 16 • Adequate air and/or water effluent-monitoring equipment should be used to demonstrate
17 compliance with the limits found in 10 CFR Part 20, Appendix B, if applicable, and tested
18 for operability at the frequency established by the manufacturer.

1

APPENDIX H

2

SAMPLE AUDIT PROGRAM

3

Sample Audit Program

1
2 An audit is conducted, in part, to fulfill the requirements of 10 CFR 20.1101 for an annual review
3 of the content and implementation of the licensee's radiation safety program. Audits should be
4 performance-based, and include observations of licensed activities, interviews with personnel,
5 and inspection of facilities and equipment. It should also identify program weaknesses and allow
6 licensees to take early corrective actions (before an NRC inspection). During an audit, the
7 auditor needs to keep in mind not only the requirements of the NRC's regulations, but also the
8 licensee's commitments in its applications and other correspondence with the NRC. The auditor
9 should also evaluate whether the licensee is maintaining exposures to workers and the
10 general public as low as is reasonably achievable (ALARA) and, if not, make suggestions
11 for improvement.

12 The form in this appendix can be used to document the annual audit of the radiation safety
13 program. Guidance on completing each section of the form is provided below. In the "remarks"
14 portions of the form, note any deficiencies identified and the corrective actions taken (or to
15 be taken).

16 Section 1 Audit History

17 Enter the date of the last audit, whether any deficiencies were identified, and whether actions
18 were taken to correct the deficiencies.

19 Section 2 Organization and Scope of Program

20 Give a brief description of the organizational structure, noting any changes in personnel or
21 procedures, and amendments to the license. Describe the scope of licensed activities at the
22 audited location. Check whether the Radiation Safety Officer (RSO) is the person identified in
23 the license and fulfills the duties specified in the license.

24 Section 3 Training, Retraining, and Instructions to Workers

25 Ensure that workers have received the training required by 10 CFR 19.12. Be sure that the user
26 has received training and has a copy of the licensee's safe use and emergency procedures
27 before being permitted to use byproduct material. Note whether refresher training is conducted,
28 in accordance with licensee commitments. Ensure that each worker has a copy of the licensee's
29 procedures, and, by interview or observation of selected workers, that he or she can
30 implement them.

31 Section 4 Audits

32 Verify that audits fulfill the requirements of 10 CFR 20.1101, are conducted in accordance with
33 licensee commitments, and are properly documented.

34 Section 5 Facilities

35 Verify that the licensee's facilities are as described in its license documents.

36

1 **Section 6 Materials**

2 Verify that the license authorizes the quantities and types of byproduct material that the
3 licensee possesses.

4 **Section 7 Leak Tests**

5 Verify that all sealed and plated foil sources are tested for leakage at the prescribed frequency
6 and in accordance with licensee commitments. Records of results should be maintained.

7 **Section 8 Inventories**

8 Verify that inventories are conducted at least once every 6 months to account for all sources;
9 inventory records should be maintained.

10 **Section 9 Radiation Surveys**

11 Verify that the licensee has appropriate, operable, and calibrated radiation survey instruments
12 available and that the instruments are calibrated (at the required frequency) in accordance with
13 license conditions and in accordance with 10 CFR 20.2103. Calibration records must be
14 retained for 3 years after the record is made. Check that radiation levels in areas adjacent to
15 use are within regulatory limits and in accordance with 10 CFR 20.2103. Verify compliance with
16 10 CFR 20.1301. Records of surveys must be retained for 3 years after the record is made.

17 **Section 10 Receipt and Transfer of Radioactive Material (Includes Waste Disposal)**

18 Verify that packages received from others containing byproduct material are received, opened,
19 and surveyed in accordance with 10 CFR 20.1906, "Procedures for receiving and opening
20 packages." Ensure that transfers are performed in accordance with 10 CFR 30.41. Records of
21 surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103 and
22 10 CFR 30.51.

23 **Section 11 Transportation**

24 Determine compliance with Department of Transportation (DOT) requirements.

25 **Section 12 Personnel Radiation Protection**

26 Evaluate the licensee's determination that unmonitored personnel are not likely to receive more
27 than 10 percent of the allowable limits. Alternately, if personnel dosimetry is provided and
28 required, verify that it complies with 10 CFR 20.1501(c) and licensee commitments. Review
29 personnel monitoring records, compare exposures of individuals doing similar work, and
30 determine reasons for significant differences in exposures. If any worker declared her
31 pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208. Check whether
32 records are maintained, as required by 10 CFR 20.2101, 2102, 2103, 2104, and 2106.

33 **Section 13 Auditor's Independent Measurements (If Made)**

34 The auditor should make independent survey measurements and compare the results with
35 those made or used by the licensee.

1 **Section 14 Notification and Reports**

2 Check on the licensee's compliance with the notification and reporting requirements in
3 10 CFR Parts 19, 20, and 30. Ensure that the licensee is aware of the telephone number for
4 NRC's Emergency Operations Center: 301-816-5100.

5 **Section 15 Posting and Labeling**

6 Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 20.1902,
7 20.1904, and 21.6.

8 **Section 16 Recordkeeping for Decommissioning**

9 Check to determine compliance with 10 CFR 30.35(g), 10 CFR 40.36(f), and/or
10 10 CFR 70.25(g).

11 **Section 17 Bulletins and Information Notices**

12 Check to determine if the licensee is receiving bulletins, information notices, NMSS Newsletters,
13 etc., from the NRC. Check whether the licensee took appropriate action in response to
14 NRC mailings.

15 **Section 18 Special License Conditions or Issues**

16 Verify compliance with any special conditions on the licensee's license. If the licensee has any
17 unusual aspect of its work, review and evaluate compliance with regulatory requirements.

18 **Section 19 Continuation of Report Items**

19 This section is self-explanatory.

20 **Section 20 Problems or Deficiencies Noted; Recommendations**

21 This section is self-explanatory.

22 **Section 21 Evaluation of Other Factors**

23 Evaluate licensee management's involvement with the radiation safety program, whether the
24 RSO has sufficient time to perform his/her duties, and whether the licensee has sufficient staff
25 to handle the workload and maintain compliance with regulatory requirements.

26 Note: All areas indicated in audit notes may not be applicable to every license and may not
27 need to be addressed during each audit.

28

1 **Sample Checklist**

2

3 Audit Report No. _____ License No. _____

4

5 Licensee's name and mailing address:

6 _____
7 _____
8 _____
9 _____

10 Audit of activities at (address):

11 _____
12 _____
13 _____
14 _____

15 Contact at audit location: _____ Telephone No.: _____

16

17 Date of this audit: _____

18

19 Summary of Findings and Action:

- 20 No deficiencies
- 21 Deficiencies
- 22 Action on previous deficiencies

23 Recommendations:

24

25

26

27

28 Auditor: _____ Date: _____

29 (Signature)

30

31

1 1. AUDIT HISTORY N/A (N/A means "Not applicable" – Initial Audit)

2 A. Last audit of this location conducted

3 B. Problems/deficiencies identified during last 2 audits or 2 years,
4 whichever is longer Y N

5 C. Open problems/deficiencies from previous audits:

Status Requirement	Problem/Deficiency	Corrective Action Taken (Y/N)	Open/Closed
6			
7			
8			
9			
10			
11			

12 D. Any previous problem/deficiency not corrected or repeated Y N N/A

13 Explain:

14 2. ORGANIZATION AND SCOPE OF PROGRAM

15 A. Briefly describe organizational structure

16 1. Structure described as in license documents Y N

17 2. Multiple authorized locations of use (License Condition (L/C)) Y N

18 3. Brief description of scope of activities involving byproduct
19 material, frequency of use, staff size, etc. Y N

20 4. Amendments and program changes (L/C) Y N

21 B. Radiation Safety Officer Y N

22 1. Authorized on license (L/C) Y N

23 2. Fulfills duties as RSO Y N

24 C. Use only by authorized individuals (L/C) Y N

25 D. Commensurate security program implemented
26 (10 CFR 20.1801 and 10 CFR 20.1802) Y N

27 Remarks:

28 3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

29 A. Instructions to workers in accordance with (10 CFR 19.12) Y N

- 1 B. Training program required Y N
- 2 C. Training records maintained Y N
- 3 D. Evaluation of individuals' understanding of procedures and
4 regulations based on interviews and observations of selected
5 workers Y N
- 6 1. Each has an up-to-date copy of the licensee's safe use and
7 emergency procedures
- 8 2. Adequate understanding of the following:
- 9 • Current safe use procedures Y N
- 10 • Emergency procedures Y N
- 11 E. Revised 10 CFR Part 20
- 12 Workers cognizant of requirements for the following:
- 13 1. Radiation Safety Program (10 CFR 20.1101) Y N
- 14 2. Annual dose limits (10 CFR 20.1301
15 and 10 CFR 20.1302) Y N
- 16 3. New NRC Forms 4 and 5 Y N
- 17 4. Ten percent monitoring threshold (10 CFR 20.502) Y N
- 18 5. Dose limits to embryo/fetus and declared pregnant
19 women (10 CFR 20.1208) Y N
- 20 6. Procedures for opening packages (10 CFR 20.1906) Y N
- 21 Remarks:
- 22 4. INTERNAL AUDITS, REVIEWS, OR INSPECTIONS
- 23 A. Audits are conducted. Y N
- 24 1. Audits conducted by _____
- 25 2. Frequency _____
- 26 B. Content and implementation of the radiation protection
27 program reviewed at least annually [10 CFR 20.1101(c)]. Y N
- 28 C. For programs possessing Category 1 or 2 materials:
- 29 1. Access program content and implementation Y N NA
30 [10 CFR 37.33(a)]

- 1 2. Security program content and implementation Y N NA
2 [10 CFR 37.57(a)]
- 3 D. Records are maintained (10 CFR 20.2102). Y N
- 4 5. FACILITIES
- 5 A. Facilities are described as in the license application (L/C). Y N
- 6 B. Security procedures implemented
7 (20.1801, 20.1802; Part 37, if applicable) Y N
- 8 Remarks:
- 9 6. MATERIALS
- 10 Isotopes, quantities, and use are as authorized on license (L/C). Y N
- 11 Remarks:
- 12 7. LEAK TESTS
- 13 A. Leak test is performed as described in correspondence
14 with the NRC (consultant, leak test kit, and
15 licensee performed) (L/C). Y N
- 16 B. Frequency of tests is every 6 months or another interval,
17 as approved by the NRC or Agreement State (L/C). Y N
- 18 C. Records with appropriate information are maintained (L/C). Y N
- 19 Remarks:
- 20 8. INVENTORIES
- 21 A. Inventories are conducted at 6-month intervals (L/C). Y N
- 22 B. Records with appropriate information are maintained (L/C). Y N
- 23 Remarks:
- 24 9. RADIATION SURVEYS
- 25 A. Instruments and equipment: Y N
- 26 1. Appropriate operable radiation survey instrumentation
27 is possessed or is readily available. Y N
- 28 2. Instruments and equipment are calibrated
29 as required (10 CFR 20.1501). Y N
- 30 3. Calibration records are maintained [10 CFR 20.2103(a)]. Y N

- 1 B. Briefly describe survey requirements [10 CFR 20.1501(a):
- 2 C. Surveys are performed as required [10 CFR 20.1501(a)]. Y N
- 3 1. Radiation levels are within regulatory limits. Y N
- 4 2. Corrective action was taken and documented. Y N
- 5 D. Records are maintained (10 CFR 20.2103). Y N
- 6 E. Protection of members of the public:
- 7 1. Adequate surveys are made to demonstrate that (i)
- 8 the TEDE to the individual who is likely to receive the
- 9 highest dose does not exceed 100 mrem in a year or
- 10 (ii) that if an individual were continuously present in an
- 11 unrestricted area, the external dose would not exceed
- 12 2 mrem in any hour and 50 mrem in a year
- 13 [10 CFR 20.1301(a)(1) and 10 CFR 20.1302(b)]. Y N
- 14 2. Unrestricted area radiation levels do not exceed 2 mrem
- 15 in any 1 hour [10 CFR 20.1301(a)(2)]. Y N
- 16 3. Records are maintained (10 CFR 20.2103 and
- 17 10 CFR 20.2107). Y N
- 18 Remarks:
- 19 10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE
- 20 DISPOSAL)
- 21 A. Procedures describe how packages are
- 22 received and by whom. Y N
- 23 B. Written package opening procedures are established and
- 24 are followed (10 CFR 20.1906(e)). Y N
- 25 C. If a package shows evidence of degradation, it is
- 26 monitored for contamination and radiation levels. Y N N/A
- 27 D. Monitoring of degraded packages is performed within time
- 28 specified (10 CFR 20.1906(c)). Y N N/A
- 29 E. A transfer(s) between licensees (including "disposal")
- 30 is performed in accordance with (10 CFR 30.41). Y N N/A
- 31 F. Records of receipt/transfer are maintained
- 32 (10 CFR 20.2103(a) and 10 CFR 30.51). Y N
- 33 G. Transfers within licensee's authorized users or locations
- 34 are performed as required (license condition (L/C)). Y N N/A

- 1 H. Package receipt/distribution activities are evaluated for
2 compliance with (10 CFR 20.1301 and 10 CFR 20.1302). Y N N/A
- 3 I. Reports of transactions involving nationally tracked sources
4 are submitted as required (10 CFR 20.2207). Y N N/A
- 5 Remarks:
- 6 11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189) Y N N/A
- 7 A. Licensee shipments are as follows:
- 8 1. Shipments were delivered to common carriers. Y N N/A
- 9 2. Shipments were transported in licensee's own
10 private vehicle. Y N N/A
- 11 3. No shipments were made since last audit. Y N N/A
- 12 B. Hazmat Training
- 13 1. Applicability and responsibility for training and
14 testing (49 CFR 172.702). Y N N/A
- 15 2. Training requirements (49 CFR 172.704). Y N N/A
- 16 C. Packages N/A
- 17 1. Authorized packages were used
18 [49 CFR 173.415, 173.416(b)]. Y N N/A
- 19 2. Packages were closed and sealed during transport
20 [49 CFR 173.475(f)]. Y N
- 21 D. Shipping Papers N/A
- 22 1. Shipping papers were prepared and used
23 [49 CFR 172.200(a)]. Y N
- 24 2. Papers included proper shipping name, hazard class,
25 UN number, quantity, package type, radionuclide,
26 reportable quantities, radioactive material, physical
27 and chemical form, activity, category of the label,
28 T1, shipper's name, certification and signature,
29 emergency response phone number, and "Cargo
30 Aircraft Only" (if applicable) (49 CFR 172.200 through
31 49 CFR 172.204). Y N
- 32 3. Papers were readily accessible during transport
33 [49 CFR 177.718(e)]. Y N

- 1 E. Vehicles [] Y [] N
- 2 1. The cargo was blocked and braced
3 [49 CFR 177.842(d)]. [] Y [] N
- 4 2. Placarded, if needed (49 CFR 172.504). [] Y [] N
- 5 3. Proper overpacks, if used (with shipping name,
6 UN number, cargo labeled, and statement that
7 indicates that the inner package complies
8 with the specification package) (49 CFR 173.25). [] Y [] N
- 9 F. Any incidents reported to DOT (49 CFR 171.15 and
10 49 CFR 171.16). [] Y [] N
- 11 Remarks:
- 12 12. PERSONNEL RADIATION PROTECTION
- 13 A. ALARA considerations are incorporated into the Radiation
14 Protection Program (10 CFR 20.1101(b)). [] Y [] N
- 15 B. Evaluations are performed showing that unmonitored
16 individuals receive less than the limits in 10 CFR 20.1502(a).
17 The evaluations consider doses to minors
18 [10 CFR 20.1502(a)(2)] and declared pregnant women
19 [10 CFR 20.1502(a)(3)]. [] Y [] N [] N/A
- 20 C. Unmonitored individuals' activities changed during the
21 year in a way that could put them over the limits in
22 10 CFR 20.1502(a). [] Y [] N [] N/A
- 23 If yes, new evaluation was performed. [] Y [] N [] N/A
- 24 D. External dosimetry is required [i.e., when individuals are
25 likely to receive greater than the limits in 10 CFR 20.1502(a)],
26 and provided to individuals. [] Y [] N
- 27 If yes, address the following:
- 28 1. The dosimetry supplier is approved by the National
29 Voluntary Laboratory Accreditation Program
30 [10 CFR 20.1501(c)]. [] Y [] N [] N/A
- 31 2. Dosimeters are exchanged at the appropriate frequency. [] Y [] N [] N/A
- 32 3. Dosimetry reports are reviewed and signed by the RSO
33 when they are received. [] Y [] N [] N/A
- 34 4. Records are based on NRC forms or the equivalent
35 [10 CFR 20.2104(d) and 20.2106(c)]. [] Y [] N [] N/A

- 1 a. NRC Form 4, "Cumulative Occupational Exposure
2 History," are complete. Y N N/A
- 3 b. NRC Form 5, "Occupational Dose Record for a
4 Monitoring Period," are complete. Y N N/A
- 5 E. Declared pregnant workers in the workforce. Y N
- 6 1. Dose equivalent to an embryo/fetus complied with
7 10 CFR 20.1208. Y N N/A
- 8 2. Records of doses to an embryo/fetus complied with
9 10 CFR 20.2106(e). Y N N/A
- 10 F. Records of exposures, surveys, monitoring, and evaluations
11 maintained (10 CFR 20.2102, "Records of radiation protection
12 programs;" 10 CFR 20.2103, "Records of surveys;"
13 10 CFR 20.2106, "Records of individual monitoring results"). Y N N/A
- 14 Remarks:
- 15 13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)
- 16 A. Radiation survey instrument: Serial No.: Last calibration:
- 17 B. The auditor's measurements were compared to the licensee's
18 measurements. Y N
- 19 C. Describe the type, location, and results of the measurements:
- 20 14. NOTIFICATION AND REPORTS N/A
- 21 A. The licensee is in compliance with 10 CFR 19.13 and
22 10 CFR 30.50 (reports to individuals, public, and
23 occupational, monitored to show compliance with
24 10 CFR Part 20). Y N N/A
- 25 B. The licensee is in compliance with 10 CFR 20.2201 and
26 10 CFR 30.50 (theft or loss). Y N None
- 27 C. The licensee is in compliance with 10 CFR 20.2202 and
28 10 CFR 30.50 (incidents). Y N None
- 29 D. The licensee is in compliance with 10 CFR 20.2203 and
30 10 CFR 30.50 (overexposures and high radiation levels). Y N None
- 31 E. The licensee is aware of the telephone number for the
32 NRC Emergency Operations Center (301-816-5100). Y N
- 33 15. POSTING AND LABELING
- 34 A. NRC Form 3, "Notice to Workers," is posted (10 CFR 19.11). Y N

- 1 B. 10 CFR 19, 20, 21; Section 206 of the Energy
2 Reorganization Act of 1974; procedures adopted pursuant
3 to Part 21; and license documents are posted, or a notice
4 indicating the documents can be examined is posted
5 (10 CFR 19.11 and 10 CFR 21.6). Y N
- 6 C. Other posting and labeling activities, in accordance with
7 10 CFR 20.1902 and 10 CFR 1904, and the license are
8 not exempted by 10 CFR 20.1903 and 10 CFR 1905. Y N
- 9 Remarks:
- 10 16. RECORD KEEPING FOR DECOMMISSIONING (IF NEEDED) N/A
- 11 A. Records of information important to the safe and effective
12 decommissioning of the facility are maintained in an
13 independent and identifiable location until license
14 termination. Y N
- 15 B. Records include all information outlined in 10 CFR 30.35(g). Y N
- 16 Remarks:
- 17 17. BULLETINS AND INFORMATION NOTICES
- 18 A. Receipt of NRC bulletins, NRC information notices, NMSS
19 newsletters, and other communications Y N
- 20 B. Appropriate action was taken in response to bulletins,
21 information notices, and other communications. Y N
- 22 Remarks:
- 23 18. SPECIAL LICENSE CONDITIONS OR ISSUES N/A
- 24 A. Review special license conditions or other issues and
25 describe findings (L/C):
- 26 B. Problems/deficiencies identified at the licensee's facilities
27 other than at audit location (L/C):
- 28 C. Evaluation of compliance (L/C):
- 29 19. CONTINUATION OF REPORT ITEMS N/A
- 30 (If more space is needed, use separate sheets and attach them to the report.)
- 31 20. PROBLEMS OR DEFICIENCIES NOTED—RECOMMENDATIONS N/A
- 32 A. Briefly state the requirement and explain how and when it was violated.
- 33 B. Provide recommendations for improvement.

