NUREG-1556
Vol. 6

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses

Final Report

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ABSTRACT

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 6, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses," dated January 1999, is the sixth program-specific guidance developed for the new process and is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States. This document updates the guidance found in NMSS Policy and Guidance Directive, FC 84-23, "Standard Review Plan for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage, and Panoramic Wet Source-Storage Irradiators," dated December 27, 1984. This report, where applicable, provides a more risk-informed, performance-based approach to licensing 10 CFR Part 36 irradiators consistent with the current regulations. "This final report should be used in preparing Part 36 Irradiator License Applications. NRC staff will use this final report in reviewing these applications."

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FOREWORD

The NRC is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a list of volumes currently included in the NUREG-1556 series. Additional volumes are planned.

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses	Final Report
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses	Final Report
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope	Draft for Comment
8	Program-Specific Guidance about Licenses for Exempt Distribution	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Draft for Comment
10	Program-Specific Guidance About Master Materials Licenses	Draft for Comment
11	Program-Specific Guidance About Licenses of Broad Scope	Draft for Comment
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses	Draft for Comment

The current document, NUREG-1556, Vol. 6, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiators," dated January 1999, is the sixth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It updates the guidance for applicants and licensees previously found in NMSS Policy and Guidance Directive, FC 84-23, "Standard Review Plan for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage, and Panoramic Wet Source-Storage Irradiators," dated December 27, 1984. In addition, this report also contains pertinent information found in

Technical Assistance Requests and Information Notices. See Appendix A for a list of the documents considered in the preparation of this report. In addition, it reflects consideration of the comments received during the comment period on draft NUREG-1556, Vol. 6. See the Addendum for summaries of comments, staff responses, and other changes.

This report takes, where applicable, a risk-informed, performance-based approach to licensing 10 CFR Part 36 irradiators consistent with the current regulations. A team composed of NRC staff from regional offices and headquarters drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to irradiators. A representative of NRC's Office of the General Counsel provided a legal perspective.

NUREG-1556, Vol. 6, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiators," dated January 1999, represents a step in the transition from the current paper-based process to the new electronic process. This document is available on the Internet at the following address: <http://www.nrc.gov/NRC/NUREGS/SR1556/V6/index.html>.

This report describes and makes available to the public information on: methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations; techniques the staff uses in evaluating applications, including specific problems or postulated accidents; and data the NRC staff needs to review applications for licenses. NUREG-1556, Vol. 6, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiators," dated January 1999, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide a basis for the staff to make the determinations needed to issue or continue a license.

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ABBREVIATIONS

ACI	American Concrete Institute
ALARA	As Low As Is Reasonably Achievable
ANSI	American National Standards Institute
bkg	Background
BPR	Business Process Redesign
Bq	Becquerel
BSR	Bulk Shielding Reactor
C	Celsius
CaF_2	Calcium Fluoride
CFR	Code of Federal Regulations
C/kg	Coulomb per kilogram
cm	Centimeter
Co-60	Cobalt-60
cpm	Counts per minute
Cs-137	Cesium-137
d	Day
DOE	United States Department of Energy
DOT	United States Department of Transportation
F	Fahrenheit
ft	Foot
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	Hour
IN	Information Notice
IP	Inspection Procedure
kg	Kilogram
LiF	Lithium Fluoride
m	Meter
MC	Manual Chapter
min	Minute
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
MOU	Memorandum of Understanding
NaI(Tl)	Sodium Iodide (Thallium-activated)
NCRP	National Council on Radiation Protection and Measurements
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NLTNIF	National Low-Temperature Neutron Irradiation Facility
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer

OCR	Optical Character Reader
OMB	Office of Management and Budget
ORNL	Oak Ridge National Laboratory
OSHA	Occupational Safety and Health Administration
OSP	Office of State Programs
P&GD	Policy and Guidance Directive
RG	Regulatory Guide
RQ	Reportable Quantities
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated from the French Le Systeme Internationale d'Unites)
SSD	Sealed Source and Device
std	Standard
Sv	Sievert
TAR	Technical Assistance Request
TEDE	Total Effective Dose Equivalent
TI	Transportation Index
TLD	Thermoluminescent Dosimeters
URL	Uniform Resource Locator
wk	Week
yr	Year

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a license application for 10 CFR Part 36 irradiators[1] as well as NRC criteria for evaluating a license application. It is not intended to address the research and development or the commercial aspects of manufacturing, distributing, and servicing 10 CFR Part 36 irradiators and their associated sources. Within this document, the phrases or terms, "10 CFR Part 36 irradiators," "irradiators," or "irradiators subject to the requirements of 10 CFR Part 36" are used interchangeably.

This report addresses the variety of radiation safety issues associated with irradiators, of various designs, whose dose rates exceed 5 Gray (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable to the irradiator's design. Table 1.1 describes the characteristics of commonly authorized irradiators. Figures 1.1, 1.2, and 1.3 illustrate several irradiators. Because of differences in design, manufacturers provide appropriate written instructions and recommendations for proper operation and maintenance.

Table 1.1 Categories and Types of 10 CFR Part 36 Irradiators

Irradiator Type	Panoramic	Panoramic dry-source-storage	Panoramic wet-source-storage	Pool	Underwater
Sources stored in pool and removed to irradiate package/product	✔		✔	✔	
Sources stored in pool and package/product lowered into pool to be irradiated				✔	✔
Dry source storage and in-air irradiation of package/product	✔	✔			
Teletherapy unit converted to non-human use	✔	✔			

[1] Self-shielded irradiators are not subject to the requirements of 10 CFR Part 36 and are discussed in NUREG-1556, Vol. 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiators," dated October 1998.