1 21. EVALUATION OF OTHER FACTORS

2 A. Senior licensee management is appropriately involved with the
3 radiation safety program and/or Radiation Safety Officer (RSO)
4 oversight Y N

5 B. The RSO has sufficient time to perform his/her radiation
6 safety duties and is not too busy with other assignments. Y N

7 C. The licensee has sufficient staff. Y N

8 Remarks/recommendations:

1

APPENDIX I

2

RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND MODEL

3

RADIATION SURVEY INSTRUMENT CALIBRATION PROGRAM

4

Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications

Licensees should possess and use calibrated and operable radiation detection and measurement instruments that are sufficiently sensitive to detect and measure the type and energy of the radiation used. Applicants should consider the scope of activities that will be performed at their facility in order to determine the number and type of instruments necessary to support licensed activities. Licensees typically possess one or more portable or hand-held instruments to monitor radiological conditions, detect contamination, and perform package preparation and receipt surveys. Portable instrumentation includes ionization chambers as well as other instrumentation, such as count-rate meters that are supported by a variety of handheld probes or detectors that can be used to detect various types of radiation. These include Geiger-Mueller (GM) detectors, sodium iodide (NaI(Tl)) scintillation detectors, and plastic scintillation detectors. Additionally, licensees may possess stationary or fixed instrumentation, such as well-type scintillation counters, area monitors, stack monitors, or continuous air monitors.

When deciding on which types of instruments are appropriate for the intended use, licensees may wish to consult with the instrumentation or equipment manufacturer or vendor to obtain specifications. The instrument should be capable of detecting the type of radiation (alpha, beta, gamma) and be sensitive to the energy or energy range of the radiation to be measured (e.g., keV, MeV). The characteristics of the instrument, including principles of operation and expected efficiency for the type and energy of the radiation being measured, should be understood by the licensee prior to use.

Applicants may wish to consider the following instrument selection guidelines:

- Alpha emitters and low-energy beta emitters, such as carbon-14 and sulfur-35, may be detected with thin windowed proportional counters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted with a liquid scintillation counter to verify potential removable contamination.
- Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15 percent to 40 percent, depending on the beta energy.
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20 percent. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting any established action levels.
- Medium- to high-energy gamma emitters, such as I-131 or high-energy photon emitters, such as F-18, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.

1 • Neutron emitters, such as a neutron generator, californium 252, or beryllium ring on a
2 high specific-activity alpha source such as americium 241, can be detected by tissue
3 equivalent proportional counters or helium-3 proportional counters.

4 Further guidance regarding instrumentation can be found in Chapter 9 of the Handbook
5 of Health Physics and Radiological Health, Third Edition, Edited by Bernard Shleien,
6 Lester A. Slaback, Jr., and Brian Kent Birky, 1998.

7 **Model Radiation Survey Instrument Calibration Program**

8 **Training**

9 Before independently calibrating radiation survey instruments, an individual should complete
10 both classroom and on-the-job training as follows:

11 • Classroom training may be in the form of lecture, video, computer-based, or self-study
12 and will cover the following subject areas:

13 – principles and practices of radiation protection

14 – radioactivity measurements, monitoring techniques, and the use of radiation
15 detection instruments

16 – mathematics related to the use and measurement of radioactivity

17 – biological effects of radiation

18 • On-the-job training will consist of the following:

19 – observing authorized personnel performing radiation survey instrument calibration

20 – conducting radiation survey meter calibrations under the supervision and in the
21 physical presence of an individual already authorized to perform calibrations

22 **Facilities and Equipment for Calibration of Dose and Dose Rate Measuring Instruments**

23 To reduce doses received by individuals not calibrating radiation survey instruments,
24 calibrations will be conducted in an isolated area of the facility or at times when no one else is
25 present.

26 The calibration source should be well-collimated, and the calibration area should be designed to
27 minimize scatter of radiation, which could affect the calibration process.

28 The calibration area should be appropriately controlled so that persons entering the area will be
29 aware if a radiation source is in use.

30 Evaluate posting of the calibration area with appropriate radiation warning signs, as required by
31 Subpart J of 10 CFR 20.

32 Individuals conducting calibrations of radiation survey instruments will wear assigned dosimetry.

1 Individuals conducting calibrations will use a calibrated and operable radiation survey
2 instrument to ensure that unexpected changes in exposure rates are identified and corrected.

3 **Frequency of Calibration of Radiation Measurement Instruments and Equipment**

4 A licensee committed to a routine or emergency radiation survey program should perform an
5 acceptable calibration of all radiation measurement instruments and equipment at the frequency
6 specified in NRC regulations, annually, or at the frequency recommended by the manufacturer,
7 whichever period is shorter.

8 Special calibrations should be performed at any time there is reason to believe that the
9 operating characteristics of a radiation measurement instrument have changed, by repair or
10 alteration, or whenever system performance is observed to change significantly.

11 Routine maintenance of radiation measurement instruments should be performed as
12 recommended by the manufacturer.

13 Primary or secondary standard instruments used to calibrate radiation measurement
14 instruments should be inspected frequently for consistency of performance.

15 **Calibration Sources for Dose and Dose Rate Measuring Instruments**

16 A radioactive sealed source(s) will be used for calibrating dose and dose rate measuring
17 radiation survey instruments, and this source should have the following characteristics:

- 18 • The source should approximate a point source.
- 19 • Calibration fields from gamma sources should be known with an accuracy when
20 compared to secondary or primary national standards of 5 percent for dose rates greater
21 than or equal to 1.0 $\mu\text{Gy/h}$ (0.1 mrad/h) and 10 percent for dose rates less than
22 1.0 $\mu\text{Gy/h}$ (0.1 mrad/h).
- 23 • The source should contain a radionuclide that emits radiation of identical or similar type
24 and energy as the environment in which the calibrated device will be used.
- 25 • The source should be strong enough to give an exposure rate of at least
26 7.7 microcoulomb per kilogram per hour (30 milliroentgen per hour) at 100 centimeters
27 (e.g., 3.1 gigabecquerels (85 millicuries) of cesium-137 or 780 megabecquerels
28 (21 millicuries) of cobalt-60).

29 **Note:** Inverse square and radioactive decay laws should be used to correct changes in
30 exposure rate due to changes in distance or source decay.

31 **Calibration of Dose or Dose Rate Measuring Instruments**

32 There are three kinds of scales frequently used on dose and dose-rate survey meters. These
33 are calibrated as follows:

- 34 • **Linear readout instruments** with a single calibration control for all scales should be
35 adjusted at the point recommended by the manufacturer or at a point within the normal
36 range of use. Instruments with calibration controls for each scale should be adjusted on

1 each scale. After adjustment, check the response of the instrument at approximately
2 20 percent and 80 percent of full scale. Instrument readings should be within $\pm x$ of the
3 conventionally true value for the following ranges:

- 4 – Background to 10 $\mu\text{Gy/h}$ (1.0 mrad/h); $\pm x = \pm 30\%$
- 5 – 10 $\mu\text{Gy/h}$ (1.0 mrad/h) to 1.0 mGy/h (100 mrad/h); $\pm x = \pm 20\%$
- 6 – 1.0 mGy/h (100 mrad/h) to 10 Gy/h (1,000 Rad/h); $\pm x = \pm 10\%$

7 • **Logarithmic readout instruments**, which commonly have a single readout scale
8 spanning several decades, normally have two or more adjustments. Adjust the
9 instrument for each scale according to site specifications or the manufacturer's
10 specifications. After adjustment, check the calibration at a minimum of one point on
11 each decade. Instrument readings should have a maximum deviation from the
12 conventionally true value as described for linear readout instruments.

13 • **Digital readout instruments** should be calibrated the same as linear
14 readout instruments.

15 **Note:** Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 roentgen (R)/h) need not be
16 calibrated, unless the licensee expects to make measurements at higher dose rates; regardless,
17 such scales should be checked for operation and response to radiation.

18 **Calibration of Surface Contamination Measurement Instruments**

19 Instruments used to detect surface contamination usually consist of a count-rate meter and a
20 detector that is appropriate for the type of radiation(s) being measured.

21 The efficiency of radiation survey meters must be determined by using radiation sources with
22 similar energies and types of radiation that users of the radiation survey instrument intend
23 to measure.

24 If each scale has a calibration potentiometer, the reading should be adjusted to respond to the
25 calibration source at approximately 80 percent of full scale, and the response at approximately
26 20 percent of full scale should be observed. If only one calibration potentiometer is available,
27 the response should be adjusted at mid-scale on one of the scales, and response on the other
28 scales should be observed. The instrument efficiency factor (e.g., cpm/dpm) thus obtained
29 should have a signal-to-noise ratio, including the compilation of source and instrument
30 uncertainties, of $\pm x$ for the following ranges:

- 31 • alpha measurement
 - 32 0.01 Bq/cm² to 2.0 Bq/cm² (60 to 12,000 dpm/100 cm²); $\pm x = \pm 20\%$
 - 33 2.0 Bq/cm² to 200 Bq/cm² (12,000 to 1,200,000 dpm/100 cm²); $\pm x = \pm 10\%$
- 34 • beta measurement
 - 35 0.05 Bq/cm² to 2.0 Bq/cm² (300 to 12,000 dpm/100 cm²); $\pm x = \pm 20\%$

1 2.0 Bq/cm² to 200 Bq/cm² (12,000 to 1,200,000 dpm/100 cm²); $\pm x = \pm 10\%$

2 **Calibration of Analytical Instruments Such As Liquid Scintillation Counters, Gamma**
3 **Counters, Gas Flow Proportional Counters, and Multichannel Analyzers**

4 Analytical instruments used to determine radioactivity in a sample may be specialized
5 equipment according to the type of samples to be analyzed and the types and quantities of
6 radioactivity to be measured. Typically, the sample sizes and activities are very small, and can
7 be difficult to measure. Sample collection and preparation may differ for the various analytical
8 instruments, so manufacturer procedures and industry standard practices should be followed.
9 Such analytical instruments should be calibrated in accordance with the manufacturer's
10 instructions. Analytical instruments typically require routine maintenance and verification
11 procedures to ensure that they are operating properly when used.

12 As with calibration of other radiation measurement instruments, calibration of analytical
13 instruments use radioactive sealed source(s). These should be suitable for the geometry of
14 the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and
15 be of similar type and energy as the radioactive materials to be analyzed. The analysis should
16 be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for
17 quenching, self-absorption, and other factors may be required, depending on the analytical
18 instrument, the samples type, and other environmental conditions.

19 **Calibration Records**

20 Calibration records for all radiation survey instruments should indicate the procedure used and
21 the results of the calibration. The records should include the following:

- 22 • the owner or user of the radiation survey instrument
- 23 • a description of the radiation survey instrument that includes the manufacturer's name,
24 model number, serial number, and type of detector
- 25 • a description of the calibration source, including the exposure rate at a specified
26 distance or activity on a specified date
- 27 • for each calibration point, the calculated exposure rate or count rate, the indicated
28 exposure rate or count rate, the deduced correction factor (the calculated exposure rate
29 or count rate divided by the indicated exposure rate or count rate), and the scale
30 selected on the radiation survey instrument
- 31 • the exposure reading indicated with the radiation survey instrument in the "battery
32 check" mode (if available on the instrument)
- 33 • for radiation survey instruments with external detectors, the angle between the radiation
34 flux field and the detector (i.e., parallel or perpendicular)
- 35 • for radiation survey instruments with internal detectors, the angle between the radiation
36 flux field and a specified surface of the instrument
- 37 • for radiation detectors with removable shielding, an indication of whether the shielding
38 was in place or removed during the calibration procedure

- 1 • the exposure rate or count rate from a check source, if used
- 2 • the name and signature of the individual who performed the calibration and the date on
- 3 which the calibration was performed

4

5 The following information will be attached to the radiation survey instrument as a calibration
6 sticker or tag:

- 7 • for dose and dose rate measuring instruments, the source radionuclide used to calibrate
- 8 the radiation survey instrument (with correction factors) for each scale

- 9 • for surface contamination measurement instruments, the efficiency of the radiation
- 10 survey instrument, for each radionuclide the instrument will be used to measure (if
- 11 efficiency is not calculated before each use)

- 12 • for each scale or decade not calibrated, an indication that the scale or decade was
- 13 checked only for function but not calibrated

- 14 • the date of calibration and the next calibration due date

- 15 • the apparent exposure rate or count rate from the check source, if used

16 **Air Sampler Calibration**

17 To assess accurately the air concentration of radioactive materials in a given location, the
18 volume of air sampled and the quantity of contaminant in the sample must be determined.
19 Accurate determination of the volume of air sampled requires standard, reproducible, and
20 periodic calibration of the air metering devices that are used with air sampling instruments.

21 Licensees can find guidance on total air sample volume calibration methods acceptable to NRC
22 staff in the publication titled "Air Sampling Instruments," which can be found in the 9th Edition,
23 American Conference of Governmental Industrial Hygienists, 2001. This information is
24 supplemented below.

25 **Frequency of Calibration of Air Sampling Equipment**

- 26 • A licensee committed to a routine or emergency air sampling program should perform an
- 27 acceptable calibration of all airflow or volume metering devices at least annually
- 28 (Regulatory Guide 8.25, "Air Sampling in the Workplace").

- 29 • Special calibrations should be performed at any time there is reason to believe that the
- 30 operating characteristics of a metering device have been changed, by repair or
- 31 alteration, or whenever system performance is observed to have changed significantly.

- 32 • Routine instrument maintenance should be performed as recommended by
- 33 the manufacturer.

- 34 • Primary or secondary standard instruments used to calibrate air sampling instruments
- 35 should be inspected frequently for consistency of performance.

1

2 **Error Limit for Measurement of Air Sample Volume**

3 Most methods of calibrating airflow or air volume metering devices require direct comparison to
4 a primary or secondary standard instrument to determine a calibration curve or a correction
5 factor. An example of a primary standard is a spirometer that measures total air volume directly
6 with high precision by liquid displacement. An example of a secondary standard is a wet-test
7 meter that has been calibrated against a primary standard.

8 The following are significant errors associated with determining the total air volume sampled:

9 E_C : The error in determining the calibration factor. (An acceptable estimate is the
10 percentage error associated with the standard instrument used in the calibration.)¹

11 E_S : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage
12 equivalent of one-half of the smallest scale division, compared to the scale reading.)

13 E_t : The percentage error in measurement of sampling time that should be kept within
14 1 percent.

15 E_V : The most probable value of the cumulative percentage error in the determination of the
16 total air volume sampled. E_V can be calculated from the following equation, provided
17 there are no additional significant sources of errors:

18
$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

19 The most probable value of the cumulative error E_V , in the determination of total volume, should
20 be less than 20%.

21 A sample calculation of the most probable value of the cumulative error in total volume
22 measured is as follows: If accuracies of the scale reading, the calibration factor, and sample
23 time are ± 4 , 2, and 1%, respectively, and there are no other significant sources of error, the
24 cumulative error would be:

25 $E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\%$ or approx. 5%

26 If there are significant differences in pressure and temperature between the calibration site and
27 the sampling site, appropriate corrections should be made using the ideal gas laws provided
28 below:

29 $V_s = V_1 * (P_1/760) * (273/T_1)$

30 where V_s = volume at standard pressure and temperature (760 mm Hg and 273K

¹The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20 percent, licensees should include an additional error term in the calculation above.

1 V_1 = volume measured at conditions P_1 and T_1

2 T_1 = temperature of V_1 in K

3 P_1 = pressure of V_1 in mm Hg

4 **Documentation of Calibration of Air Metering Devices**

5 The licensee should maintain records of all routine and special calibrations of airflow or volume
6 metering devices, including the primary or secondary standard used, method employed, and
7 estimates of accuracy of the calibrated metering devices. All instruments should be clearly
8 labeled as to the date and results of the most recent calibration and should include the
9 appropriate correction factors to be used.

10 **References:**

- 11 • Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992.
- 12 • NUREG-1400, "Air Sampling in the Workplace," September 1993 (available at the
13 ADAMS Accession No. ML102371083)
- 14 • Health Physics and Radiological Health, 4th Edition. Edited by Thomas E. Johnson and
15 Brian Kent Birky, 2012.
- 16 • American National Standards Institute (ANSI) N323AB-2013, "American National
17 Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey
18 Instruments."
- 19 • "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists,
20 9th Edition, 2001.

21

1

APPENDIX J

2

MATERIAL RECEIPT AND ACCOUNTABILITY

3

1 **Material Receipt and Accountability**

2 The licensee can possess only the radionuclides in the types and forms listed on the license,
3 and the total quantity possessed under the license may not exceed the maximum possession
4 limit listed on the license. Therefore, the RSO must know how much material is possessed
5 under the license, in all locations, at any time. The licensed inventory includes all radioactive
6 materials in use, in storage, and in waste. The regulations in 10 CFR 30.51, 40.61, 70.51 and
7 10 CFR Part 74 require the licensee to maintain records of receipt, transfer, and disposal of all
8 licensed materials.

9 **Sample Procedure for Ordering and Receiving Radioactive Material**

- 10 • The RSO should approve or place all orders for radioactive material and should ensure
11 that the requested material, quantities, (and for sealed sources and/or devices, the
12 manufacturer and model of the source/device) are authorized by the license and that the
13 possession limits are not exceeded.
- 14 • During normal working hours, carriers should be instructed to deliver radioactive
15 packages directly to the Radiation Safety Office (or designated receiving area).
- 16 • During off-duty hours, security or other designated trained personnel should accept
17 delivery of radioactive packages, in accordance with the procedure outlined in the
18 sample memorandum below:

<p>Sample Memorandum</p> <p>Memorandum for Security Personnel</p> <p>From: RSO, President, Vice President, etc.</p> <p>Subject: Procedures for Receipt of Packages Containing Radioactive Material</p> <p>If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.</p> <p>Any packages containing radioactive material that arrive between certain hours (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) must be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area. and re-lock the door.</p> <p>Radiation Safety Officer (RSO): _____</p> <p>Office Phone: _____</p> <p>Home Phone: _____</p>

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals), as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

1

For additional information on worker training, see the section titled Training for Individuals Working In or Frequenting Restricted Areas.

2 Sample Procedure for Safely Opening Packages Containing Licensed Materials

3 For packages received under the specific license, authorized individuals should implement
4 procedures for opening each package, as follows:

- 5 • Wear gloves to prevent hand contamination.
- 6 • Visually inspect the package for any sign of damage (e.g., crushed, punctured). If
7 damage is noted, stop and notify the RSO.
- 8 • Monitor the external surfaces of a labeled package according to specifications in
9 Table 8-2 of Section 8.10.3.
- 10 • Check Department of Transportation White I, Yellow II, or Yellow III label or packing slip
11 for activity of contents, so shipment does not exceed license possession limits.
- 12 • Open the outer package (following supplier's directions if provided). Open inner package
13 to verify contents (compare requisition, packing slip, and label on the bottle or other
14 container). Check integrity of the final source container (e.g., inspecting for breakage of
15 seals or vials, loss of liquid, discoloration of packaging material, high count rate on

1 smear). Again, check that the shipment does not exceed license possession limits. If you
2 find anything other than expected, stop and notify the RSO.

3 • Survey the packing material and packages for contamination before discarding. If
4 contamination is found, treat as radioactive waste. If no contamination is found,
5 obliterate the radiation labels prior to discarding in the regular trash.

6 • Maintain records of receipt, package survey, and wipe test results.

7 • Notify the final delivery carrier and the NRC Operations Center, 301-816-5100, by
8 telephone when removable radioactive surface contamination exceeds the limits of
9 10 CFR 71.87(i) or the external radiation levels exceed the limits of 10 CFR 71.47.

10

11 **Sample Procedure for Accountability for Unsealed Materials**

12 • The RSO should maintain an accountability log (inventory) of all radioactive materials
13 possessed under the license that demonstrate that the license limits are not exceeded,
14 that all materials received are accounted for, and that material is disposed of or
15 transferred prior to being removed from the current inventory.

16 • For each radionuclide listed on the license, the RSO should maintain a record of each
17 shipment of material received under the license, and indicate the total amount
18 possessed from all shipments.

19 • Each AU who receives material should maintain a log showing the receipt of each vial
20 and the use and disposal of the material. Material may be tracked by vial, by order, or in
21 some other unit that can be “counted.”

22 • Each AU should maintain records of the locations and quantities of licensed materials for
23 which they are responsible. For example, material may be present in stock vials,
24 ampoules, TLC or HPLC samples, etc., and in various waste forms; materials may be
25 stored in refrigerators, freezers, cold rooms, lab rooms, etc.

26 • Periodically, each AU should submit to the RSO an inventory of all licensed materials in
27 the laboratory. (NOTE: the licensee should state in its radiation safety program
28 procedures the frequency of such inventory submissions. It may be weekly, monthly, or
29 quarterly, or after each order, depending on the frequency of use and the amount of
30 materials on hand). Each AU should indicate if material they possessed was disposed of
31 or transferred from their responsibility (examples: waste in containers may be transferred
32 to a common DIS storage location under the responsibility of the RSO or another AU; or
33 the AU may have disposed of licensed material to the sewer; or the AU may have
34 transferred a vial of material to another AU.)

35 • The license accountability log (inventory) may be maintained in hard copy or
36 electronic records.

1 **Sample Transfer Policy Statements**

2 Internal Transfers

3 Licensed materials that may be transferred from one department or laboratory or AU's control to
4 another should have prior approval from the RSO. A written transfer procedure should be
5 developed by the RSO to ensure that transfers are completed in accordance with the conditions
6 of the license. All transfers should be conducted in a way that minimizes the probability of
7 spillage or breakage. Double containers should be used, including suitable shielding, for such
8 transfers.

9 External Transfers

10 Licensed material should not be transferred or shipped from one institution to another without
11 the approval of the RSO. Such transfers/shipments must be packaged and labeled in
12 accordance with DOT, NRC, and/or U.S. Postal Service Regulations, whichever is applicable.
13 Prior to any transfer from the license, the RSO should verify that the recipient is authorized to
14 receive the licensed material, as required by 10 CFR 30.41, 40.51 and 70.42.

15 Gifts

16 On occasion, licensees may be offered or have donated licensed materials by other individuals
17 as gifts (e.g., a retiring medical practitioner donating his cesium-137 needles to the university
18 medical center). All such gifts of radioactive materials must be transferred to the licensee and
19 handled in accordance with NRC requirements and the conditions of the license. In any case,
20 the RSO should approve the gift prior to the transfer.

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APPENDIX K

**GUIDANCE FOR DEMONSTRATING THAT INDIVIDUAL MEMBERS OF THE
PUBLIC WILL NOT RECEIVE DOSES EXCEEDING THE ALLOWABLE LIMITS**

1 **Guidance for Demonstrating that Individual Members of the**
 2 **Public Will Not Receive Doses Exceeding the Allowable Limits**

3 This appendix describes methods for determining radiation doses to members of the public.

4 Licensees must ensure that:

- 5 • The radiation dose received by individual members of the public does not exceed
 6 1 millisievert (mSv) [100 millirem (mrem)] in 1 calendar year resulting from the licensee’s
 7 possession and/or use of licensed materials.

- 8 • The radiation dose in unrestricted areas does not exceed 0.02 mSv [2 mrem] in any
 9 1 hour.

- 10 • Air emissions of radioactive material to the environment will not result in a TEDE in
 11 excess of 10 mrem [0.1 mSv] per year. As required by in 10 CFR 20.1101(d), if the
 12 licensee exceeds the 10 mrem [0.1 mSv] per year air emission dose constraint, the
 13 licensee must report the exceedance, as provided in 10 CFR 20.2203, and promptly take
 14 appropriate corrective action to ensure against recurrence.

Members of the public include persons who live, work, study, or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed material but may work in the vicinity where such materials are used or stored.

15

Doses to Members of the Public	
<p>INCLUDES doses from</p> <ul style="list-style-type: none"> • radiation and/or radioactive material released by a licensee • sources of radiation under the control of a licensee • effluents from sources of licensed radioactive materials • licensed material in transportation or storage at the licensee’s facility 	<p>DOES NOT INCLUDE doses from</p> <ul style="list-style-type: none"> • sanitary sewerage discharges from licensee action taken in accordance with 10 CFR 20.2003 • natural background radiation • medical administration of radioactive material including patients released under 10 CFR 35.75 • voluntary participation in medical research

16 Unrestricted areas are areas, access to which is neither limited nor controlled by the licensee. Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas.

1 The licensee may show compliance with the annual dose limit for individual members of the
2 public by

3 • demonstrating by measurement or calculation that the TEDE to the individual likely to
4 receive the highest dose at the boundary of the unrestricted area does not exceed
5 1 mSv [100 mrem]

6 • demonstrating that the annual average concentration of radioactive material released in
7 gaseous and liquid effluents at the boundary of the unrestricted area does not exceed
8 the values specified in Table 2 of Appendix B to Part 20; and if an individual were
9 continuously present in an unrestricted area, the dose from external sources would not
10 exceed 0.02 mSv [2 mrem] in 1 hour and 0.5 mSv [0.05 rem] in 1 year

11 • demonstrating that air emissions of radioactive materials do not result in doses greater
12 than the constraint limit of 0.1 mSv [10 mrem] TEDE

13 In order to perform a dose assessment, licensees should identify all potential sources of
14 external and internal radiation exposure to members of the public and all locations of use,
15 transport, and storage of radioactive material at their facilities. Licensees must then take
16 radiation measurements or perform calculations to demonstrate compliance.

17 **Measurements**

18 The licensee may use measurements to demonstrate that the average annual releases are
19 within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to
20 receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv
21 [100 mrem]. These measurements may include

- 22 • dose rate surveys for radiation exposures from external radiation sources
23 • measurements of radionuclides in air and water effluent

24 The method used to measure dose will depend on the nature of the radiation source. If the
25 source of radiation is constant, it may be adequate to measure the dose rate and integrate it
26 over time. If the source of radiation differs or changes over time, it may be necessary to perform
27 continuous measurements.

28 Radioactivity releases may be determined by effluent monitoring or effluent sampling and
29 analysis. Airborne effluents may be discharged when volatile materials are used, such as during
30 iodinations, but the discharge is usually not continuous, because volatile materials are often
31 used periodically rather than continuously. Liquid effluents may be discharged continuously or
32 may be stored and subsequently discharged on a batch basis. For each type of source and for
33 each route of potential exposure, consider the location of measurement points, whether
34 continuous or periodic monitoring is required, the frequency of sampling and measurement, and
35 any additional information. For discharges of airborne radionuclides, for example, it may be
36 necessary to obtain information on the efficiency of filters and the air flow rate of the discharge
37 system, as well as meteorological data and the distance to the nearest individual member of
38 the public.

1 **Calculation Method**

2 Using a calculation method, the licensee must determine the highest dose an individual is likely
3 to receive at the boundary of the unrestricted area. The licensee must take into account the
4 individual's exposure from external sources and the concentration of radionuclides in gaseous
5 and liquid releases. In practice, the licensee may wish to make conservative assumptions to
6 simplify the dose calculation.

7 The public dose limit applies to the individual who is likely to receive the highest dose from
8 licensed operations. Therefore, the dose calculations must consider the location with the
9 potential for the highest internal and external exposures. A conservative calculation should
10 assume that the individual was continuously present 24 hours a day, 365 days a year, or an
11 occupancy factor of 1 (see Table K-1). If the result of the calculation, using an occupancy factor
12 of 1, demonstrates that the public dose limit is not exceeded, then there is no need for
13 further evaluation.

14 If the calculation demonstrates that the public dose limit is exceeded, with an occupancy factor
15 of 1, then more realistic assumptions of the individual's occupancy at the points of highest
16 internal and external exposures may be made. The licensee may use the occupancy factors in
17 Table K-1 or may calculate a specific occupancy factor by determining the likely fraction of time
18 that the individual is present.

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, and unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

19 **Records**

20 The licensee must maintain records to demonstrate compliance with the dose limit for individual
21 members of the public until the Commission terminates the license. In general, survey and
22 monitoring records of ambient radiation and effluent radioactivity should be adequate.

23 Records demonstrating the dose to an individual member of the public should identify the
24 instruments used in the survey; the name of the surveyor; the date of the survey; the location of
25 the survey(s), including a description or drawing of the area surveyed; survey results; and if
26 applicable, the occupancy factors used and justification for their use. In addition, records
27 demonstrating the dose to an individual member of the public that involve effluent sampling
28 analysis should include information on concentrations of specific radionuclides, minimum
29 detectable activity of the system, and the estimated uncertainty of measurements.

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APPENDIX L

2

GENERAL TOPICS FOR SAFE POSSESSION AND USE OF RADIOACTIVE MATERIALS AND MODEL EMERGENCY PROCEDURES

3

4

General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures

This appendix describes general topics for safe possession and use of radioactive materials and procedures for handling and reporting emergencies.

General Topics for Safe Possession and Use of Radioactive Materials

Each area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include the following:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure L-1).
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

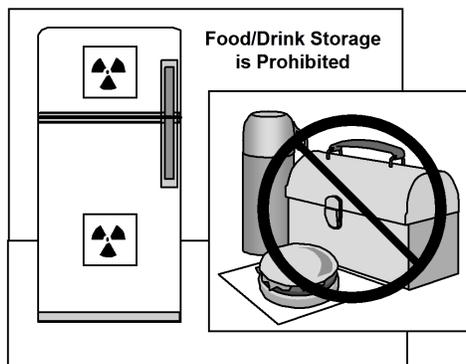


Figure L-1. Storage of Food and Drink. Food or drink may not be stored in refrigerators with radionuclides.

1 **Security of Radioactive Materials**

- 2 • Licensed materials in use in controlled or unrestricted areas must be under
3 constant surveillance.
- 4 • Licensed materials will be secured by one or more of the following methods.
- 5 – storing and using licensed materials only in restricted areas
- 6 – limiting access to an entire facility or building or portion of the building to
7 radiation workers
- 8 – providing storage areas that can be locked to prevent access to the licensed material

9 **Radionuclide-specific Procedures**

10 Licensees should develop written procedures for use of different radionuclides so that users
11 know the types of shielding, protective clothing, radiation survey instruments, surveys, and
12 decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq [1 mCi] of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use
- Bioassay procedures for individuals working with millicurie quantities of radioiodine
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications; also recommended that the RSO be present during new procedures
- Procedures for measuring the concentration of radioiodine effluents from the hoods

Example 2:

If requesting more than 37 MBq [1 mCi] of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding and high-density materials, layered properly, in order to keep bremsstrahlung radiation to a minimum
- A mandatory radiation survey and wipe test for radioactive contamination after each use
- The use of extremity monitors for procedures that involve one millicurie or more
- A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications; also recommended that the RSO be present during new procedures
- The use of eye protection for procedures that involve 10 millicuries or more

1 Sample Procedures for Handling Emergencies

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

2 General Safety Procedures to Handle Spills

- 3 • Name and telephone number of RSO or an alternate person(s) should be posted
4 conspicuously in areas of use, so that it is readily available to workers in case of
5 emergencies. The licensee should have emergency equipment readily available for
6 handling spills. Spill kits should include the following:
 - 7 – disposable gloves
 - 8 – housekeeping gloves
 - 9 – disposable lab coats
 - 10 – disposable head coverings
 - 11 – disposable shoe covers
 - 12 – roll of absorbent paper with plastic backing
 - 13 – masking tape
 - 14 – plastic trash bags with twist ties
 - 15 – “Radioactive Material” labeling tape
 - 16 – marking pen

- 1 – pre-strung “Radioactive Material” labeling tags
- 2 – box of wipes
- 3 – instructions for “Emergency Procedures”
- 4 – clipboard with a copy of the Radioactive Spill Report Form for the facility
- 5 – pencil
- 6 – appropriate radiation survey instruments, including batteries (for radiation
- 7 survey meters)

8 Minor Spills of Liquids and Solids

- 9 • Instructions to Workers
- 10 – Notify persons in the area that a spill has occurred.
- 11 – Prevent the spread of contamination by covering the spill with absorbent paper.
- 12 – (Paper should be dampened if solids are spilled.)
- 13 – Clean up the spill, wearing disposable gloves and using absorbent paper.
- 14 – Carefully fold the absorbent paper with the clean side out and place in a plastic bag
- 15 – for transfer to a radioactive waste container. Put contaminated gloves and any other
- 16 – contaminated disposable material in the bag.
- 17 – Survey the area with an appropriate low-range radiation survey meter or other
- 18 – appropriate technique. Check the area around the spill for contamination. Also check
- 19 – hands, clothing, and shoes for contamination.
- 20 – Report the incident to the Radiation Safety Officer (RSO) promptly.
- 21 – Allow no one to return to work in the area unless approved by the RSO.
- 22 – Cooperate with RSO/RSO’s staff (e.g., investigation of root cause, provision of
- 23 – requested bioassay samples).
- 24 – Follow the instructions of the RSO/RSO’s staff (e.g., decontamination techniques,
- 25 – surveys, provision of bioassay samples, requested documentation).
- 26 • Reminders to RSO
- 27 – Follow up on the decontamination activities and document the results.
- 28 – As appropriate, determine cause and corrective actions needed; consider bioassays
- 29 – if licensed material may have been ingested, inhaled, and/or absorbed through
- 30 – the skin.
- 31 – If necessary, notify NRC.

1 Major Spills of Liquids and Solids

2 • Instructions to Workers

3 – Clear the area. If appropriate, survey all persons not involved in the spill and vacate
4 the room.

5 – Prevent the spread of contamination by covering the spill with absorbent paper
6 (paper should be dampened if solids are spilled), but do not attempt to clean it up. To
7 prevent the spread of contamination, limit the movement of all personnel who may
8 be contaminated.

9 – Shield the source only if it can be done without further contamination or significant
10 increase in radiation exposure.

11 – Close the room and lock or otherwise secure the area to prevent entry. Post the
12 room with a sign to warn anyone trying to enter that a spill of radioactive material
13 has occurred.

14 – Notify the RSO immediately.

15 – Survey all personnel who could possibly have been contaminated. Decontaminate
16 personnel by removing contaminated clothing and flushing contaminated skin with
17 lukewarm water and then washing with a mild soap.

18 – Allow no one to return to work in the area unless approved by the RSO.

19 – Cooperate with RSO and RSO's staff (e.g., investigation of root cause, provision of
20 requested bioassay samples).

21 – Follow the instructions of the RSO and RSO's staff (e.g., decontamination
22 techniques, surveys, provision of bioassay samples, requested documentation).

23 • Reminders to RSO

24 – Confirm decontamination of personnel. If decontamination of personnel was not
25 fully successful, consider inducing perspiration by covering the area with plastic.
26 Then wash the affected area again to remove any contamination released by
27 the perspiration.

28 – Supervise decontamination activities and document the results. Documentation
29 should include location of surveys and decontamination results.

30 – Determine cause and needed corrective actions; consider need for bioassays if
31 licensed material may have been ingested, inhaled, and/or absorbed through
32 the skin.

33 – If necessary, notify the NRC.