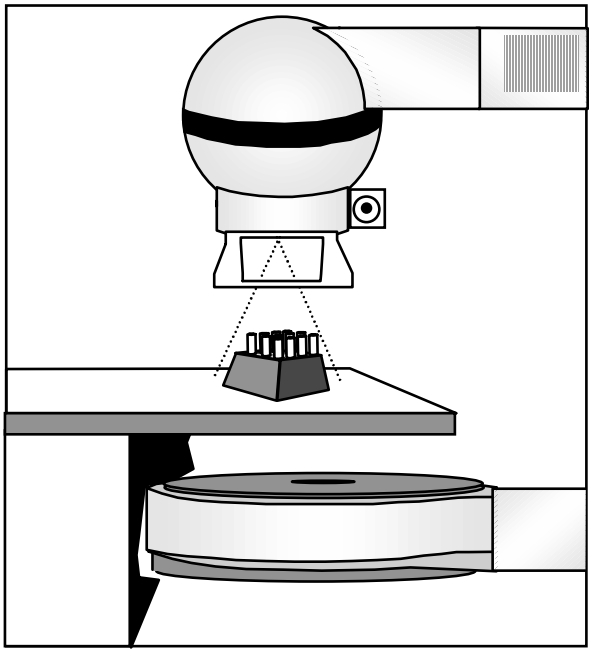

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Figure 1.1 Teletherapy Unit Converted to Non-Human Use. *A teletherapy unit used for research is an example of a panoramic dry source-storage irradiator.*

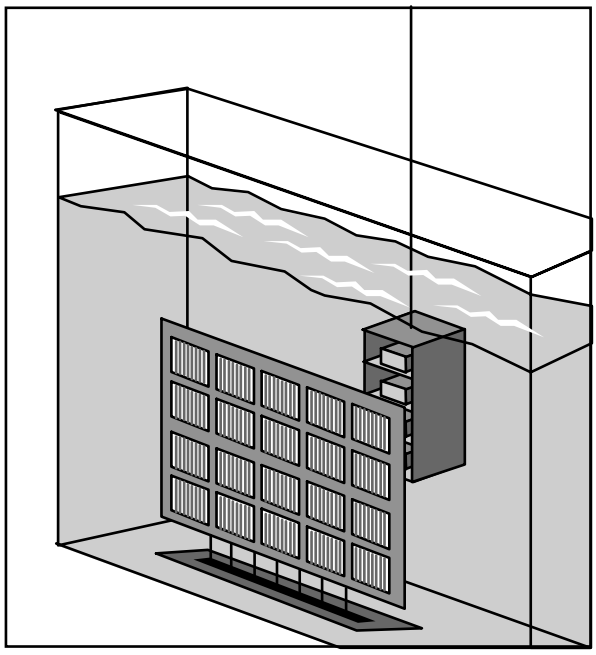

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Figure 1.2 Underwater Irradiator. *The sealed sources remain in the water at all times. The product to be irradiated is placed in a water-tight container and lowered into the water.*

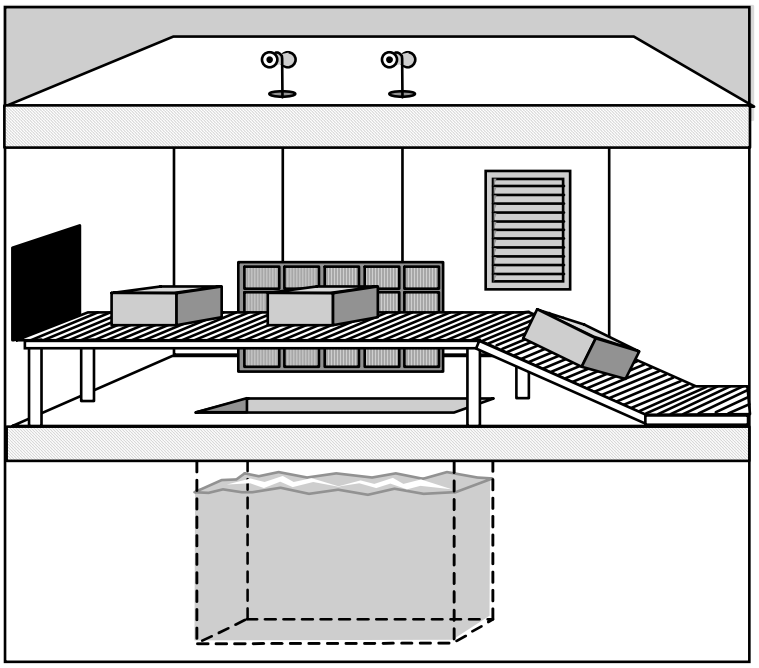

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Figure 1.3 Commercial Wet-Source-Storage Irradiator. *The sealed sources are stored in water and raised into the air to irradiate a product that may be moved into the irradiation room on a conveyor system. This is an example of a panoramic wet-source-storage irradiator.*

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for the use of sealed sources in 10 CFR Part 36 irradiators. The information collection requirements in 10 CFR Parts 30 and 36 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, 3150-0158, and 3150-0120, respectively.

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

- Regulations — references the regulations applicable to the item
- Criteria — outlines the criteria used to judge the adequacy of the applicant's response
- Discussion — provides additional information on the topic sufficient to meet the needs of most readers
- Response from Applicant — provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and References are self-explanatory and may not be necessary for each item on NRC Form 313.