34

1 Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- 2 • Instructions to Workers
 - 3 – Notify all personnel to vacate the room immediately.
 - 4 – Shut down ventilation system, if appropriate, to prevent the spread of contamination
 - 5 throughout the system and other parts of the facility.
 - 6 – Vacate the room. Seal the area, if possible.
 - 7 – Notify the RSO immediately.
 - 8 – Ensure that all access doors to the area are closed and posted with appropriate
 - 9 warning signs, or post guards (trained) at all access doors to prevent accidental
 - 10 opening of the doors or entry to the area.
 - 11 – Survey all persons who could have possibly been contaminated. Decontaminate, as
 - 12 directed by the RSO.
 - 13 – Promptly report suspected inhalation and ingestion of licensed material to the RSO.
 - 14 – Decontaminate the area only when advised and/or supervised by the RSO.
 - 15 – Allow no one to return to work in the area unless approved by the RSO.
 - 16 – Cooperate with RSO/RSO's staff (e.g., investigation of root cause, provision of
 - 17 requested bioassay samples).
 - 18 – Follow the instructions of the RSO/RSO's staff (e.g., decontamination techniques,
 - 19 surveys, provision and collection of bioassay samples, requested documentation).
- 20 • Reminders to RSO
 - 21 – Supervise decontamination activities.
 - 22 – Perform air sample surveys in the area before permitting resumption of work with
 - 23 licensed materials.
 - 24 – Provide written directions to potentially contaminated individuals about providing and
 - 25 collecting urine, breath, blood, or fecal samples, etc.
 - 26 – Consider the need for a medical exam and/or whole body count before permitting
 - 27 involved individuals to return to work with licensed material.
 - 28 – Determine cause and corrective actions needed; consider need for bioassays if
 - 29 licensed material may have been ingested, inhaled, and/or absorbed through the
 - 30 skin. Document the incident.
 - 31 – If necessary, notify the NRC.
 - 32

1 Minor Fires

- 2 • Instructions to Workers (Licensees should develop procedures and instructions, in
3 accordance with local fire safety requirements, OSHA regulations, etc., and provide
4 training as needed)
 - 5 – Immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if
6 other fire hazards or radiation hazards are not present.
 - 7 – Notify all persons present to vacate the area and have one individual immediately
8 call the RSO and fire department (as instructed by the RSO).
 - 9 – Once the fire is out, isolate the area, to prevent the spread of possible contamination.
 - 10 – Survey all persons involved in combating the fire for possible contamination.
 - 11 – Decontaminate personnel by removing contaminated clothing and flushing
12 contaminated skin with lukewarm water, then washing with a mild soap.
 - 13 – In consultation with the RSO, determine a plan of decontamination and the types of
14 protective devices and survey equipment that will be necessary to decontaminate
15 the area.
 - 16 – Allow no one to return to work in the area unless approved by the RSO.
 - 17 – Cooperate with the RSO and RSO's staff (e.g., investigation of root cause, provision
18 of requested bioassay samples).
 - 19 – Follow the instructions of the RSO and RSO's staff (e.g., decontamination
20 techniques, surveys, provision of bioassay samples, requested documentation).
- 21 • Reminders to RSO
 - 22 – Supervise decontamination activities.
 - 23 – If decontamination of personnel was not fully successful, consider inducing
24 perspiration by covering the area with plastic. Then wash the affected area again to
25 remove any contamination released by the perspiration.
 - 26 – Consult with fire safety officials to ensure that there are no other possibilities of
27 another fire starting.
 - 28 – Determine cause and needed corrective actions; consider need for bioassays if
29 licensed material may have been ingested, inhaled, and/or absorbed through the
30 skin. Document the incident.
 - 31 – If necessary, notify the NRC.

32 Fires, Explosions, or Major Emergencies

- 33 • Instructions to Workers

- 1 – Notify all persons in the area to leave immediately.
- 2 – Notify the fire department.
- 3 – Notify the RSO and other facility safety personnel.
- 4 – Upon arrival of firefighters, inform them where radioactive materials are stored or
- 5 where radionuclides were being used; inform them of the present location of the
- 6 licensed material and the best possible entrance route to the radiation area, as well
- 7 as any precautions to avoid exposure or risk of creating radioactive contamination by
- 8 use of high-pressure water, etc.
- 9 – Cooperate with RSO/RSO's staff (e.g., investigation of root cause, provision of
- 10 requested bioassay samples).
- 11 – Allow no one to return to work in the area unless approved by the RSO.
- 12 – Follow the instructions of the RSO and RSO's staff (e.g., decontamination
- 13 techniques, surveys, provision of bioassay samples, requested documentation).
- 14 • Reminders to RSO
- 15 – Coordinate activities with facility's industrial hygienist or environmental health and
- 16 safety office, and with local fire department.
- 17 – Consult with the firefighting personnel and set up a controlled area where the
- 18 firefighters can be surveyed for contamination of their protective clothing and
- 19 equipment after the fire is extinguished.
- 20 – Once the fire is extinguished, do not allow the firefighters to enter the radiation area
- 21 until a thorough evaluation and survey are performed to determine the extent of the
- 22 damage to the licensed material use and storage areas.
- 23 – Perform thorough contamination surveys of the firefighters and their equipment
- 24 before they leave the controlled area and decontaminate, if necessary.
- 25 – Supervise decontamination activities.
- 26 – Consider bioassays if licensed material may have been ingested, inhaled, and/or
- 27 absorbed through the skin. Document the incident.
- 28 – Notify the NRC.

29 Incidents Involving Sealed Sources

30

31 For an emergency situation that may occur concerning a sealed source that has been exposed
32 unintentionally, is unshielded or compromised, the following safety instructions should be
33 considered:

34

- 1 • Immediately secure and post the restricted area; maintain continuous surveillance and
2 restrict access to the restricted area.
- 3 • Notify the RSO, RSO designee, and management personnel immediately.
- 4 • Retrieval operations should be supervised by the RSO.
- 5 • No source or suspected source should be handled directly with bare hands.
- 6 • Determine if additional dosimetry will be required during source retrieval.
- 7 • Appropriate survey instruments should be used for the response activity.
- 8 • Expedient methods of reducing unintended exposure to staff and the public, such as
9 lead shot bags, sandbags, steel plates, and remote handling devices.
- 10 • The RSO should make required notifications to the NRC.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

11 **Procedures for Collecting Bioassay Samples**

12 In the event of an emergency in which an individual may become contaminated and radioactive
13 material was taken into the body through skin absorption or other means, or is suspected of
14 having ingested or inhaled radioactive material, an estimate of the amount of material taken into
15 the body may be required. The following items should be considered in developing
16 your procedures:

- 17 • the type of bioassay that must be performed (direct or indirect)
- 18 • the number of samples or data points to be collected
- 19 • the frequency of sampling (e.g., hourly, daily, weekly, once)
- 20 • the size of the sample to be collected (e.g., 24-hour urine collection)
- 21 • the ease or difficulty of sample collection
- 22 • the need for written instructions to be provided to the sample collector, who may be the
23 contaminated individual

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APPENDIX M

2

**TYPICAL U. S. NUCLEAR REGULATORY COMMISSION (NRC)
NOTIFICATION AND REPORTING REQUIREMENTS FOR INCIDENTS**

3

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**Typical U.S. Nuclear Regulatory Commission (NRC)
Notification and Reporting Requirements for Incidents**

Note: The following list of notification and reporting requirements is provided to inform licensees about typical notification and reporting requirements that apply to their licensed activities. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, notification and reporting requirements change; therefore, licensees should consult the regulations for definitive information about current requirements.

Table M-1. Typical NRC Notifications and Reporting Requirements for Incidents			
Event	Telephone Notification	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination or external radiation levels exceeding the limits in 10 CFR 20.1906(d)	Immediate (NRC and the final delivery carrier must be notified)	none	20.1906(d)
Theft or loss of licensed material	immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sv [25 rems]	immediate	30 days	10 CFR 20.2202(a)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gy [250 rads]	immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	none	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv [0.1 rem]	none	30 days	10 CFR 20.2203(a)(2)(iv)

Table M-1. Typical NRC Notifications and Reporting Requirements for Incidents

Event	Telephone Notification	Written Report	Regulatory Requirement
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a) & (c)(2); 40.60(a) & (c)(2); and 70.50(a) & (c)(2)
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest annual limits of the 10 CFR Part 20, Appendix B for the material and requires the area to be restricted for a reason other than to allow radionuclides with half-lives less than 24 hours to decay	24 hours	30 days	10 CFR 30.50(b)(1) & (c)(2); 40.60(b)(1) & (c)(2) and 70.50(b)(1) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2); 40.60(b)(2) & (c)(2) ; and 70.50(b)(2) & (c)(2)

Table M-1. Typical NRC Notifications and Reporting Requirements for Incidents

Event	Telephone Notification	Written Report	Regulatory Requirement
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2); 40.60(b)(4) & (c)(2); and 70.50(b)(4) & (c)(2)
Determination that any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	none	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	10 CFR 37.41(a)(3)
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response, but no later than 4 hours after discovery	30 days	10 CFR 37.57(a) & (c)

Table M-1. Typical NRC Notifications and Reporting Requirements for Incidents

Event	Telephone Notification	Written Report	Regulatory Requirement
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA agency	none	10 CFR 37.57(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination notify LLEA and NRC operations center	30 days and periodic updates (10 CFR 37.79(c))	10 CFR 37.81(a)&(g)
Determination that a shipment containing a Category 2 quantity of material is lost or missing in transport	Within 4 hours of the determination. Within 24 hours if the material has not yet been located and secured	30 days	10 CFR 37.81(b)&(g)
Discovery along the route of any actual or attempted theft or diversion, or suspicious activity, related to a Category 1 quantity of material in transport	Upon discovery notify LLEA and NRC operations center as soon as possible	30 days (except no report for suspicious activity)	10 CFR 37.81(c)&(g)
Discovery of any actual or attempted theft or diversion, or suspicious activity, related to a Category 2 quantity of material in transport	As soon as possible	30 days (except no report for suspicious activity)	10 CFR 37.81(d)&(g)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible	None	10 CFR 37.81(e)

Table M-1. Typical NRC Notifications and Reporting Requirements for Incidents			
Event	Telephone Notification	Written Report	Regulatory Requirement
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	None	10 CFR 37.81(f)

- 1
- 2 **Note:** Telephone notifications must be made to the NRC Operations Center at 301-816-5100
- 3 or by facsimile to 301-951-0550, except as noted. The Center is staffed 24 hours a day
- 4 and accepts collect calls.
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APPENDIX N
RADIATION SAFETY SURVEY TOPICS

Radiation Safety Survey Topics

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before independently performing radiation surveys, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
 - principles and practices of radiation protection
 - radioactivity measurements, monitoring techniques, and using instruments
 - mathematics and calculations basic using and measuring radioactivity
 - biological effects of radiation
- Appropriate on-the-job-training consists of the following:
 - observing authorized personnel using survey equipment, collecting samples, and analyzing samples
 - using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single- or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements). See Appendix K.

Ambient Radiation Level Surveys

Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv [2.5 mrem/h] or more [50 mSv/year divided by 2,000 h/year].

10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv [0.1 rem] in a year, and the dose in any unrestricted area from external sources does not exceed 0.02 mSv [2 mrem] in any 1 hour.

1 The frequency of ambient surveys depends on the quantity and use of radioactive materials, as
 2 well as the specific protective facilities, equipment, and procedures designed to protect the
 3 worker and members of the public from external exposure to radiation. While the regulations do
 4 not specify a specific survey frequency, the licensee is required to ensure that the dose rate
 5 limits are not exceeded.

6 **Contamination Surveys**

7 Licensees' contamination surveys should be sufficient to identify areas of contamination that
 8 might result in doses to workers or to the public. The total contamination (combined removable
 9 and fixed contamination) should be surveyed using appropriate radiation-detection equipment.
 10 Removable contamination can be detected and measured through a wipe test of the surface,
 11 which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a
 12 sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

13 Contamination surveys should be performed

- 14 • to evaluate radioactive contamination that could be present on surfaces of floors, walls,
 15 laboratory furniture, and equipment
- 16 • after any spill or contamination event
- 17 • when procedures or processes have changed
- 18 • to evaluate the potential contamination of users and the immediate work area, at the end
 19 of the day or before leaving the area of use, when licensed material is used
- 20 • in unrestricted areas at frequencies consistent with the types and quantities of materials
 21 in use but generally not less frequently than quarterly
- 22 • in areas adjacent to restricted areas and in all areas through which licensed materials
 23 are transferred and temporarily stored before shipment

24 **Contamination Survey Frequency**

25 Personnel should survey for contamination in locations where individuals are working with an
 26 unsealed form of radioactive material. These surveys should be done at a frequency appropriate
 27 to the types and quantities of radioactive materials in use. If the activity used is greater than or
 28 equal to the smallest annual limit on intake (ALI) (for either inhalation or ingestion) as identified
 29 in 10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily
 30 and records retained in accordance with 10 CFR 20.2103.

31 Table N–1 contains suggested contamination survey frequencies based on ALIs. The suggested
 32 frequency of surveys is based on the amount of licensed material “in use” at any one time at any
 33 particular location. If licensed material it has not been used for a period of time greater than the
 34 required survey frequency, then it is considered to be “not in use.”

Table N–1. Suggested Contamination Survey Frequency			
	< 0.1 ALI	≥ 0.1 ALI < 1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

1 **Alternate Survey Frequency**

2 **Classification of Areas**

3 **(Ref: Excerpted from IAEA Safety Standard, Safety Series No. 1, “Safe Handling of**
 4 **Radionuclides, 1973 Edition”)**

5 The object is to determine how often to survey an area. To do this, determine the isotope group
 6 in Table N–4, then multiply the activity used in the area by the appropriate Modifying Factor
 7 in Table N–3, then determine the survey frequency category of Low, Medium, or High in
 8 Table N–2.

9 Survey Frequency of:

- 10 • Low—Not less than once a month
 11 • Medium—Not less than once per week
 12 • High—Not less than once per normal working day

Table N–2. Survey Frequency Category

Group	Low	Medium	High
1	< 370 kBq [10 µCi]	370 kBq [10 µCi] to 37 MBq [1 mCi]	> 37 MBq [1 mCi]
2	< 37 MBq [1 mCi]	37 MBq [1 mCi] to 3.7 GBq [100 mCi]	> 3.7 GBq [100 mCi]
3	< 3.7 GBq [100 mCi]	3.7 GBq [100 mCi] to 370 GBq [10 Ci]	> 370 GBq [10 Ci]
4	< 370 GBq [10 Ci]	370 GBq [10 Ci] to 37 TBq [1000 Ci]	> 37 TBq [1000 Ci]

13 The tables use proportional fractions for more than one isotope.

Table N–3. Survey Frequency Category Modifiers

Modifying Factors	Factors
Simple storage	× 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	× 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	× 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	× 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	× 0.1
Exposure of non-occupational persons	× 0.1
Dry and dusty operations (e.g., grinding)	× 0.01

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Table N-4. Isotope Groups

Group	Isotope
1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-227 Th-228 Th-230 Pa-231 U-230 U-232 U-233 U-234 Np-237 Pu-238Pu-239 Pu-240 Pu-241 Pu-242 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252
2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230 Th-234 U-236 Bk-249
3	Be-7 C-14 F-18 Na-24 Cl-38 Si-31 P-32 P-33 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-131m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-131 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171 Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-191 Pt-193 Pt-197 Au-196 Au-198 Au-199 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239
4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-91m Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m Th-232 Th-Nat U-235 U-238 U-Nat

1
2 **Contamination in Unrestricted Areas**

3 Contamination found in unrestricted areas should be immediately decontaminated to
4 background levels. When it is not possible to get to background levels, the licensee must ensure
5 that the amounts do not exceed the contamination levels listed in Table N-5, taken from the
6 NRC Policy and Guidance Directive FC 83-23, "Guidelines for Decontamination of Facilities and
7 Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct,
8 Source, or Special Nuclear Material" (May 1987). Note that, for the purposes of release of
9 facilities for unrestricted use or termination of the license, these values have been superseded
10 by 10 CFR 20, Subpart E, "Radiological Criteria for License Termination," and cannot be used
11 for that purpose. In particular, the acceptable contamination levels listed below for most alpha
12 emitters exceed the levels, which will meet the 10 CFR 20, Subpart E criteria. Table N-5 levels
13 can continue to be used for release of equipment and material from licensed material facilities
14 during operational activities prior to license termination. (*Federal Register*, Volume 63, No. 222,
15 November 18, 1998, page 64134)

- 1 For equipment that is potentially contaminated and is to be released for unrestricted use,
 2 Table N-5 provides the maximum acceptable residual levels for equipment. Additional guidance
 3 for release of equipment can be found in NUREG-1575, Supplement 1, "Multi-Agency Radiation
 4 Survey and Assessment of Materials and Equipment Manual (MARSAME)." Table N-5 values
 5 also may be acceptable criteria for contamination in facilities during facilities in operation.
- 6 A standardized method for smear testing of a relatively uniform area should be used to aid in
 7 comparing contamination at different times and places. A smear taken from an area of 100 cm²
 8 is acceptable to indicate levels of removable contamination.

Table N-5. Acceptable Surface Contamination Levels for Equipment			
Nuclide*	Average†‡	Maximum†§	Removable†
U-nat, U-235, U-238, and associated decay products	83.3 Bq/100 cm ² [5,000 dpm/100 cm ²]	250 Bq/100 cm ² [15,000 dpm /100 cm ²]	16.7 Bq/100 cm ² [1,000 dpm/100 cm ²]
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	1.7 Bq/100 cm ² [100 dpm/100 cm ²]	5.0 Bq/100 cm ² [300 dpm/100 cm ²]	0.3 Bq/100 cm ² [20 dpm/100 cm ²]
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	16.7 Bq/100 cm ² [1,000 dpm/100 cm ²]	50.0 Bq/100 cm ² [3,000 dpm/100 cm ²]	3.3 Bq/100 cm ² [200 dpm/100 cm ²]
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm ² [5,000 dpm/100 cm ²]	250 Bq/100 cm ² [15,000 dpm/100 cm ²]	16.7 Bq/100 cm ² [1,000 dpm/100 cm ²]
<p>*Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.</p> <p>†As used in this table, disintegrations per minute (dpm) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.</p> <p>‡Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.</p> <p>§The maximum contamination level applies to an area of not more than 100 centimeters squared (cm²).</p> <p> The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.</p>			

9 **Decommissioning Surveys for Release for Unrestricted Use**

- 10 When a facility will be closed and released for unrestricted use, the values in Table N-6 provide
 11 acceptable residual contamination levels, known as "screening values," for building surfaces. To

1 the extent practicable, facilities should be decontaminated to levels that are as low as
2 reasonably achievable (ALARA). Surveys should be conducted for both removable
3 contamination (not to exceed 10 percent of the values in Table N–6) and for total residual
4 contamination before the facilities or equipment are released from restricted to unrestricted use,
5 to ensure that they meet the applicable limits.