Appendix C provides a format to respond to items 5 through 11 on NRC Form 313, which is shown as Appendix B. Applicants can also use it to check their applications for completeness; NRC staff can use it in reviewing applications. Applicants who use Appendix C to provide supporting information should attach it to NRC Form 313, and submit them to NRC. Otherwise, as indicated on NRC Form 313, the answers to those items 5 through 11 are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. Appendices D through R provide additional information on a variety of topics. Appendix S contains sample licenses for several types of irradiators subject to 10 CFR Part 36. The sample licenses contain the conditions most often found on these licenses, although not all licenses will have all conditions.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. These terms are defined in 10 CFR Part 20. Rem, and its SI equivalent Sievert (1 rem = 0.01 Sievert (Sv)), is used to describe units of radiation exposure or dose. This is because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen, and the sealed sources used in irradiators are designed to emit gamma rays, which means that 1 roentgen = 1 rad = 1 rem.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant other than a Federal agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application; file these applications with State officials, not with the NRC.

In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that licensees ask their local contact for the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, US territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site ***not*** subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

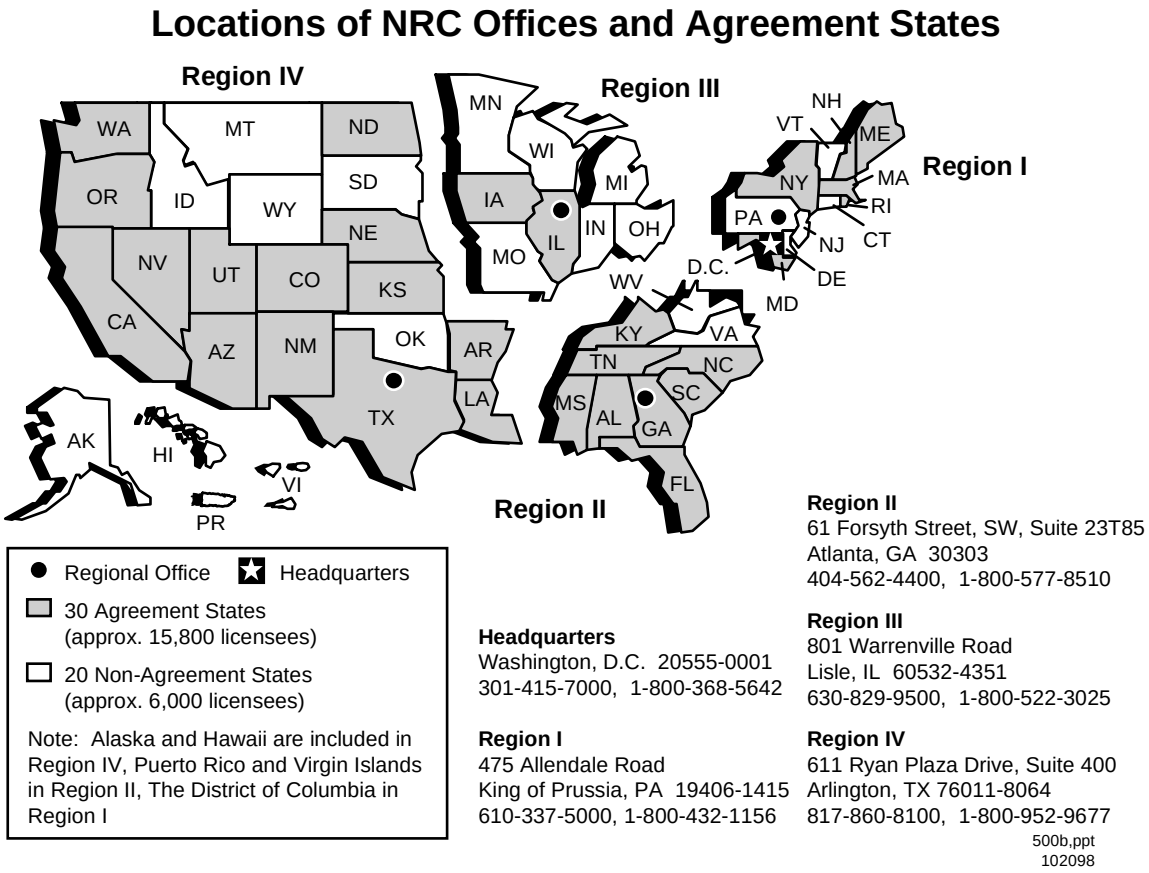

Figure 2.1 U.S. Map. *Location of NRC Offices and Agreement States.*

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices. Or visit the NRC Office of State Programs' (OSP's) Home Page <http://www.hsrd.ornl.gov/nrc> and choose "Directories" and then "State Program Directors."

All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by calling OSP; call NRC's toll free number (800) 368-5642 and then ask for extension 415-3340. Or visit OSP's Home Page <http://www.hsrd.ornl.gov/nrc>, choose "NRC-State Communications," and then choose "Other"; scroll down to find "1996" and then "SP-96-022."

3 MANAGEMENT RESPONSIBILITY

The NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. NRC also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conducting and controlling the 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.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility 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 NRC (10 CFR 30.9)
- Knowledge about the contents of the license and application
- Meticulous compliance with current NRC and DOT regulations and the licensee's operating and emergency procedures
- 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 meticulous compliance with regulations is maintained
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program
- Selection of management representative(s) (e.g., RSO) with authority to stop unsafe operation
- Prohibition against discrimination of employees engaged in protected activities (10 CFR 30.7)
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, respectively.
- Obtaining NRC's prior written consent before transferring control of the license; and
- Notifying appropriate NRC regional administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see current version of NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions,", Manual Chapter 2815, "Construction and Preoperational Inspection of

Panoramic, Wet-Source-Storage Gamma Irradiators," and Inspection Procedure 87100, Appendix F, "Commercial Irradiator Inspection Field Notes"; see Notice of Availability (on the inside front cover of this report). NUREG-1600 is also available on the Internet. Visit NRC's Home Page <http://www.nrc.gov>, choose "Nuclear Materials," then "Enforcement," "Enforcement Guidance Documents," and then "Enforcement Policy."