6 Units are disintegrations per minute per 100 square centimeters [dpm/100 cm²]. One dpm is
7 equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of
8 individual radionuclides that would be deemed in compliance with the 0.25 mSv [25 mrem] in a
9 year unrestricted release dose limit in 10 CFR 20.1402. For radionuclides in a mixture, the “sum
10 of fractions” rule applies; see 10 CFR Part 20, Appendix B, Note 4 for an example of the “sum of
11 fractions” calculation. Refer to the NRC NUREG–1757 for further information on application of
12 the values in this table.

13 Table N–6 was derived using the DandD screening code, Version 1 (DandD v1.0) and its default
14 input parameters. Table N–6 provides criteria that permit licensees to demonstrate compliance
15 with the unrestricted release dose criterion in the License Termination Rule in Subpart E of
16 10 CFR Part 20. Sites with building surface contamination levels below those listed in
17 Table N–6 would be deemed acceptable for release for unrestricted use, in accordance with the
18 dose criteria in 10CFR 20.1402, provided that residual radioactivity has been reduced to ALARA
19 levels. The table is intended for use as criteria to facilitate license termination for many simple,
20 routine decommissioning cases without a site-specific dose assessment. For facilities with
21 contamination levels above those in Table N–6, additional site-specific dose assessments may
22 be necessary, and licensees should refer to NUREG–1757, Volumes 1 and 2, “Consolidated
23 Decommissioning Guidance,” regarding acceptable methods for conducting the appropriate
24 dose assessment, such as using the current version of DandD, to develop site-specific
25 screening criteria. The most recent version of the DandD code can be installed by downloading
26 the self-extracting program file, setup.exe, accessed through the Web site at

27 http://www.marssim.com/Dose_Modeling.htm. Links to other useful software and guidance
28 documents are also found at that Web site.

29 Table N–6 does not include screening values for radionuclides that emit alpha particles or for
30 soil contamination. Screening values for radionuclides not listed above may be found in
31 “Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for
32 License Termination” (63 FR 64132; November 18, 1998) for building surfaces; “Supplemental
33 Information on the Implementation of the Final Rule on Radiological Criteria for License
34 Termination” (64 FR 68395; December 7, 1999) for soils; and “Use of Screening Values to
35 Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination”
36 (65 FR 37186; June 13, 2000), which references Tables 5.19 (surface contamination) and 6.91
37 (surface soil) from NUREG/CR–5512, Vol. 3, “Residual Radioactive Contamination from
38 Decommissioning, Parameter Analysis, Draft Report for Comment, October 1999.” Tables 5.19
39 (surface contamination) and 6.91 (surface soil) are for use in determining acceptable screening
40 values for radionuclides not listed in the first two *Federal Register* notices.

Radionuclide	Symbol	Screening levels for unrestricted release (dpm/100 cm²)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Manganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-57	Co-57	2.1×10^5
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Zinc-65	Zn-65	4.8×10^4
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Europium-152	Eu-152	1.3×10^4
Tungsten-181	W-181	1.1×10^6
Iridium-192	Ir-192	7.4×10^4

*Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100 percent of surface contamination is removable; and, therefore, the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10 percent to 100 percent range) may calculate site-specific screening levels using the DandD, Version 1 computer code.

1

The type of surveys to be performed for decommissioning of facilities, and the number and locations of survey points or samples to be collected, should be determined using the guidance found in NUREG-1757. Most licensees will be able to use the "Simple Approaches for Conducting Final Radiological Surveys" found in Appendix B of NUREG-1757, Volume 2. If the decommissioning of facilities is too complex to use one of the "simple approaches," then licensees may have to develop a more formal decommissioning plan.

2 **Survey Record Requirements**

3 Each survey record should include the following:

- 4 • a diagram of the area surveyed (See Figure N-1)
- 5 • a list of items and equipment surveyed
- 6 • specific locations on the survey diagram where wipe test was taken
- 7 • ambient radiation levels with appropriate units
- 8 • contamination levels with appropriate units
- 9 • make and model number of instruments used
- 10 • background levels
- 11 • name of the person making the evaluation and recording the results and date

12 Licensees should record contamination levels observed and procedures followed for incidents
 13 involving contamination of individuals. The record should include names of individuals involved,
 14 description of work activities, calculated dose, probable causes (including root causes),

1 steps taken to reduce future incidents of contamination, times and dates, and the
2 surveyor's signature. In addition, 10 CFR 30.35(g), 40.36(f) and 70.25(g) state, in part, that
3 records of information important to the decommissioning of a facility, including records of spills
4 or other unusual occurrences involving the spread of contamination in and around the facility,
5 equipment, or site, must be maintained.

6 **Air Monitoring in the Workplace**

7 Air sampling can be used to do the following:

- 8 • determine whether the confinement of radioactive materials is effective
- 9 • measure airborne radioactive material concentrations in the workplace
- 10 • estimate worker intakes of radioactive material
- 11 • determine posting requirements
- 12 • determine what protective equipment and measures are appropriate
- 13 • warn of significantly elevated levels of airborne radioactive materials

14 If bioassay measurements are used to determine worker doses of record, air sampling may be
15 used to determine time of intake and to determine which workers should have bioassay
16 measurements. The use of engineering controls and a good air sampling program may
17 eliminate the need for bioassays.

18 Refer to Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992
19 and NUREG-1400, "Air Sampling in the Workplace," dated September 1993, for further
20 guidance on air sampling. NUREG-1400 is available in ADAMS at Accession No.
21 ML102371083.

22 **Airborne Effluent Release Monitoring**

23 When practicable, airborne radioactive effluents should be released from monitored release
24 points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to
25 estimate public exposure. Licensees should verify the performance of effluent monitoring
26 systems by regular calibration (at least annually) to ensure their reliability. Regulatory
27 Guide 4-20, Rev 1, "Constraint on Releases of Airborne Radioactive Materials to the
28 Environment for Licensees Other than Power Reactors," April 2012, provides guidance on
29 methods (calculation or COMPLY code) acceptable to the NRC for compliance with the
30 constraint on air emissions to the environment.

31 Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," issued July 1993,
32 provides guidance on designing an acceptable program for establishing and maintaining ALARA
33 levels for gaseous and liquid effluents at materials facilities.

34 For release points where monitoring is not practicable, the licensee should estimate the
35 magnitude of the unmonitored effluents. These unmonitored releases will occur any time
36 unsealed material is handled outside a fume hood or other device that will control the releases.
37 The licensee should include these estimates when demonstrating compliance with dose limits
38 and ALARA goals. Unmonitored releases may be estimated based on the quantity of material
39 used in these areas, the number of procedures performed, or other appropriate methods. The
40 unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or
41 10 percent of the permissible air effluent concentrations found on column 1 of Table 2 in
42 10 CFR Part 20, Appendix B, whichever is greater.

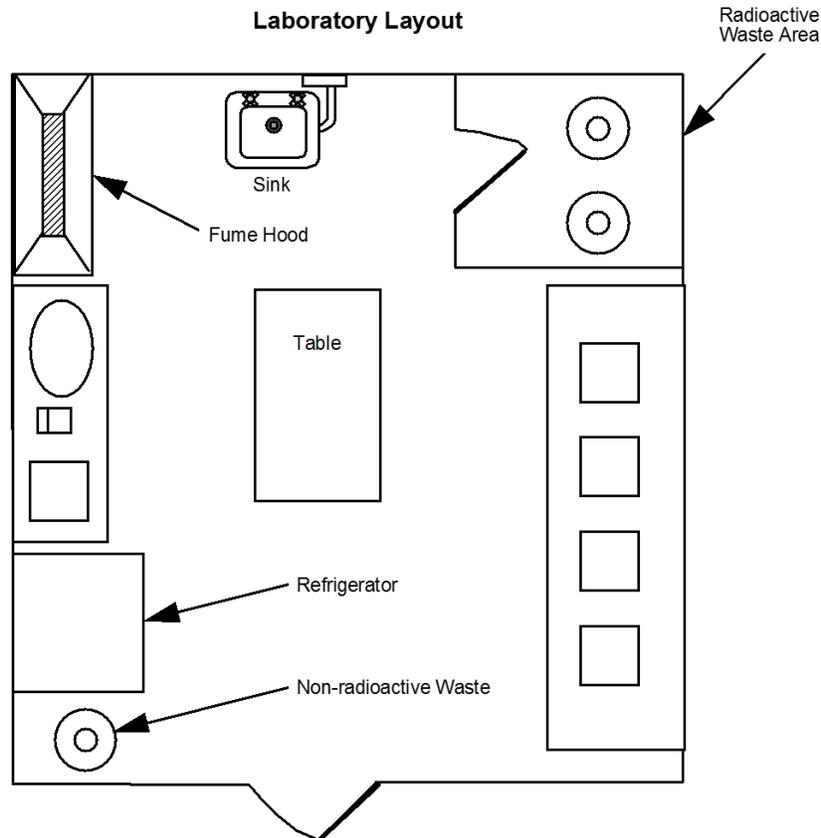


Figure N-1. Laboratory Layout. *This is an example of a laboratory survey map.*

1 Effluent monitoring systems should be designed in accordance with ANSI N13.1-2011,
 2 "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and
 3 Ducts of Nuclear Facilities," and ANSI N42.18-1991, "Specification and Performance of On-site
 4 Instrumentation for Continuously Monitoring Radioactive Effluents."

5 **Liquid Effluent Release Monitoring**

6 The licensee should evaluate the concentrations of radioactive material in water that is released
 7 to the environment and to the sanitary sewer. The licensee must show that these releases meet
 8 the limits in 10 CFR 20.1301 and 20.2003, respectively.

9 The topic of sanitary sewerage releases is more fully discussed in Section 8.11 and Appendix Q
 10 of this NUREG.

11 **Bioassay Monitoring**

12 Frequency of Required Bioassay Measurements

13 Determining the appropriate frequency of routine bioassay measurements depends on the
 14 exposure potential and the physical and chemical characteristics of the radioactive material and
 15 the route of entry to the body. Consider the following elements:

- 16 • potential exposure of the individual
- 17 • retention and excretion characteristics of the Radionuclides

- 1 • sensitivity of the measurement technique
- 2 • acceptable uncertainty in the estimate of intake and committed dose equivalent

3 Bioassay measurements used for demonstrating compliance with the occupational dose limits
4 should be conducted often enough to identify and quantify potential exposures and resultant
5 intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10 percent
6 ALI criterion is consistent with 10 CFR 20.1502(b), which requires licensees to monitor intakes
7 and assess occupational doses for exposed individuals who are likely to exceed 10 percent of
8 the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

9 Separate categories of bioassay measurements, routine measurements, and special
10 measurements further determine the frequency and scope of measurements.

11 Routine Bioassay Measurements

12 Routine bioassay measurements include baseline measurements, periodic measurements, and
13 termination measurements. These measurements should be conducted to confirm that
14 appropriate controls exist and to assess dose. The method of bioassay selected (e.g., whole
15 body counting, urinalysis, etc.) and the samples collected will vary according to the radionuclide
16 and the compound to which it is attached. Sample collection procedures should be developed to
17 ensure that appropriate types, sizes, and numbers of samples are collected that will provide
18 appropriate physiological information for the dose assessment.

19 An individual's baseline measurement of radioactive material within the body should be
20 conducted before beginning work that involves exposure to radiation or radioactive materials for
21 which monitoring is required.

22 In addition to the baseline measurements, periodic bioassay measurements should be
23 performed. The frequency of periodic measurements should be based on the likelihood of
24 significant exposure of the individual. In determining the worker's likely exposure, consider such
25 information as the worker's access, work practices, measured levels of airborne radioactive
26 material, and exposure time. Periodic measurements should be made when the cumulative
27 exposure to airborne radioactivity, since the most recent bioassay measurement is > 0.02 ALI
28 (40 derived air concentration (DAC) hours). Noble gases and airborne particulates with a
29 radioactive half-life of less than 2 hours should be excluded from the evaluation, since external
30 exposure generally controls these radionuclides.

31 At a minimum, periodic measurements should be conducted annually. Periodic measurements
32 provide additional information on any long-term accumulation and retention of radioactive
33 material in the body, especially for exposures to concentrations of airborne radioactive material
34 below monitoring thresholds.

35 When an individual is no longer subject to the bioassay program, because of change in
36 employment status, termination bioassay measurement should be made, when practicable, to
37 ensure that any unknown intakes are quantified.

38 Special Bioassay Monitoring

39 Because of uncertainty in the time of intakes and the absence of other data related to the
40 exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to
41 actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent

1 intakes from situations such as a failed respiratory protective device, inadequate engineering
2 controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be
3 evaluated on a case-by-case basis. When determining whether potential intakes should be
4 evaluated, consider the following circumstances:

- 5 • the presence of unusually high levels of facial or nasal contamination
- 6 • entry into airborne radioactivity areas without appropriate exposure controls
- 7 • operational events with a reasonable likelihood that a worker was exposed to unknown
8 quantities of airborne radioactive material (e.g., loss of system or container integrity)
- 9 • known or suspected incidents of a worker ingesting radioactive material
- 10 • incidents that result in contamination of wounds or other skin absorption
- 11 • evidence of damage to or failure of a respiratory protective device.

12 **References:**

- 13 • Regulatory Guide 4.20, Revision 1, "Constraints on Release of Airborne Radioactive
14 Materials to the Environment for Licensees Other than Power Reactors," April 2012
- 15 • Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and
16 Assumptions for a Bioassay Program," July 1993
- 17 • Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," September 1979
18 (Note: DG-8050, *Proposed Revision 2 of Regulatory Guide 8.20, dated September*
19 *1979, "Applications of Bioassay for I-125 and I-131," ADAMS Accession*
20 *No. ML102800439*)
- 21 • Regulatory Guide 8.23, Revision 1, "Radiation Safety Surveys at Medical Institutions,"
22 January 1981
- 23 • Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992
- 24 • Regulatory Guide 8.32, "Criteria for Establishing a Tritium Bioassay Program," July 1988
- 25 • Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational
26 Doses," July 1992
- 27 • Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993
- 28 • NUREG-1400, "Air Sampling in the Workplace," September 1993
- 29 • NUREG-1549, "Decision Methods for Dose Assessment to Comply with Radiological
30 Criteria for License Termination," July 1998, ADAMS Accession No. ML993250291
- 31 • NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual
32 (MARSSIM)," Revision 1, August 2000

- 1 • NUREG-1575, Supplement 1, "Multi-Agency Radiation Survey and Assessment of
2 Materials and Equipment Manual (MARSAME)"
- 3 • NUREG-1757, "Consolidated Decommissioning Guidance,"
 - 4 ○ Volume 1, Decommissioning Process for Materials Licensees (Revision 2),
5 September 2006
 - 6 ○ Volume 2, Characterization, Survey, and Determination of Radiological Criteria
7 (Revision 1), September 2006
- 8 • NUREG/CR-4884, "Interpretation of Bioassay Measurements," July 1987
- 9 • NUREG/CR-5512, Volume 2, "Residual Radioactive Contamination from
10 Decommissioning User's Manual DandD Version 2.1," April 2001, ADAMS Accession
11 No. ML010940257
- 12 • NUREG/CR-5512, Volume 3, "Residual Radioactive Contamination from
13 Decommissioning, Parameter Analysis, Draft Report for Comment," October 1999
14 [containing Tables 5.19 (surface contamination) and 6.91 (surface soil)], ADAMS
15 Accession No. ML082460902
- 16 • *Federal Register*: "Supplemental Information on the Implementation of the Final Rule on
17 Radiological Criteria for License Termination," 63 FR 67132-34, November 18, 1998
- 18 • *Federal Register*: "Supplemental Information on the Implementation of the Final Rule on
19 Radiological Criteria for License Termination," 64 FR 68395-96, December 7, 1999
- 20 • *Federal Register*: "Use of Screening Values to Demonstrate Compliance With the Final
21 Rule on Radiological Criteria for License Termination," 65 FR 37186, June 13, 2000
- 22 • ANSI N13.1-2011, "Sampling and Monitoring Releases of Airborne Radioactive
23 Substances from the Stacks and Ducts of Nuclear Facilities," 2011
- 24 • ANSI N13.30-2011, "Performance Criteria for Radiobioassay," 2011
- 25 • ANSI N42.18-2004, "Specification and Performance of On-site Instrumentation for
26 Continuously Monitoring Radioactive Effluents," 2004
- 27 • NCRP Commentary No. 3, "Screening Techniques for Determining Compliance with
28 Environmental Standards," published in January 1989, and the addendum published
29 October 1989
- 30 • U.S. Department of Energy, DOE G 441.1-1C, Admin Chg 1, "Radiation Protection
31 Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835,
32 Occupational Radiation Protection," July 8, 2011

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APPENDIX O
MODEL LEAK TEST PROGRAM

Model Leak Test Program

2 Training

3 Before allowing an individual to perform leak testing, the licensee must ensure that he or she
4 has sufficient classroom and on-the-job training to show competency in performing leak testing
5 and sample analysis independently.

6 Classroom training may be in the form of lecture, online, video, hands-on, or self-study and
7 should cover the following subject areas:

- 8 • principles and practices of radiation protection
- 9 • radioactivity measurements, monitoring techniques, and instrument use
- 10 • mathematics and calculations used for measuring radioactivity
- 11 • biological effects of radiation

12 Appropriate on-the-job training consists of the following:

- 13 • observing authorized personnel collecting and analyzing leak test samples
- 14 • collecting and analyzing leak test samples under the supervision and in the physical
15 presence of an individual authorized to perform leak testing and sample analysis

16 Facilities and Equipment

- 17 • To ensure achieving the required sensitivity of measurements, analyze leak tests in a
18 low-background area.
- 19 • Use a calibrated and operable survey instrument to check leak test samples for gross
20 contamination before they are analyzed.
- 21 • Analyze the leak test sample using an instrument that is appropriate for the type of
22 radiation to be measured (e.g., NaI(Tl) well-counter system for gamma emitters, liquid
23 scintillation for beta emitters, and gas-flow proportional counter for alpha emitters).
- 24 • If the sensitivity of the counting system is unknown, determine the minimum detectable
25 activity (MDA). The MDA may be determined using the following formula:

$$26 \quad \text{MDA} = \frac{2.71 + 4.65 \sqrt{\text{bkg} \times t}}{t \times E}$$

- 27 where: *MDA* = minimum detectable activity in disintegrations per minute (dpm)
28 *bkg* = background count rate in counts per minute (cpm)
29 *t* = background counting time in minutes
30 *E* = detector efficiency in counts per disintegration

31 For example:

- 32 where: *bkg* = 200 cpm
33 *E* = 0.1 counts per disintegration (10 percent efficient)
34 *t* = 2 minutes

1
$$MDA = \frac{2.71 + 4.65 \sqrt{200 \text{ cpm} \times 2 \text{ minutes}}}{2 \times 0.1} = \frac{2.71 + 4.65 \sqrt{400}}{0.2}$$

2

3
$$= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

4

5
$$= \frac{478.55 \text{ disintegrations}}{\text{minute}}$$

6

7 becquerels (Bq) =
$$\frac{1 \text{ disintegration}}{\text{second}}$$

8

9
$$MDA = \frac{478.55 \text{ disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 7.976 \text{ Bq}$$

10 **Note:** The MDA equation shown assumes that counting times for the background measurement
11 and for the sample will be equal. MDA equations for non-equal counting times, as well as
12 derivations of equations and discussions of limitations, can be found in “Decommissioning
13 Health Physics—A Handbook for MARSSIM Users,” Eric W. Abelquist, published by Taylor &
14 Francis Group, 2001.