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to 10 CFR Part 36 irradiators:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 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 32, "Specific Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees or applicants who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the United States Department of Transportation (DOT) that are found in 49 CFR Parts 170 through 189. In addition, the licensee may need to be familiar with Food and Drug Administration (FDA) regulations found in 29 CFR Part 17. Copies of DOT regulations can be ordered from the Government Printing Office (GPO) whose address and telephone number are listed below.

- 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"
- 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC"

To request copies of the above documents, call GPO's order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199 from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact GPO electronically at <http://www.gpo.gov>. Request single copies of the above documents from NRC's Regional

Offices (see Figure 2.1 for addresses and telephone numbers). Note that NRC publishes amendments to its regulations in the Federal Register.

5 HOW TO FILE

5.1 PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself.
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C.
- For each separate sheet, other than Appendix C, that is submitted with the application, identify and key it to the item number on the application or the topic to which it refers.
- Submit all documents on 8-1/2 x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original application and one copy.
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32 (c), applications must be signed **by a duly authorized representative**; see section in this report entitled "Certification."

Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

All license applications will be available for review by the general public in NRC's Public Document Rooms. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, i.e., home address, home telephone number, social security number, date of birth, radiation dose information, should not be submitted unless specifically requested by NRC.

As explained in the Foreword to this document, NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications. However, these will be scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Futura, Univers; the text of this document is in a serif font called Times New Roman.

- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 ELECTRONIC APPLICATION

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or compact disk with read-only memory (CD-ROM), and through the Internet. Additional filing instructions will be provided as these new mechanisms become available. The existing paper process will be used until the electronic process is available.

6 WHERE TO FILE

Applicants wishing to possess or use licensed material in any state or U.S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes and identifies Agreement States.

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

7 LICENSE FEES

Each application for which a fee is specified, including applications for new licenses and license amendments, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the new license prior to fee receipt. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC headquarters in Rockville, Maryland, (301) 415-7554. As an alternative, call NRC's toll free number (800) 368-5642 and then ask for extension 415-7554.

8 CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on NRC Form 313 (Appendix B).

8.1 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
[ ] A. New License	Not Applicable
[ ] B. Amendment to License No.	XX-XXXXX-XX
[ ] C. Renewal of License No.	XX-XXXXX-XX

Check box A for a new license request.

Check box B for an amendment[2] to an existing license, and provide license number.

Check box C for a renewal[2] of an existing license, and provide license number.

8.2 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

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

Notify NRC of changes in mailing address; these changes do not require a fee.

Note: NRC must be notified before control of the license is transferred or bankruptcy proceedings have been initiated; see below for more details. NRC Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

[2] See "Amendments and Renewals to a License" later in this document.

Timely Notification of Transfer of Control

Regulations: 10 CFR 30.34(b).

Criteria: Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license, or, as some licensees call it, "transferring the license."

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

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of licensed material and records; and
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: None from an applicant for a new license; Appendix D, excerpted from IN 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, identifies the information to be provided about transfers of control.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain copies of IN 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, and IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997.

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

Criteria: Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. NRC needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). NRC shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety issues can be resolved before bankruptcy actions are completed.

Response from Applicant: None at time of application for a new license. Generally, licensees should notify NRC within 24 hours of filing a bankruptcy petition.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain copies of Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," (dated August 8, 1996) and Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing."

8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A Post Office Box address is not acceptable; see Figure 8.1.

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local requirements (e.g., local zoning requirements or local ordinances requiring registration of radioactive material).

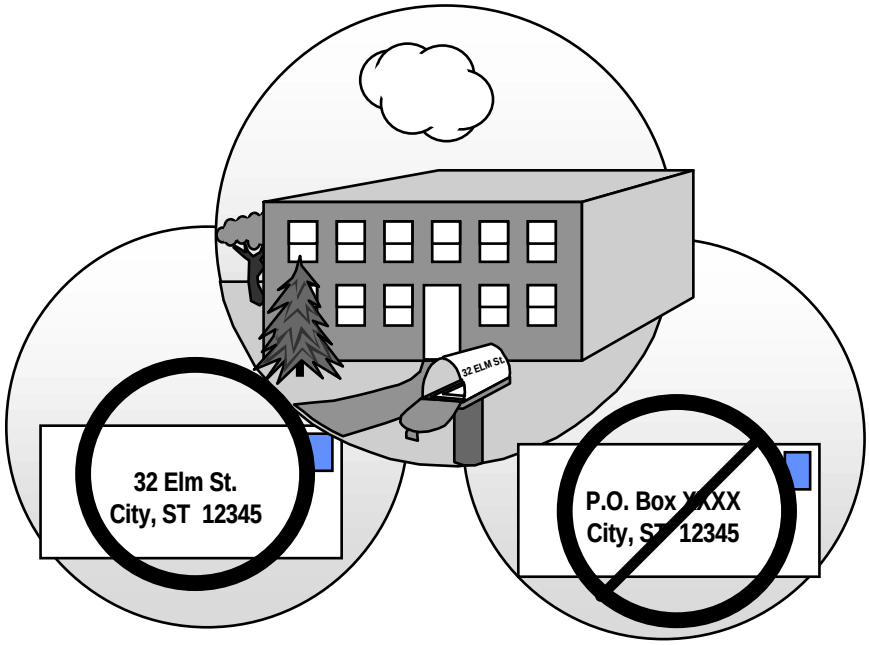

Figure 8.1 Location of Use. *An acceptable location of use specifies street address, city, state, and zip code and does* ***not*** *include a post office box number.*

Note: As discussed later in the section "Financial Assurance and Record Keeping for Decommissioning," licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where licensed material was used or stored and any information relevant to leaking radioactive sources.