15 **Frequency for Conducting Leak Tests of Sealed Sources**

16 Leak tests will be conducted at the frequency specified in the respective Sealed Source and
17 Device registration certificate. If a sealed source is not registered, leak tests should be
18 conducted at 6 month intervals, unless a different interval is established during the licensing
19 process. Leak testing of sealed sources may be required by license condition.

20 **Procedure for Performing Leak Testing and Analysis**

- 21 • For each source to be tested, list identifying information such as the sealed source serial
22 number, manufacturer, model number, radionuclide, and activity.
- 23 • Use a radiation survey meter to monitor exposure.
- 24 • Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- 25 • Number each wipe to correlate with identifying information for each source.
- 26 • Wipe the most accessible area where contamination would accumulate if the sealed
27 source were leaking, but do not wipe the surface of a plated or foil source (see
28 manufacturer’s instructions).

- 1 • Select instrumentation that is sensitive enough to detect 185 becquerels (Bq)
2 (0.005 microcurie) of the radionuclide contained in the sealed source.
- 3 • Using the selected instrument, count and record background count rate.
- 4 • Check the instrument's counting efficiency using a standard source of the same
5 radionuclide as the source being tested or one with similar energy characteristics. The
6 calibration source should be in the same configuration as the sample. Accuracy of
7 standards should be within plus or minus 5 percent of the stated value and traceable to
8 primary radiation standards such as those maintained by the National Institute of
9 Standards and Technology.
- 10 • Calculate the counting efficiency of the detector.

11 Efficiency in cpm/Bq = $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}}$

12 where cpm = counts per minute
13 std = standard
14 bkg = background
15 Bq = becquerel

- 16 • Count each wipe sample; determine net count rate.
- 17 • For each sample, calculate and record estimated activity in becquerels (or microcuries).
18 The activity of the sample in becquerels may be calculated using the following formula:

19 Activity of sample [Bq] = $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}}$

- 20 • Sign and date the list of sources, data, and calculations. Retain records for 3 years
21 [under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2103(a)].
- 22 • If the wipe test activity is 185 becquerels (0.005 microcuries) or greater, notify the
23 radiation safety officer so that the source can be withdrawn from use and disposed of
24 properly. Also, notify the U.S. Nuclear Regulatory Commission.

1

APPENDIX P

2

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

3

U.S. Department of Transportation Regulations

Note: The following list of U.S. Department of Transportation (DOT) regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: <http://www.dot.gov/>.

- Table of Hazardous Materials and Special Provisions—49 CFR 172, Subpart B
 - 49 CFR 172.101—Hazardous Materials Table [proper shipping name, hazard class, identification number]
 - 49 CFR 172.101—List of Hazardous Substances and Reportable Quantities, Table 2 to Appendix A—Radionuclides
- Shipping Papers—49 CFR 172, Subpart C
 - 49 CFR 172.201—Preparation and retention of shipping papers
 - 49 CFR 172.202—Description of hazardous material on shipping papers
 - 49 CFR 172.203—Additional description requirements
 - 49 CFR 172.204—Shipper’s certification
- Marking—49 CFR 172, Subpart D
 - 49 CFR 172.300—Applicability
 - 49 CFR 172.301—General marking requirements for non-bulk packagings
 - 49 CFR 172.304—Marking requirements
 - 49 CFR 172.310—Class 7 (radioactive) materials
 - 49 CFR 172.324—Hazardous substances in non-bulk packagings [designation of “reportable quantities” with the letters “RQ”]
- Labeling—49 CFR 172, Subpart E
 - 49 CFR 172.400—General labeling requirements
 - 49 CFR 172.400a—Exceptions from labeling
 - 49 CFR 172.401—Prohibited labeling
 - 49 CFR 172.403—Class 7 (radioactive) material
 - 49 CFR 172.406—Placement of labels
 - 49 CFR 172.436—RADIOACTIVE WHITE-I label
 - 49 CFR 172.438—RADIOACTIVE YELLOW-II label
 - 49 CFR 172.440—RADIOACTIVE YELLOW-III label
- Placarding—49 CFR 172, Subpart F
 - 49 CFR 172.500—Applicability of placarding requirements
 - 49 CFR 172.504—General placarding requirements
 - 49 CFR 172.516—Visibility and display of placards
 - 49 CFR 172.556—RADIOACTIVE placard

- 1
- 2 • Emergency Response Information—49 CFR 172, Subpart G
- 3
- 4 – 49 CFR 172.600—Applicability and general requirements
- 5 – 49 CFR 172.602—Emergency response information
- 6 – 49 CFR 172.604—Emergency response telephone number
- 7
- 8 • Training—49 CFR 172, Subpart H
- 9
- 10 – 49 CFR 172.702—Applicability and responsibility for training and testing
- 11 – 49 CFR 172.704—Training requirements
- 12
- 13 • Safety and Security Plans—49 CFR 172, Subpart I
- 14
- 15 – 49 CFR 172.800—Purpose and applicability
- 16 – 49 CFR 172.802—Components of a security plan
- 17
- 18 • Shippers—General Requirements for Shipments and Packagings—49 CFR Part 173
- 19
- 20 – 49 CFR 173.25—Authorized packagings and overpacks
- 21 – 49 CFR 173.403—Definitions
- 22 – 49 CFR 173.411—Industrial packages
- 23 – 49 CFR 173.412—Additional design requirements for Type A packages
- 24 – 49 CFR 173.413—Requirements for Type B packages
- 25 – 49 CFR 173.415—Authorized Type A packages
- 26 – 49 CFR 173.416—Authorized Type B packages
- 27 – 49 CFR 173.433—Requirements for determining basic radionuclide values, and
- 28 for the listing of radionuclides on shipping papers and labels
- 29 – 49 CFR 173.435—Table of A₁ and A₂ values for radionuclides
- 30 – 49 CFR 173.441—Radiation level limitations and exclusive use provisions
- 31 – 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission
- 32 approved packages
- 33 – 49 CFR 173.475—Quality control requirements prior to each shipment of Class 7
- 34 (radioactive) materials
- 35 – 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials
- 36
- 37 • Carriage by Public Highway—49 CFR Part 177
- 38
- 39 – 49 CFR 177.817—Shipping papers
- 40 – 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for
- 41 blocking and bracing during transport]
- 42

43 **Note:** The following reference charts are for reference only and are not a substitute for DOT and
 44 U.S. Nuclear Regulatory Commission transportation regulations.
 45
 46

1. Minimum Required Packaging for Class 7 (Radioactive) Material ^[1] (49 CFR 173 and 10 CFR 71) ^[2] These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.					
Minimum Packaging Required for Radioactive Materials other than Low Specific Activity (LSA) Material and Surface Contaminated Objects (SCO) based on Activity of Package Contents					
Radioactive Material Quantity ^[3]		Excepted Quantities and Articles	Type A ^[4]	Type B	
Activity Restrictions		≤ the limits specified in Table 4 of §173.425	≤ A ₁ for special form ≤ A ₂ for normal form	> A ₁ for special form > A ₂ for normal form	
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package	
	Fissile	N/A	Type AF package	Type B(U)F or Type B(M)F package	
Minimum Packaging Required for LSA Material and SCO ^{[5], [6]}					
Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport ^{[7], [8]}	Unpackaged ^[9] IP-1: solids, or liquids/exclusive use IP-2: liquids/non-exclusive use Specification tank cars or cargo tank motor vehicles: liquids/exclusive use	- IP-2: exclusive use IP-3: liquids or gases/non-exclusive use	- IP-2: exclusive use IP-3: non-exclusive use	Unpackaged ^[9] IP-1 - -	- IP-2 -
Alternative Provisions for Domestic only Transport ^[9]	Packaging shall meet the requirements of §§173.24, 24a, and 410 Transportation shall be an exclusive use shipment Activity per shipment must be less than an A ₂ quantity				

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.
[2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (see §71.5).
[3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in §173.436 or the values derived according to the instructions in §173.433, must be regulated in transport as Class 7 (radioactive) material.
[4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) materials greater than A₁ or A₂.
[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 m from the unshielded material or objects (see §173.427(a)(1)).
[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages. For alternate domestic transport provisions, see §173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.
[7] For LSA material and SCO, transport of combustible solids, all liquids and all gases classified as LSA-II and LSA-III material, and transport of all SCO-I and SCO-II is limited to a maximum activity of 100 A₂ in a conveyance (see §173.427(a)(2)).
[8] Unless excepted by §173.427(c) or (d), the material or object(s) shall be appropriately packaged in a Type IP, DOT-7A Type A or Type B package.
[9] Certain LSA-I and SCO-I may be transported unpackaged under the conditions specified in §173.427(c).

2. Radiation Level, TI and CSI Limits for Transportation by Road, Rail and Air ^[1] (49 CFR 172 - 177, and 10 CFR 71)					
Type of Transport	Non-exclusive use		Exclusive use		
Mode of Transport	Road, Rail, Vessel and Air		Road and Rail	Vessel	Air (cargo only)
Radiation Level Limits ^[2]					
Package Surface ^[1]	2 mSv/h (200 mrem/h)		2 mSv/h (200 mrem/h); other than closed vehicles 10 mSv/h (1000 mrem/h): closed vehicles	None specified	2 mSv/h (200 mrem/h) ^[3]
Conveyance ^[4]	N/A		2 mSv/h (200 mrem/h): outer surfaces (sides, top and underside) of vehicle ^[5] 0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle ^[6]	N/A	N/A
Occupied position	N/A		0.02 mSv/h (2 mrem/h): at any normally occupied area ^[6]	Requirement of §176.708 applies	N/A
Transport Index (TI) Limits ^[2]					
Package ^[1, 7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft		No limit		10
Conveyance ^[4]	50: road, rail and passenger aircraft 50 to No limit: vessels ^[8] 200: cargo aircraft		No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels ^[8] 3: passenger aircraft, 10: cargo aircraft		N/A		No limit ^[8] N/A
Criticality Safety Index (CSI) Limit for fissile material ^[4]					
Package ^[1, 7]	50		100		100
Conveyance ^[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels ^[8] 200 to No limit: for a total vessel ^[8]		100		200 to No limit: for a total vessel ^[8] 100
Overpack	50: road, rail, vessels ^[8] and air		N/A		N/A

[1] The limits in this table do not apply to excepted packages.
[2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, also the sum of the CSIs.
[3] Higher package surface radiation levels may be allowed through an approved special arrangement.
[4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft.
[5] The outer surfaces (sides, top and underside) of vehicles are defined for road and rail vehicles in §173.441.
[6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.
[7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages. Also, see CSI limits established by §71.59.
[8] For details on TI and CSI limits for transport by vessel, see §176.708.

**3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials:
(49 CFR 173.443 and 173.475, and 10 CFR 71)**

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport

The level of non-fixed (removable) radioactive contamination on external surfaces of packages offered for transport must be kept as low as reasonable achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§173.443(a), Table 9)		
	Bq/cm ²	µCi/cm ²	dpm/cm ²
Beta, gamma and low toxicity alpha emitters	4	10 ⁻⁴	220
All other alpha emitting radionuclides	0.4	10 ⁻⁵	22

The non-fixed contamination shall be determined by:

- (a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
- (b) ensuring each wipe area is 300 cm² in size;
- (c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.

Provisions for Control of Contamination on Radioactive Material Packages Prior to Shipment

Prior to shipment, the non-fixed contamination on each package of radioactive material:

- must be kept as low as reasonable achievable; and
- may not exceed the limits set forth in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in §173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each transport vehicle used for transporting the radioactive material packages must be surveyed with appropriate radiation detection instruments after each use. If contamination values exceed acceptable levels, the transport vehicle may not be returned to service until the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination specified in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination in Closed Rail and Road Vehicles that are used Solely for the Transportation of Radioactive Material

- The contamination levels must not exceed 10 times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each vehicle shall be stenciled with the words "For Radioactive Materials Use Only" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

Provisions for Quality Control Prior to Each Shipment of Radioactive Material (§173.475)

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
 - (a) the packaging is proper for the contents to be shipped;
 - (b) the packaging is in unimpaired physical condition, except for superficial marks;
 - (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
 - (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
 - (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
 - (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
 - (g) each packaging containing liquid in excess of an A₂ quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
 - (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
 - (i) the external radiation and contamination levels are within the allowable limits specified in §173.441 and 443.

4. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR 172, Subpart C)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Shipping Paper Entries		
Always Required	Sometimes Required	Optional Entries
<p><u>Basic description (in sequence):</u></p> <ul style="list-style-type: none"> • UN Identification number • Proper Shipping Name • Hazard Class (7) • Total activity contained in each package in SI units (e.g. Bq, TBq, etc.), or in both SI and customary units (e.g. Ci, mCi, etc.) with customary units in parentheses following the SI units • Number and type of packages <p><u>Additional description:</u></p> <ul style="list-style-type: none"> • Name of each radionuclide^[1] • Description of physical and chemical form (unless special form) • Category of label used • Transport index (TI) of each package bearing a Yellow-II or Yellow-III label <p><u>Additional entry requirements:</u></p> <ul style="list-style-type: none"> • 24 hour emergency telephone number • Shipper's Certification shall be provided by each person offering radioactive material for transportation^[2] • Proper page numbering (e.g. Page 1 of 4) 	<p><u>Materials-based Requirements:</u></p> <ul style="list-style-type: none"> • The criticality safety index (CSI) or "Fissile Excepted" for fissile material • The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities • The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8) • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste <p><u>Package-based Requirements:</u></p> <ul style="list-style-type: none"> • The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package <p><u>Shipment- and Administrative-based Requirements:</u></p> <ul style="list-style-type: none"> • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT-SP" followed by the special permit number^[3] for a special permit shipment 	<ul style="list-style-type: none"> • The weight in grams or kilograms of radionuclides may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information
Special Considerations/Exceptions for Shipping Papers		
<ul style="list-style-type: none"> • For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, <u>or</u> be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, <u>or</u> be designated by an "X" (or "RQ" if appropriate). • Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle. • Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste. • For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat. 		

[1] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with §173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

[2] The shipper's certification shall satisfy the requirements of either §172.204(a)(1) or 204(a)(2); or if transported by air of §172.204(c); but is not required if the shipper is a private carrier and the shipment is not reshipped or transferred from one carrier to another.

[3] Shipments made under an exemption or special permit issued prior to October 1, 2007 may bear the notation "DOT-E" followed by the number assigned.

**5. Hazard Communication for Class 7 (Radioactive) Materials: Marking of Packagings:
(49 CFR 172, Subpart D; and 49 CFR 178.3 and 178.350)**

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages		
Markings Always Required Unless Excepted ^[1]	Additional Markings Sometimes Required	Optional Markings
<p>Markings for Non-bulk Packagings:</p> <ul style="list-style-type: none"> • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: <ul style="list-style-type: none"> ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee <p>Markings for Bulk Packages:</p> <ul style="list-style-type: none"> • Identification number on orange rectangular panel: <ul style="list-style-type: none"> ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more, or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or ▪ on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer 	<p>Package-based marking requirements:</p> <ul style="list-style-type: none"> • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb) • Package type as appropriate, i.e., "TYPE IP-1," "TYPE IP-2," "TYPE IP-3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"^[1] • Marked with international vehicle registration code of country of origin for IP-1, IP-2, IP-3 or Type A package design^[2] • Radiation (trefoil) symbol^[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design  • For NRC or DOE packaging, model number, serial number, gross weight, and package identification number for each certified package (Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) • For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §178.3 and §178.350. <p>Materials-based requirements:</p> <ul style="list-style-type: none"> • For non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation^[4], where the symbol is placed on two opposite sides of the packaging  • If a hazardous substance in non-bulk package, mark outside of each package with the letters "RQ" in association with the proper shipping name <p>Administrative-based requirements:</p> <ul style="list-style-type: none"> • For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in U.S. Competent Authority Certificate • Mark "DOT-SP" followed by the special permit number assigned for each package authorized by special permit • Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type C, Type CF, Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required 	<ul style="list-style-type: none"> • Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.
Special Considerations for Marking Requirements		
<ul style="list-style-type: none"> • All markings are to be (a) on the outside of each packaging, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments. 		

[1] Some exceptions exist as specified in §§172.301(a) and 302(a); and in §§173.421(a), 422(a).

[2] The international vehicle registration code for packages designed by a U.S. company or agency is the symbol "USA."

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water that conform to the requirements of Appendix B to Part 172.

[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

6. Hazard Communications for Class 7 (Radioactive) Materials:

Labeling of Packages (49 CFR 172.400-450)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Requirements for Labels ^[1]

- Label each package except for (a) excepted packages containing a limited quantity of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported domestically and when material or object contains less than an A₂ quantity.
- Labeling is required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) un-obscured by markings or other attachments, and (f) representative of hazardous material content.
- Display duplicate labels on at least two opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material except as noted above for excepted packages, and packaged or unpackaged LSA material and SCO.

Radioactive Category Labels ^[3]

Other Labels ^[2]

White-I	Yellow-II	Yellow-III	Fissile	Empty								
<p>Radiation Surface Level (RSL):</p> <table border="1"> <tr> <td>mSv/h:</td> <td>RSL ≤ 0.005</td> <td>0.005 < RSL ≤ 0.5</td> <td>0.5 < RSL ≤ 2^[4]</td> </tr> <tr> <td>mrem/h:</td> <td>RSL ≤ 0.5</td> <td>0.5 < RSL ≤ 50</td> <td>50 < RSL ≤ 200^[4]</td> </tr> </table>			mSv/h:	RSL ≤ 0.005	0.005 < RSL ≤ 0.5	0.5 < RSL ≤ 2 ^[4]	mrem/h:	RSL ≤ 0.5	0.5 < RSL ≤ 50	50 < RSL ≤ 200 ^[4]	<p>Fissile labels required for each package containing fissile material, other than fissile-excepted material; and labels must be affixed adjacent to radioactive category labels.</p>	
mSv/h:	RSL ≤ 0.005	0.005 < RSL ≤ 0.5	0.5 < RSL ≤ 2 ^[4]									
mrem/h:	RSL ≤ 0.5	0.5 < RSL ≤ 50	50 < RSL ≤ 200 ^[4]									
<p>Transport Index (TI):^[4]</p> <table border="1"> <tr> <td>TI = 0^[4]</td> <td>0^[4] < TI ≤ 1</td> <td>1 < TI ≤ 10^[4, 5]</td> </tr> </table>			TI = 0 ^[4]	0 ^[4] < TI ≤ 1	1 < TI ≤ 10 ^[4, 5]	<p>Empty labels required for shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible</p>						
TI = 0 ^[4]	0 ^[4] < TI ≤ 1	1 < TI ≤ 10 ^[4, 5]										

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in §172.433(g); and, for LSA-I material, the term "LSA-I"; (b) activity in appropriate SI units (e.g. Bq, TBq), or appropriate customary units (e.g. Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units.
- Each fissile label must contain the relevant Criticality Safety Index (CSI).

[1] Additional labeling may be required if the radioactive material also meets the definition of one or more other hazard classes. See §§172.402 and 403 for details on label requirements. See §§172.403, 421 and 427 for details when labels are not required, and see §172.407 for details on label design, size, color, form identification, exceptions, etc.

[2] An additional "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only.

[3] The category of the label must be the higher of the two values specified for RSL and TI; see §172.403(b).

[4] The TI is determined from radiation level 1 m from package surface; see definition for TI in §173.403 for details. If the measured TI is not greater than 0.05, the value may be considered to be zero.

[5] RSLs less than or equal to 10 mSv/h (1000 mrem/h), and TIs more than 10 are allowed for shipments under exclusive-use; see §§172.403(a) – 403(c). In addition; any package containing a Highway Route Controlled Quantity (HRCQ) must bear a YELLOW-III label.

7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR 172, Subpart F)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Conditions when Display of Radioactive Placards is Required [§§172.504, 507(a), 508 and 512(b)(2)]

- On bulk packages, road transport vehicles, rail cars, and freight containers, and on aircraft unit load devices having a capacity of 640 cubic feet or more^[1], on each side and each end when they contain either a package with a Radioactive Yellow-III label, or low specific activity (LSA) material or surface contaminated objects (SCO) being transported under exclusive use.
- On a square background on any motor vehicle used to transport a package containing Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) materials^[2].

Visibility and Display of Radioactive Placards [§172.516]

- Placards are required to:
 - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled^[3];
 - be securely attached or affixed thereto or placed in a holder thereon;
 - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins;
 - be located, so far as practical, so dirt or water is not directed to it from transport vehicle wheels;
 - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness;
 - have authorized words or identification number printed on it displayed horizontally, reading from left to right;
 - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter;
 - be affixed to background of contrasting color, or dotted or solid line outer border which contrasts with the background color.

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)



White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black.
[see §172.556 for detailed requirements]

PLACARD FOR HRCQ



Square background must consist of a white square surrounded by black border. The placard inside the square is identical to that for other than HRCQ.
[see §172.527 for detailed requirements]

Special Considerations/Exceptions for Placarding

- Placards must conform to the specifications set forth in §172.519.
- A corrosive placard is required for more than 454 kg (1001 pounds) or more gross weight of fissile or low specific activity uranium hexafluoride.

[1] See §172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See §173.403 for definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels; see §172.507(a).

[3] Required placarding of the front of a motor vehicle may be on the front of a truck tractor instead of or in addition to the placarding on the front of the cargo body to which a truck tractor is attached; §172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G, 49 CFR 171.15 and 49 CFR 172, Subparts G and H)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by §107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
 - a highway route-controlled quantity of radioactive material;
 - a shipment in a bulk packaging with a capacity \geq 13,248 L (3,500 gallons) for liquids or gases, or $>$ 13.24 cubic meters (468 cubic feet) for solids; or
 - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with §107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§107.612 and 616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required (see Part 172, Subpart C), emergency response information shall
 - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
 - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
 - be immediately available for use at all times the hazardous material is present; and
 - include and make available the emergency response telephone number (see §172.604) to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§172.602 and 604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of §172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less than 0.005 mSv/h (0.5 mrem/h) and the non-fixed radioactive surface contamination levels are below the values the limits in §173.443(a), Table 9 [see Chart 3].
- Each aircraft used routinely, and each motor vehicle used, for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §173.443(a), Table 9 [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use. [see §§174.750(a) and 750(e), and §177.843(b)]

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§171.15 and 16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see §171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800-424-8802 (toll free) or 202-267-2675 (toll call) or online at <http://www.nrc.uscg.mil>.
 - Each notice must include the information specified in §171.15(a)(1) – (a)(7).
- A detailed incident report must also be submitted as required by §171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the specific or generic hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current Emergency Response Guidebook is available at the following URL:
<http://www.phmsa.dot.gov/hazmat/library/erg>



**9. Requirements for Training and Security for Class 7 (Radioactive) Materials:
(49 CFR 172, Subparts H and I, and 49 CFR 173)**

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Provisions for Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects radioactive materials transportation safety, a systematic program shall be established to ensure that the person:
 - has familiarity with the general provisions of [Part 172, Subpart H](#);
 - is able to recognize and identify radioactive materials;
 - has knowledge of specific requirements of [Part 172](#) that are applicable to functions performed by the employee;
 - has knowledge of emergency response information, self protection measures and accident prevention methods and procedures; and
 - does not perform any function related to the requirements of [Part 172](#) unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of [§§172.704\(a\) and \(b\)](#), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
 - (a) general awareness training providing familiarity with applicable regulatory requirements;
 - (b) function-specific training applicable to functions the employee performs;
 - (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
 - (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
 - (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of [§172.704\(c\)](#)
- Records of training shall be created and retained in compliance with the requirements of [§172.704\(d\)](#).

Provisions for Security (49 CFR 172, Subpart I and 49 CFR 173)

- A security plan for hazardous materials that conforms to the requirements of [Part 172, Subpart I](#) must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
 - (a) IAEA Code of Conduct Category 1 and 2 materials (see [§172.800\(b\)\(15\)](#));
 - (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in [§173.403](#) (see [§172.800\(b\)\(15\)](#));
 - (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM-QC) by the NRC (see [§172.800\(b\)\(15\)](#)); or
 - (d) a quantity of uranium hexafluoride requiring placarding under [§172.505\(b\)](#) (see [§172.800\(b\)\(14\)](#)).
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and en route security.
- The security plan must be
 - (a) in writing;
 - (b) retained for as long as it remains in effect;
 - (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
 - (d) revised and updated as necessary to reflect changing circumstances; and
 - (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in [Part 172](#), provided such security plans address the requirements specified in [Part 172, Subpart I](#).
- Additional security planning requirements may apply for rail transport of a highway route controlled quantity of radioactive material (see [§§172.820 and 173.403](#)).

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APPENDIX Q

MODEL WASTE MANAGEMENT PROCEDURES

1

Model Waste Management Procedures

2 General Guidelines

3 • All radioactivity labels must be defaced or removed from containers and packages prior
4 to disposal into ordinary “non-radioactive” waste streams. If waste is compacted, all
5 labels that are visible in the compacted mass must be defaced or removed.

6 • Remind workers that non-radioactive waste such as leftover reagents, boxes, and
7 packaging material should not be mixed with radioactive waste.

8 • Occasionally monitor all procedures to ensure that radioactive waste is not created
9 unnecessarily. Review all new procedures to ensure that waste is handled in a manner
10 consistent with established procedures.

11 • In all cases, consider the entire effect of various available disposal routes. Consider
12 occupational and public exposure to radiation, other hazards associated with the
13 material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity,
14 flammability), and costs.

15 • The waste management program should include waste handling procedures for the
16 users within their laboratories or assigned areas and for waste handlers who may collect
17 waste from areas of use to bring to the storage area for eventual disposal.

18 • Housekeeping staff should be provided adequate training to avoid the possibility of
19 unauthorized disposal or exposure of these individuals to radioactive materials or
20 to radiation.

21 • A waste generator, collector, or processor who transports, or offers for transportation,
22 low-level radioactive waste intended for ultimate disposal at a licensed low-level
23 radioactive waste land disposal facility must prepare a Manifest in accordance with
24 Title 10 of the Code of Federal Regulations (10 CFR) Part 20, Appendix G,
25 “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at
26 Licensed Land Disposal Facilities and Manifests.”

27 Model Procedure for Disposal by Decay-in-Storage (DIS)

28 Applicants should ensure that adequate space and facilities are available for the storage of
29 waste for decay-in-storage (DIS). Licensees can minimize the need for storage space if the
30 waste is segregated according to physical half-life.

31 • Only short-lived waste (physical half-life of less than or equal to 120 days) may be
32 disposed of by DIS.

33 • Short-lived waste should be segregated from long-lived waste.

34 • Waste should be stored in suitable well-marked containers, and the containers should
35 provide adequate shielding.

36 • Liquid and solid wastes should be stored separately.

- 1 • When the container is full, it should be sealed. The sealed container should be identified
2 with a label affixed or attached to it.

- 3 • The identification label should include the date when the container was sealed, the
4 longest-lived radionuclide in the container, total activity, and the name of the individual
5 who sealed the container. The container may be transferred to the DIS area. When
6 large quantities are held for DIS, sufficient quantities may be present even after many
7 half-lives and persons performing surveys should be aware of the potential for
8 measurable radiation.

- 9 • The contents of the container should be allowed to decay for a period of time after which
10 it is expected that the radiation levels would not be distinguishable from background.
11 The period of time depends on both the half-life of the radionuclide(s) and the original
12 amount present.

- 13 • Prior to disposal as ordinary trash, each container should be monitored with an
14 appropriate radiation detection instrument, on the lowest setting, as follows:
 - 15 – Check the radiation survey meter for proper operation.
 - 16 – Survey the contents of each container in a low-background area.
 - 17 – Remove any shielding from around the container.
 - 18 – Monitor all surfaces of the container.
 - 19 – Discard the contents as ordinary trash only if the surveys of the contents indicate no
20 residual radioactivity (i.e., surface readings are indistinguishable from background).
 - 21 – If the surveys indicate residual radioactivity, return the container to DIS area and
22 contact the radiation safety officer for further instructions.
 - 23 – If the surveys indicate no residual radioactivity, record the date when the container
24 was sealed, the disposal date, type of waste (e.g., used or unused material, gloves,
25 etc.), radiation survey instrument used, and the name of the individual performing
26 surveys and disposing of the waste.

- 27 • All radiation labels must be defaced or removed from containers and packages prior to
28 disposal as ordinary trash. Syringes/needles placed into sealed waste containers for
29 decay do not need the labels removed, provided that the following is done: waste
30 barrels are sealed prior to delivery to the waste disposal firm and delivered directly from
31 the licensee's facility; labels are removed from the waste barrels/containers; waste is
32 incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open
33 the container prior to incineration.

34 **Model Procedure for Disposal of Liquids into Sanitary Sewerage**

- 35 • Confirm that the sewer system is a public system, not a private sanitary sewer system,
36 septic system, or leach field.

- 1 • Confirm that the liquid waste being discharged is soluble (or is biological material that is
2 readily dispersible) in water.
- 3 • Calculate the amount of each radionuclide that can be discharged by using the
4 information from prior, similar discharges and the information in 10 CFR Part 20,
5 Appendix B.
- 6 • Make sure that the amount of each radionuclide does not exceed the monthly and
7 annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20,
8 Appendix B, Table 3.
- 9 • If more than one radionuclide is released, the sum of the ratios of the average monthly
10 discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B,
11 Table 3 must not exceed unity.
- 12 • Confirm that the total quantity of licensed material released into the sanitary sewerage
13 system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of H-3
14 (tritium), 37 GBq [1 Ci] of C-14, and 37 Gbq [1 Ci] of all other radionuclides combined.
- 15 • Record the date, radionuclide(s), estimated activity of each radionuclide, location where
16 the material is discharged, and the name of the individual discharging the waste.
- 17 • Liquid waste should be discharged only via designated sinks, toilets, or other release
18 points.
- 19 • Discharge liquid waste slowly to minimize splashing with water running, to be sure that
20 the material moves out of the sink and into the sewer system.
- 21 • Survey the sink and surrounding work surfaces to confirm that no residual material or
22 contamination remained in the sink or on work surfaces.
- 23 • Decontaminate all areas or surfaces if found to be contaminated.
- 24 • For all releases to the sanitary sewer from the licensed facility, maintain records of each
25 radionuclide and its quantity and concentration that is released into the sewer system
26 that demonstrate compliance with the regulatory limits for total quantity released and
27 concentrations released by the licensed facility.

28 **Model Procedure for Incineration**

- 29 • These guidelines apply to non-commercial waste disposal (i.e., incineration of a
30 licensee's own waste). You do not need specific U.S. Nuclear Regulatory Commission
31 (NRC) approval to incinerate certain categories of radioactive waste. For example, 10
32 CFR 20.2005 provides that tritium and carbon-14 in low-level concentrations in liquid
33 scintillation media and animal tissue may be disposed of without regard to radioactivity.
34 After you review your program and confirm that you have waste that requires specific
35 NRC approval for incineration, please provide the following information.
- 36 • Describe the training and experience of the person who will be responsible for the
37 on-site and day-to-day supervision of incinerator operations.

- 1 • Describe the waste that is proposed to be incinerated, to include: the chemical and/or
2 physical form of the waste containing licensed material and a description of how the
3 waste is segregated, packaged, and labeled for transfer from the generation site to the
4 incinerator; the name of the radionuclide; concentration of radioactivity averaged over
5 the weight of the material to be incinerated (microcuries per gram of waste medium) for
6 each isotope to be incinerated; and the total radioactivity of each isotope per burn and
7 the total number of burns per year. Describe procedures for ensuring that these
8 frequencies and activities will not be exceeded.

- 9 • Describe the procedures for packaging, handling, securing, and monitoring of waste to
10 prevent contamination and/or unnecessary exposure to personnel or property during the
11 waste life cycle.

- 12 • Describe the method for measuring or estimating the concentration of radioactive
13 material remaining in the ash residue. Describe the procedures for collection, handling,
14 and disposal of the ash residue.

- 15 • Describe the recordkeeping procedures for the waste incineration program. Records
16 must be adequate to document all receipts, incinerations, environmental releases of
17 effluents, and any disposals of ash generated in the incineration process. These records
18 must be maintained in the same units as applicable regulations.

- 19 • Describe the characteristics of the incinerator and site location, including height of the
20 stack, rated air flow (cubic feet per hour or similar units), proximity of the stack or other
21 discharge to occupied areas (e.g., residences, school, hospital), and distance to the
22 nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air
23 cleaning equipment that is present.

- 24 • State how the concentration of radionuclides released, both as airborne effluent and as
25 any liquid effluent from scrubbers, condensers, or associated systems, will be measured
26 or otherwise determined. Describe any stack monitoring that is planned.

- 27 • Provide a copy of the written safety analysis that demonstrates the applicant will be able
28 to incinerate the types and quantities of radioactivity specified in the application without
29 exceeding the environmental release limits specified in 10 CFR Part 20.

- 30 • Provide a written commitment that the applicant has coordinated with appropriate State
31 and local authorities and that you have obtained such permits and other authorizations,
32 as may be necessary.

- 33 • Provide a copy of the radiation safety procedures for monitoring personnel involved in
34 incineration operations and for monitoring all effluent generated by the incineration
35 process. The procedures must ensure that regulatory limits for environmental releases of
36 radioactivity will not be exceeded. The applicant should describe the disposal method for
37 any ash generated that exceeds regulatory limits.

38 **Model Procedure for Compaction**

39 The following information should be provided by licensees that propose to compact waste.

- 1 • Describe the compactor to demonstrate that it is adequately designed and manufactured
2 to safely compact the type and quantity of waste generated during licensed operations.
3 Provide manufacturer's specifications, annotated sketches or photographs, and other
4 information about the compactor design.
- 5 • Describe the type, quantities, and concentrations of waste to be compacted.
- 6 • Provide an analysis of the potential for airborne release of radioactive material during
7 compaction activities.
- 8 • Provide the location of the compactor(s) within the waste processing area(s), as well as
9 a description of the ventilation and filtration systems used in conjunction with the
10 compactors. Include a description of the procedures for monitoring filter blockage
11 and exchange.
- 12 • Discuss the methods used to monitor worker breathing zones and/or exhaust systems.
- 13 • Discuss the types and frequencies of surveys that will be performed for contamination
14 control in the compactor area.
- 15 • Discuss the instruction provided to compactor operators, including instructions for
16 protective clothing, checks for proper functioning of equipment, method of handling
17 uncompacted waste, and examining containers for defects.

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APPENDIX R

SAFETY CULTURE POLICY STATEMENT

Safety Culture

The Safety Culture Policy Statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf>. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC) Agencywide Documents Access and Management System, Accession No. ML11146A047.

Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture, commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders,

authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this statement of policy.

Nuclear Safety Culture is defined as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance

of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production, schedule, and the cost of the effort versus safety). It should be noted that although the term "security" is not

expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

1 The following are traits of a positive safety culture:

- 2 (1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in
3 their decisions and behaviors,
- 4 (2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly
5 identified, fully evaluated, and promptly addressed and corrected commensurate with
6 their significance,
- 7 (3) *Personal Accountability*—All individuals take personal responsibility for safety,
- 8 (4) *Work Processes*—The process of planning and controlling work activities is implemented
9 so that safety is maintained,
- 10 (5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out
11 and implemented,
- 12 (6) *Environment for Raising Concerns*—A safety conscious work environment is maintained
13 where personnel feel free to raise safety concerns without fear of retaliation, intimidation,
14 harassment, or discrimination,
- 15 (7) *Effective Safety Communication*—Communications maintain a focus on safety,
- 16 (8) *Respectful Work Environment*—Trust and respect permeate the organization, and
- 17 (9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge
18 existing conditions and activities in order to identify discrepancies that might result in
19 error or inappropriate action.

20 There may be traits not included in this statement of policy that are also important in a positive
21 safety culture. It should be noted that these traits were not developed to be used for
22 inspection purposes.

23 It is the Commission's expectation that all individuals and organizations, performing or
24 overseeing regulated activities involving nuclear materials, should take the necessary steps to
25 promote a positive safety culture by fostering these traits as they apply to their organizational
26 environments. The Commission recognizes the diversity of these organizations and
27 acknowledges that some organizations have already spent significant time and resources in the
28 development of a positive safety culture. The Commission will take this into consideration as the
29 regulated community addresses the statement of policy.