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer, unless the applicant has named a different person as the contact. The NRC will contact this individual if there are questions about the application.

Notify NRC if the contact person or his or her telephone number changes so that NRC can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

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

8.5 ITEM 5: RADIOACTIVE MATERIAL

8.5.1 SEALED SOURCES AND DEVICES

Regulation: 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210, 10 CFR 36.21.

Criteria: For each sealed source requested, applicants must identify the sealed source by radionuclide, manufacturer (or distributor), and model number. Applicants will be authorized to possess only those sealed sources specifically approved or registered by NRC or an Agreement State for use in the requested irradiator. Also, identify any depleted uranium that is used as shielding material (teletherapy units and other exposure devices may contain depleted uranium).

Discussion: 10 CFR 36.21 and 10 CFR 32.210 list criteria for sealed sources used in irradiators. Normally, tests used to demonstrate that the criteria can be met are conducted by the source manufacturer (or distributor), not the applicant. The manufacturer (or distributor) then applies to the NRC or an Agreement State agency for approval for use in irradiators. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Therefore, if sealed sources are approved for use in the requested irradiator by NRC or an Agreement State agency, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources in its license application to demonstrate that the requirements are met.

Before the SSD registration process was formalized, some older sealed sources may not have been evaluated in this way, but were specifically approved on a license. Licensees can continue to use sealed sources that are specifically listed on their licenses. If a licensee wishes to install sealed sources that are not currently listed on the license, the new sources must meet the requirements of 10 CFR 36.21.

Licensees may not make any changes to the sealed sources that would alter the description or specifications from those indicated in the respective registration certificates without obtaining NRC's prior permission in a license amendment. A custom registration review may also be required. This would increase the time needed to process a licensing action.

Response from Applicant:

- Identify each radionuclide that will be used in each irradiator.
- Identify the manufacturer (or distributor) and model number of each sealed source.

- Identify the manufacturer (or distributor) and model number of each irradiator, if applicable.
- For dry-source-storage irradiators, specify the maximum activity per source.
- Specify the maximum activity per irradiator.
- If depleted uranium is used as shielding material (e.g., teletherapy units and other exposure devices may contain depleted uranium), specify the total amount (in kilograms).

Note:

- For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.
- SSD reviews are not required for exposure devices in irradiators subject to 10 CFR Part 36. However, for some dry-source-storage panoramic irradiators (e.g., teletherapy units converted to non-human use), a review has been performed at the manufacturer's (or distributor's) request and this information may be useful in evaluating an application. If the irradiator has an exposure device for which a SSD review has been performed, the applicant should state that such a review has been performed and provide the registered name of the manufacturer (or distributor) and model number of the device.

8.5.2 FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.35, 10 CFR 30.34(b).

Criteria: Irradiator licensees authorized to possess sealed sources containing radioactive material in excess of the limits specified in 10 CFR 30.35 must provide evidence of financial assurance for decommissioning.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where licensed materials are used or stored and to leaking sources. Pursuant to 10 CFR 30.35, licensees must transfer these records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b)
- The appropriate NRC regional office before the license is terminated.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most irradiator applicants and licensees need to take

action to comply with the financial assurance requirements because their total inventory of licensed material exceeds the limits in 10 CFR 30.35(d); see Figure 8.2. The limits for typical radionuclides used for irradiator sealed sources are shown in Table 8.1.

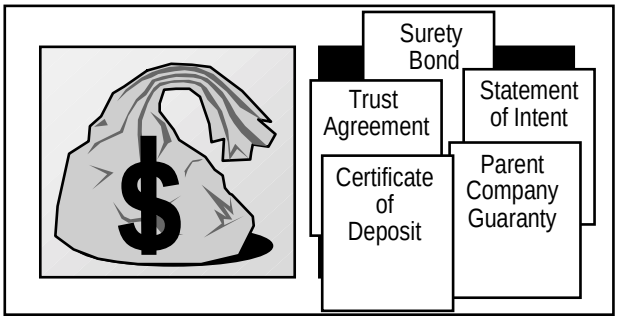

Figure 8.2 Financial Assurance for Decommissioning. *Most 10 CFR Part 36 irradiator licensees need to provide financial assurance for decommissioning and can use one of several approved financial mechanisms.*

Table 8.1 Minimum Inventory Quantity Requiring Financial Assurance

Radionuclide (Sealed Sources)	Activity in Gigabecquerels	Activity in Curies
Co-60	3.7×10^5	10,000
Cs-137	3.7×10^6	100,000

Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each of the mechanisms authorized by the regulation to guarantee or secure funds except for the Statement of Intent for Government Licensees. See Appendix E for the recommended wording for a Statement of Intent.

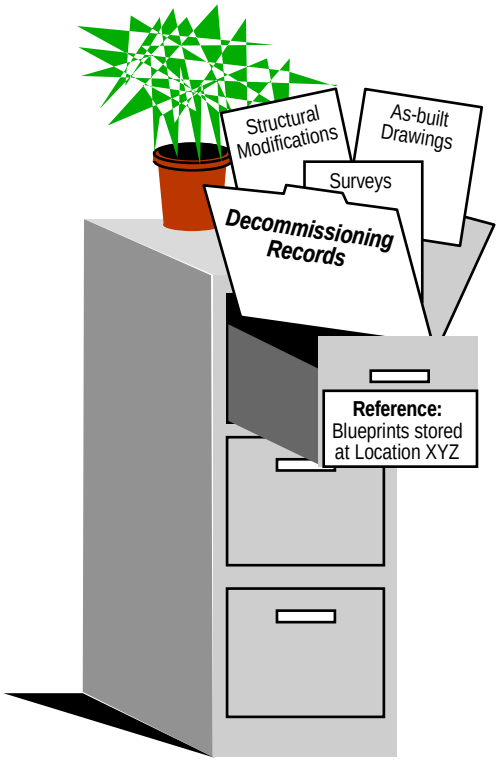

Figure 8.3 Records Important to Decommissioning. *All irradiator licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.*

Figure 8.3 illustrates the 10 CFR 30.35(g) requirements that licensees maintain records important to decommissioning in an identified location (i.e., licensees must know the locations of all documents). All irradiator licensees need to maintain records of structures and equipment for each irradiator. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records (e.g., a sketch of the room or building or a narrative description of the area) concerning the specific areas and locations. In addition, if the applicant experiences unusual occurrences (e.g., leaking sources), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For irradiator licensees whose sources have never leaked, sketches or written descriptions that include the location of each irradiator are considered acceptable records important to decommissioning.

Response from Applicants: A response is needed from most applicants. If financial assurance is required, submit documentation required by 10 CFR 30.35. Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under

10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains approved wording for each of the mechanisms authorized by the regulation to guarantee or secure funds except for the Statement of Intent for Government licensees. See Appendix E for the recommended wording for a Statement of Intent.

10 CFR 30.35(g), Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer to the new licensee

OR

- Before the license is terminated, transfer records to the appropriate NRC regional office.

Reference: See Notice of Availability (on the inside front cover of this report) to obtain copies of Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, and Policy and Guidance Directive FC 90-2, Revision 1, "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

8.6 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulation: 10 CFR 30.33(a)(1), 10 CFR 36.69.

Criteria: The proposed purpose is authorized by the Atomic Energy Act of 1954, as amended. Sealed sources that are used in irradiators should be used only for the purposes for which they were designed, according to the manufacturer's written recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on an NRC or Agreement State license.

Discussion: Requests to use sealed sources in irradiators for purposes not listed in the SSD Registration Certificate will be reviewed on a case-by-case basis. Examples might include greater than small quantities of flammable materials with a flash point below 60°C (140°F), irradiation of explosive material, or cryogenic material[3].

[3] Under certain conditions particular irradiated cryogenic material can explode.

If an applicant wants to irradiate greater than small quantities of flammable materials with a flash point below 60°C (140°F), see Appendix F. In addition, irradiation of explosives is generally prohibited; however, if an applicant wants to request irradiation of explosives, see Appendix F.

Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. NRC will evaluate the radiation safety program for each type and use of sealed sources in each irradiator requested.

Irradiation of food and certain other products intended for commercial distribution to the public are also subject to the regulations of the Food and Drug Administration (FDA) and U. S. Department of Agriculture (USDA). Contact these agencies for further information. An NRC licensee must also comply with applicable FDA or USDA regulations.

Response from Applicant: Provide either of the following:

- A specific description of use for each type of irradiator requested, e.g., "for use in irradiation of products or food. There will be no irradiation of explosives and no irradiation of more than small quantities of flammable materials with a flash point below 60°C (140°F) without specific written authorization from NRC."

OR

- If the irradiator will be used for purposes other than irradiation of food or products for human consumption or research purposes, description of these purposes and safety analyses (and procedures, if needed) to support safe use.

Note:

- Allowed uses of irradiators normally include the irradiation of food or products for human consumption or research purposes.
- Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

8.7 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM

8.7.1 RADIATION SAFETY OFFICER (RSO) TRAINING AND EXPERIENCE

Regulations: 10 CFR 30.33(a)(3), 10 CFR 36.13(d).

Criteria: A Radiation Safety Officer (RSO) must have adequate training and experience. Successful completion of training as described in Appendix G is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the RSO. The application must include the name and a description of the training and experience of the proposed RSO. This is to determine whether the individual is qualified to function as the RSO.

Consistent with the NRC staff's long-standing guidance, if the RSO has had neither previous formal training in health physics nor certification by the American Board of Health Physics, the RSO should complete a radiation safety course. Training should include approximately 40 hours covering the following topics:

- Radioactivity and radioactive decay
- Interactions of radiation with matter
- Biological effects of radiation
- Radiation detection using radiation detection instruments and personnel dosimeters
- Basic radiation protection principles and good safety practices (including time, distance, and shielding)
- Radiation protection regulations.

The course should include a written test or evaluation of the individual's comprehension of these topics.

In addition to the above general course, if the RSO was previously an RSO at a similar licensee or was trained as an irradiator operator but has not had experience working at an irradiator, he or she should have the equivalent of at least 40 hours in self-study or directed study on information directly applicable to radiation safety at irradiators. This should include applicable regulations (10 CFR Parts 20 and 36) and reports or studies describing case histories of accidents or problems at irradiators; see Appendix G. The license application should list the documents studied or to be studied in the description of the training of the proposed RSO and should

describe how the applicant will evaluate the individual's comprehension of the information studied.

The RSO should have at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

However, to allow flexibility, the NRC will determine the adequacy of the RSO's training and experience on a case-by-case basis, looking at his or her actual qualifications and drawing on the NRC staff's experience in reviewing such qualifications.

Response from Applicant: Provide the following:

- Name of the proposed RSO
- Describe the proposed RSO's training and experience specific to the irradiator that the applicant intends to use.