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APPENDIX S

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MEDICAL DISTRIBUTION

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Medical Distribution

1. INTRODUCTION

1.1 PURPOSE OF APPENDIX

The purpose of this appendix is to provide assistance in preparing applications for new licenses, license amendments, and renewals of medical distribution licenses under 10 CFR Part 32, “Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material” [i.e., licenses that authorize the distribution of radioactive drugs and sealed sources containing byproduct material to the Nuclear Regulatory Commission’s (NRC’s) and Agreement States’ medical use licensees but are not radiopharmacies]. Medical distribution by applicants registered or licensed with the U.S. Food and Drug Administration or State Agency as a drug or sealed source manufacturer is provided for in 10 CFR 32.72 and 32.74 or equivalent provisions of an Agreement State. The medical distribution license normally only authorizes distribution; it does not authorize the possession of byproduct material. NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses,” contains much of the information needed in preparing applications for medical distribution licenses. In order to avoid duplication, many sections in this appendix will refer you to Vol. 13. Some applications for manufacture and distribution of radioactive drugs require a separate application. Nuclear pharmacy applicants should refer to NUREG–1556, Vol. 13 in the preparation of an application for transfer for distribution of radioactive drugs for medical use.

- Several words and phrases used in this guide should be explained. The phrase “byproduct material” is defined in 10 CFR 30.4. The term “distribution” has the same meaning as in 10 CFR Part 32 (i.e., the routine transfer of licensed materials to others). For organizations licensed in accordance with 10 CFR 32.72 and 32.74, these transfers of licensed material are to specific licensees, in accordance with the requirements of 10 CFR 30.41; these organizations’ principal customers are medical use licensees. The phrase “medical use licensee” means a physician, podiatrist, dentist, or medical institution licensed under 10 CFR Part 35 for “medical use,” as defined in 10 CFR 35.2.

1.2 FILING AN APPLICATION FOR BROAD SCOPE LICENSES TO MANUFACTURE AND DISTRIBUTE RADIO LABELED DRUGS TO MEDICAL USE LICENSEES FOR RESEARCH

A request for an exemption from 10 CFR 32.72(a)(2) should be made from broad scope research and development licensees who are requesting to manufacture and distribute drugs containing byproduct material, pursuant to 10 CFR 32.72, to authorized recipients for human use research. An exemption may be granted if the applicant or licensee specifically requests an exemption from 10 CFR 32.72(a)(2) and provides the following supporting information with regard to the requirements of 10 CFR 32.72(a)(2):

- 32.72(a)(2)(i) – The applicant or licensee must confirm that *only* radioactive drugs for which the FDA has accepted an Investigational New Drug (IND) application containing microcurie quantities of hydrogen-3 or carbon-14 will be prepared and distributed. (The FDA, in 21 CFR 207.10(d), exempts classes of persons who manufacture or process drugs not for sale, but solely for use in research, teaching, and chemical analysis, from registering with the FDA as a drug manufacturer.)

- 1 • 32.72(a)(2)(ii) – The applicant or licensee must confirm that it is not registered with the
2 State or the FDA as a drug manufacturer.
- 3 • 32.72(a)(2)(iii) – The applicant or licensee must confirm that it is not licensed as a
4 pharmacy [in order to operate as such, you would need to employ an Authorized Nuclear
5 Pharmacist (ANP)]. The risk imposed by the radioactive drugs containing only microcurie
6 quantities of hydrogen-3 or carbon-14 does not warrant imposing the additional burden
7 of hiring an ANP for the license. The applicant or licensee may also have proprietary
8 concerns with hiring an ANP for short periods of time to work on the development of
9 new drugs.
- 10 • 32.72(a)(2)(iv) – The applicant or licensee must confirm that it is neither a nuclear
11 pharmacy nor located within a Federal institution.
- 12 • The applicant or licensee must agree to meet all other *applicable* sections of
13 10 CFR 32.72. If the exemption is granted, the following authorized use will be
14 added to the license for Hydrogen-3 and Carbon-14:
- 15 – preparation and distribution of radioactive drugs to authorized recipients in
16 accordance with 10 CFR 32.72
- 17 In addition, the following license condition will be added to the license:
- 18 – Notwithstanding 10 CFR 32.72(a)(2), the licensee is authorized to prepare
19 radioactive drugs, in accordance with an accepted U.S. Food and Drug
20 Administration (FDA) Investigational New Drug (IND) application protocol, and to
21 distribute them to medical use licensees in accordance with 10 CFR 32.72.

22 Since this exemption applies to broad scope research and development licensees, the broad
23 scope licensee will not require an exemption from 10 CFR 33.17(a)(4), which restricts broad
24 scope licensees from adding byproduct material to drugs designed for human use when
25 applying for 10 CFR 32.72 authorization. The addition of authorization to manufacture, prepare,
26 or transfer radioactive drugs containing byproduct material for medical use (10 CFR 32.72) to a
27 license authorizes Part 32 activities in addition to Part 33 (broad scope) activities. Preparation of
28 radioactive drugs is done under the Part 32 authorization and not the Part 33 authorization.

29 **2. CONTENTS OF AN APPLICATION**

30 The following paragraphs are numbered as on NRC Form 313, "Application for Material
31 License," Appendix B of this NUREG.

32 **Item 1: License Action Type**

33 See Section 8.1.

34 **Item 2: Applicant's Name and Mailing Address**

35 See Section 8.2.

36

1 **Item 3: Locations of Use**

2 See Section 8.3.

3 **Item 4: Person To Be Contacted about the Application**

4 See Section 8.3.

5 **Items 5 and 6: Radioactive Materials and Uses**

6 Identify the materials you wish to be authorized to distribute to NRC's and the Agreement
7 States' medical use licensees. The regulatory requirements and the subsequent information that
8 is needed are different for radioactive drug and for sealed source licenses.

9 For radioactive drugs, specify the radionuclide and chemical form (for generators, specify the
10 parent and daughter radionuclides and the name and model number, if appropriate, of the
11 generator). For sealed sources, specify the radionuclide, manufacturer's name and model
12 number of each source, the maximum activity in each source, and the anticipated use of the
13 sources. NRC needs to know the anticipated use of the source to perform its safety evaluation.
14 If the sealed sources are usually used in a device (e.g., bone mineral analyzer), specify the
15 manufacturer's name and the model number of the device.

16 The following examples show appropriate responses to Items 5 and 6.

- 17 • Radioactive Drugs
- 18 – Chromium-51 as Sodium Chromate
19 – Molybdenum-99 as Molybdenum-99/Technetium-99m Generator (Model MTG-1)
20 – Maximum activity per radionuclide
- 21 • Sealed Sources
- 22 – Cesium-137, XYZ Corp., Model 1234
23 – Maximum activity per source: 100 mCi
24 – To be used by medical use licensees as dose calibrator reference sources as
25 authorized in 10 CFR 35.65. Strontium-90, ABC Corp., Model 567
26 – Maximum activity per source: 150 millicuries
27 – To be used as a strontium-90 beta eye applicator for treatment of superficial
28 eye conditions
29 – Iodine-125, FGH Corp., Model 890
30 – Maximum activity per source: 300 millicuries
31 – To be used in an FGH Corp. Model BMA-1 device for bone mineral analysis

32

1 **Item 7: Individuals Responsible for Radiation Safety Program and Their Training**
2 **and Experience**

3 Enter "Not Applicable."

4 **Item 8: Training for Individuals Working in or Frequenting Restricted Areas**

5 Enter "Not Applicable."

6 **Item 9: Facilities and Equipment**

7 Enter "Not Applicable."

8 **Item 10: Radiation Safety Program**

9 According to 10 CFR 32.72 and 32.74, certain radiation safety information must be submitted
10 regarding licensed material to be distributed to medical use licensees. The information to be
11 submitted for each type of licensed material to be distributed to medical use licensees is
12 identified in the following sections and in NUREG–1556, Vol. 13, "Consolidated Guidance About
13 Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

14 **Item 10.1: Radioactive Drugs**

15 If you wish to distribute radioactive drugs to medical use licensees, pursuant to 10 CFR 35.100,
16 35.200, 35.300 or, 35.1000, you need to provide the information identified below and, where
17 applicable, in NUREG–1556, Vol. 13, "Consolidated Guidance About Materials Licenses:
18 Program-Specific Guidance About Commercial Radiopharmacy Licenses," for nuclear pharmacy
19 license applicants.

20 **Item 10.1.1: Radioactive Drugs—Commercial Distribution**

21 According to 10 CFR 32.72(a)(2), you must provide evidence that you are registered or licensed
22 with either the U.S. Food and Drug Administration (FDA) or a State Agency as a drug
23 manufacturer. See NUREG–1556, Vol. 13, "Consolidated Guidance About Materials Licenses:
24 Program-Specific Guidance About Commercial Radiopharmacy Licenses," for nuclear pharmacy
25 license applicants.

26 **Item 10.1.2: Radioactive Drugs – Instrumentation**

27 According to 10 CFR 32.72(c), you must possess and use instrumentation to measure the
28 radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for
29 commercial distribution. Measurements may be made by direct measurement or a combination
30 of direct measurement and calculation (calculation only may be used for alpha and beta
31 radiation). See NUREG–1556, Vol. 13, "Consolidated Guidance About Materials Licenses:
32 Program-Specific Guidance About Commercial Radiopharmacy Licenses," for nuclear pharmacy
33 license applicants.

34 **Item 10.1.3: Radioactive Drugs – Packaging and Shielding Licensing Criteria**

35 See NUREG–1556, Vol. 13, "Consolidated Guidance About Materials Licenses:
36 Program-Specific Guidance About Commercial Radiopharmacy Licenses."

1 **Item 10.1.4: Radioactive Drugs – Licensing Criteria for Labeling**

2 See NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses:
3 Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

4 **Item 10.1.5: Generators – —Return Program**

5 Some licensees offer a generator return program. In this program, customers may return used
6 or spent generators to the licensee. The applicant should develop and provide written
7 procedures for customers that address the return of generators.

8 **Item 10.1.5.1: Licensing Criteria**

9 If you wish to offer a generator return program, it may be helpful to supply instructions (including
10 instructions on labeling and shipping documents) to your customers. The shipper must comply
11 with 10 CFR 71.5 and with DOT regulations. As a minimum, these instructions should

- 12 • Establish the user’s responsibility and liability as the shipper.
- 13 • Provide step-by-step instructions for completing each item on each form and label that is
14 involved in the shipping process.
- 15 • Discuss all the customer’s responsibilities as a shipper under 49 CFR Parts 170 to 189.

16 **Response from Applicant:**

17 Provide a response as indicated at the end of each relevant item of NUREG–1556, Vol. 13,
18 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
19 Commercial Radiopharmacy Licenses.”

20 **Item 10.2: Sealed Sources**

21 If you intend to distribute sealed sources to medical use licensees, provide the information
22 identified in NUREG–1556, Vol. 13, “Consolidated Guidance About Materials Licenses:
23 Program-Specific Guidance About Commercial Radiopharmacy Licenses.”

24 **Item 10.2.1: Sealed Sources in Devices – Licensing Criteria for Evaluation of Design and**
25 **Construction**

26 If you are a manufacturer or initial distributor of sealed sources (or devices containing sealed
27 sources), you may need to submit a separate application for authorization to distribute the
28 sealed sources or devices. This separate application will facilitate NRC’s review and evaluation
29 of the radiation safety information for the sealed source or device and its certificate of
30 registration. To submit a source or device design for a safety evaluation and registration use
31 NUREG–1556, Vol. 3, “Consolidated Guidance About Materials Licenses: Applications for
32 Sealed Source and Device Evaluation and Registration.” This safety evaluation is required by
33 10 CFR 32.74 prior to the source or device being approved for distribution and medical use.

34

1 **Item 10.2.2: Sealed Sources – Labeling**

2 **Item 10.2.2.1: Licensing Criteria**

3 Your product labeling must fulfill the requirements of 10 CFR 20.1901, 20.1904, 20.1905, and of
4 10 CFR 32.74(a)(2)(viii) and 32.74(a)(3).

5 A label, leaflet, or brochure accompanying the sealed source or device must contain appropriate
6 instructions, from a radiation safety standpoint, for handling and storing the source or device.
7 For example, the instructions may specify the use of extremity monitors, the use of tongs or
8 other devices (rather than bare hands) to pick up sources, storage within auxiliary shielding,
9 and any special procedures needed in the handling and sterilizing of “fragile” sources
10 (e.g., iodine-125 seeds).

11 A label, leaflet, or brochure must also contain the licensing statement required by
12 10 CFR 32.74(a)(3). For sources, the statement should read, “The (name of source or device)
13 is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed
14 pursuant to (10 CFR 35.65, 35.400, 35.500, 35.600 or 35.1000) or under equivalent licenses of
15 Agreement States.”

16 For *each* type of sealed source or device you intend to distribute, you should:

- 17 • Submit copies or facsimiles of the labels that will accompany the product and specify
18 where each label will be placed (e.g., on the device, on the source shield).
- 19 • Submit copies of all leaflets and brochures that will accompany the product. For *each*
20 type of source or device to be distributed, you should provide a copy of correspondence
21 to and from the FDA that clearly shows that the FDA finds the source or device to be
22 safe and effective or “substantially equivalent” to sources or devices offered for sale in
23 the U.S. before May 1976. (Note: An NRC registration will not be issued unless the
24 applicant has submitted to NRC a substantially equivalent letter pursuant to
25 Section 510(K) of the Food, Drug, and Cosmetic Act, as amended, or a similar indication
26 of premarketing approval by the FDA.).

27 Devices and sources used in conjunction with medical applications involving computers and
28 patient planning systems are within FDA jurisdiction and must also have a substantially
29 equivalent letter, pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act, as amended,
30 or a similar indication of premarketing approval by FDA.

31 **Item 10.2.2.2: FDA and NRC Coordination**

32 FDA and NRC signed a Memorandum of Understanding to coordinate existing FDA and NRC
33 regulatory programs for medical devices, drugs, and biological products that make use of
34 byproduct, source, or special nuclear materials. The principal statute under which the FDA
35 regulates devices is the Food, Drug, and Cosmetic Act, as amended by the Safe Medical
36 Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices
37 Act of 1992.

38 Under the Memorandum of Understanding, the Agencies agree to promptly inform each other
39 whenever they receive a report or otherwise become aware of potential public health problems
40 involving products of mutual regulatory concern. Further, the Agencies will share information to

1 the extent practicable. For NRC's Office of Nuclear Materials Safety and Safeguards (NMSS),
2 this includes information on the design, manufacture, testing, quality assurance, and control,
3 etc., used by FDA and NRC for its product approval.

4 **Item 10.2.3: Sealed Sources – Return Program and Device Service**

5 **Item 10.2.3.1: Returns**

6 Some licensees offer a source return program or a device service or both. In this program,
7 customers may return unused sources for credit or may return used sources or devices for
8 disposal, service, or replacement. Similar programs have been offered by manufacturers of
9 other products. As indicated in item 10.1.5.1 licensees may want to provide assistance to
10 customers to remind customers of their responsibilities as shippers.

11 **Item 10.2.3.2: Licensing Criteria**

12 See item 10.1.5.1 for information to be included in instructions that may be provided to
13 the customers.

14 **Item 10.2.4: Calibration or Reference Sources For Medical Use – Compatibility with** 15 **10 CFR 35.65 Licensing Criteria**

16 You must request authorization to distribute calibration or reference sources that are
17 described in 10 CFR 35.65. These calibration or reference sources must not exceed the
18 activity limits of 10 CFR 35.65, and according to 10 CFR 32.74, you must confirm this in your
19 license application.

20 If a source to be distributed contains byproduct material exceeding the activity limits of
21 10 CFR 35.65, source material, or special nuclear materials, it may not be distributed to medical
22 licensees under the provisions of 10 CFR 35.65. In such cases, medical use licensees may
23 purchase such sources only if their licenses specifically authorize possession and use of them.
24 In these cases, you may not use a license issued under 10 CFR 32.74 to distribute the sources;
25 rather, you need a license issued pursuant to 10 CFR Part 30, 40, or 70, as appropriate, that
26 authorizes you to distribute such sources to your proposed customers.

27 **Response from Applicant:**

28 Provide a response as indicated at the end of each relevant item of NUREG–1556, Vol. 13,
29 “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About
30 Commercial Radiopharmacy Licenses.”

31 **Item 11: Waste Management**

32 Enter “Not Applicable.”

33 **Item 12: License Fees**

34 See Section 8.12.

35 **Item 13: Certification**

36 See Section 8.13.

1 **Termination of Activities**

2 See Section 11 of this report.

3 The distribution license does not authorize the possession and use of byproduct material;
4 therefore, termination of your distribution license only requires a letter notifying NRC of the
5 termination. If you are also terminating your possession license, 10 CFR 30.36(b) requires that
6 a licensee notify NRC promptly and request termination of the license. This notification normally
7 requires (i) a completed form NRC-314, "Certificate of Disposition of Materials," certifying that all
8 sources have been disposed of properly and (ii) the results of a final radiation survey of the
9 premises where the licensed activities were carried out.

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APPENDIX T

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**CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY
INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)**

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Checklist for Requests to Withhold Proprietary Information From Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

<input type="checkbox"/>	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
<input type="checkbox"/>	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
<input type="checkbox"/>	An affidavit that:
<input type="checkbox"/>	Is notarized.
<input type="checkbox"/>	Clearly identifies (such as by name or title and date) the document to be withheld.
<input type="checkbox"/>	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
<input type="checkbox"/>	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
<input type="checkbox"/>	Provides a rational basis for holding the information in confidence.
<input type="checkbox"/>	Fully addresses the following issues:
<input type="checkbox"/>	Is the information submitted to, and received by, the NRC in confidence? Provide details.
<input type="checkbox"/>	To the best of the applicant's knowledge, is the information currently available in public sources?
<input type="checkbox"/>	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
<input type="checkbox"/>	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

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4

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC, Add Vol., Supp., Rev.,
and Addendum Numbers, if any.)
NUREG-1556, Volume 12,
Revision 1
DRAFT

2. TITLE AND SUBTITLE

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution - Draft Report for Comment

3. DATE REPORT PUBLISHED

MONTH

YEAR

June

2016

4. FIN OR GRANT NUMBER

5. AUTHOR(S)

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6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)

Same as above

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

This technical report contains information intended to provide program-specific guidance and assistance to applicants and licensees in preparing applications for possession licenses for manufacturing and distribution. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

NUREG-1556
Volume 12
NRC Form 313
Manufacturing
Distribution
License

13. AVAILABILITY STATEMENT

unlimited

14. SECURITY CLASSIFICATION

(This Page)

unclassified

(This Report)

unclassified

15. NUMBER OF PAGES

16. PRICE



Federal Recycling Program



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS



**NUREG-1556, Vol. 12
Revision 1, Draft**

**Consolidated Guidance About Materials Licenses: Program-Specific Guidance
About Possession Licenses for Manufacturing and Distribution**

June 2016