Note: It is important to notify NRC, as soon as possible, of changes in the designation of the RSO. If the replacement is sudden, the licensee should contact the NRC Regional Office as soon as possible. While the amendment request is being reviewed by NRC, the proposed RSO may assume the responsibilities of RSO if NRC is given adequate information to ensure that the proposed individual will meet the required training.

8.7.2 RADIATION SAFETY OFFICER (RSO) RESPONSIBILITIES AND AUTHORITIES

Regulations: 10 CFR 30.33(a)(3), 10 CFR 36.13(d).

Criteria: RSOs must be in a position within the licensee's organization to have adequate authority over radiation safety activities and responsibility for regulatory compliance and protection of public health and safety.

Discussion: Consistent with the staff's long-standing guidance, the RSO should have independent authority to stop operations that he or she considers unsafe and to conduct necessary tests or measurements. The RSO should be relatively independent of production responsibilities, to the extent practicable, considering the size of the staff at the facility. The RSO should report directly to the facility manager. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that licensed materials are used in a safe manner. Typical RSO duties are illustrated in Figure 8.4 and described in Appendix H. NRC requires the name of the RSO on the license to ensure that licensee management has always

identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

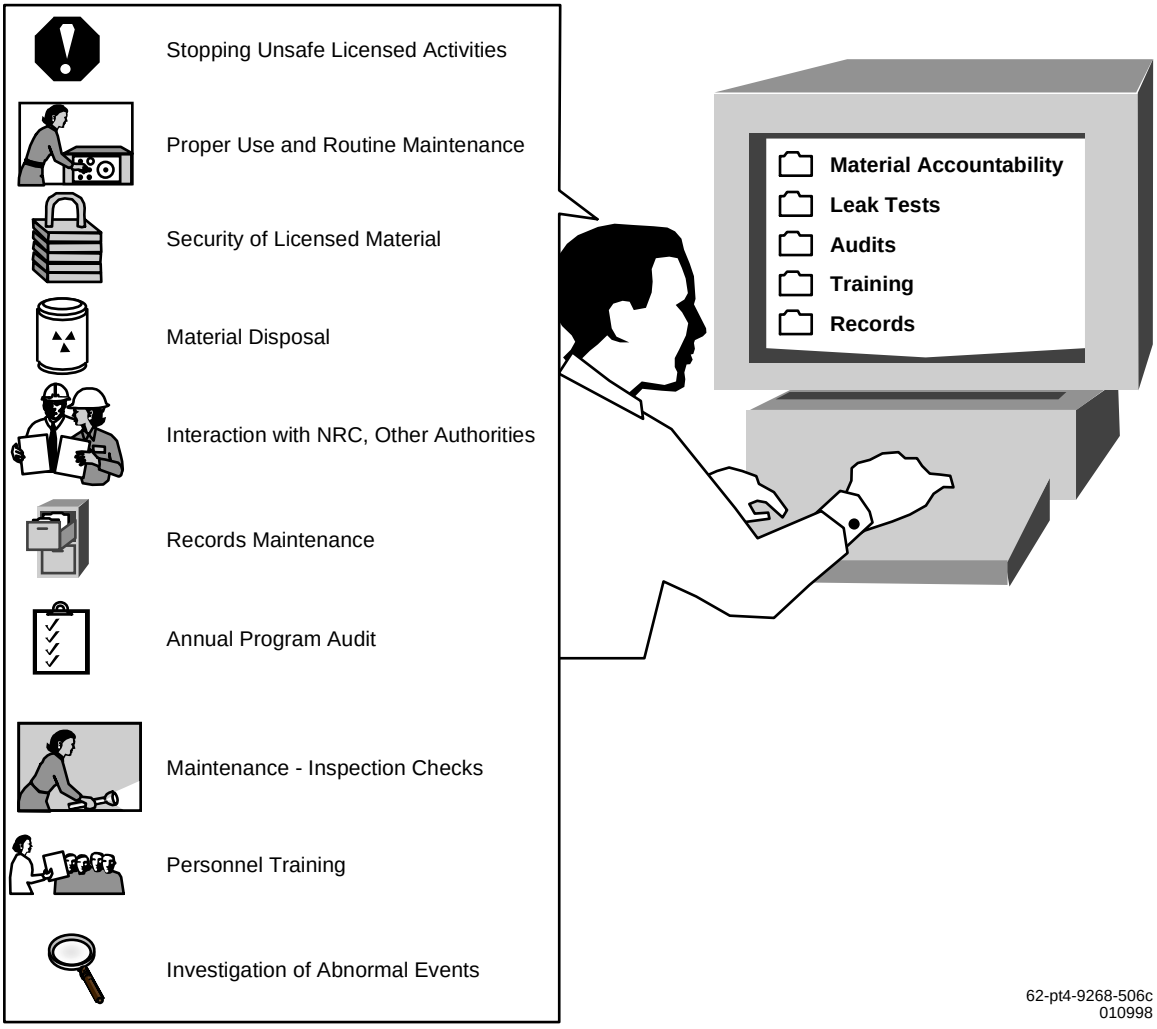

Figure 8.4 RSO Responsibilities. Typical duties and responsibilities of RSOs.

Response from Applicant: Describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the RSO and other management personnel who have important radiation safety responsibilities and authorities. In particular, the application should describe who has the authority to stop unsafe operations.

8.8 ITEM 8: INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

8.8.1 INITIAL TRAINING AND EXPERIENCE FOR IRRADIATOR OPERATORS

Regulations: 10 CFR 19.12, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33, 10 CFR 36.13(b), 10 CFR 36.23(b),10 CFR 36.51(a), 10 CFR 36.51(b), 10 CFR 36.51(c).

Criteria: Irradiator operators must have adequate training and experience. Successful completion of one of the following is evidence of adequate training and experience:

- Irradiator manufacturer's course for operators specific to the irradiator that the applicant intends to use

OR

- Training course as described in Appendix G.

The training provided to individuals to qualify them to be irradiator operators must include:

- Instruction
- On-the-job or simulator training (i.e., supervised experience)
- Means employed by the applicant to test each individual's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures
- Minimum training and experience of personnel who may provide training.

In addition, instruction must be provided to at least one other individual who will be on site during operations on how to respond to the independent backup access control alarm and to promptly render or summon assistance.

Applicants requesting to perform non-routine operations such as loading and unloading sources must provide additional training. For more information see Appendix I.

Discussion: Irradiator operators have the responsibility to ensure the proper use and security of irradiators containing licensed material. Irradiator operators must receive training and instruction, and be tested before being permitted to operate an irradiator.

Training should be commensurate with the complexity of the irradiator design and potential radiation hazard (e.g., approximately 40 hours of instruction for pool-type panoramic irradiators and approximately 20 to 30 hours of instruction for underwater irradiators). Up to 50% of that

instruction may be self-study or reading. The written test should cover the range of topics addressed in the instruction.

On-the-job training should be supervised by an experienced operator and should last at least 1 month full-time. If an approved operator does not operate the irradiator for more than a year, his or her performance during operation should:

- Be audited for at least 1 day before he or she is permitted to operate the irradiator independently; and
- Receive a safety review regarding the irradiator.

The requirements in 10 CFR 36.51(a), (b), and (c) are for an individual to become qualified initially as an irradiator operator. They do not apply to individuals qualified to be operators before July 1, 1993, the effective date of 10 CFR Part 36. The safety reviews and evaluation requirements of 10 CFR 36.51(d) and (e), however, apply to all irradiator operators. Current licensees should conduct safety reviews to discuss the new 10 CFR Part 36 regulations and any resulting changes in operating and emergency procedures. Licensees should also conduct safety reviews at intervals not to exceed 12 months thereafter.

Individuals must be trained in the following subjects to become an irradiator operator:

- The fundamentals of radiation safety as they apply to irradiators
  - — The goal is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.

- The requirements of 10 CFR Parts 19 and 36
  - — The operator is not expected to be an expert on NRC regulations or to be able to determine whether a given procedure is adequate to meet NRC regulations. Instead, operators should be instructed on NRC requirements that are directly applicable to their responsibilities.

- The operation of the licensee's irradiator
  - — The objective is to help the person understand the operating and emergency procedures, not to become an engineer.

- Licensee operating and emergency procedures that the individual will be required to perform
  - — This is the most important part of the training because operating the irradiator safely depends on following these procedures correctly. The objective is that the operator

correctly perform his or her assigned tasks. The training does not have to include procedures that the individual will not perform.

- Case histories of accidents and problems involving irradiators
  - — The individual should be taught about situations that could lead to problems associated with irradiator operations. Instruction material on accidents is often difficult to obtain. However, NUREG-1345, "Review of Events at Large Pool-Type Irradiators," provides some relevant information. See also Appendix A for a list of Information Notices (IN) describing irradiator events.

Additional training is required for irradiator operators if they will perform non-routine operations. For more information see Appendix I.

Response from Applicant: Provide either of the following:

- The statement: "Before using licensed materials, irradiator operators will have successfully completed one of the training courses described in Criteria in the section entitled 'Initial Training and Experience for Irradiator Operators' in NUREG-1556, Vol. 6, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses,' dated January 1999.";

OR

- A description of the initial training program for irradiator operators that demonstrates compliance with the requirements of 10 CFR 36.51(a), (b), and (c).

Note: Alternative responses will be evaluated using the criteria listed above.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain copies of NUREG-1345, "Review of Events at Large Pool-Type Irradiators," dated March 1989 or other documents listed in Appendix A.

8.8.2 ANNUAL SAFETY REVIEWS AND PERFORMANCE EVALUATIONS FOR IRRADIATOR OPERATORS

Regulations: 10 CFR 19.12, 10 CFR 30.33, 10 CFR 36.51(d), 10 CFR 36.51(e).

Criteria: Licensees must conduct safety reviews for irradiator operators annually. Licensees must also evaluate the safety performance of each irradiator operator annually.

Discussion: Licensees must provide refresher training called a safety review to irradiator operators as well as evaluate the safety aspects of each irradiator operator's performance (i.e., performance evaluation).

Annual Safety Reviews

Safety reviews must include, as appropriate, each of the following areas:

- Changes in operating and emergency procedures since the last review
- Changes in regulations and license conditions since the last review
- Reports on recent accidents, mistakes, or problems that have occurred at irradiator facilities
- Relevant results of inspections[4] of operator safety performance
- Relevant results of the facility's inspection and maintenance checks
- A drill to practice an emergency or abnormal event procedure.

Also, each operator must be given a brief written test on the information covered during the safety review (See 10 CFR 36.51(d)).

The duration of safety reviews should be commensurate with the complexity of the irradiator's design and potential radiation hazard (e.g., approximately 4 hours for panoramic wet-source-storage irradiators and 2 hours for dry-source-storage and underwater irradiators). Safety reviews may be conducted at intervals not to exceed 12 months or throughout the calendar year on an as-necessary basis.

The "drill" referenced in 10 CFR 36.51(d)(6) means actually going through a procedure using the actual equipment in as realistic a manner as practical. For example, for a drill on the response to a fire alarm it is not necessary that the alarm actually be enunciated if sounding the alarm would be disruptive. Operators may also correct errors as they occur rather than waiting until the drill is over. Each operator need not go through the drill, but may watch or critique as another operator does.

Annual Performance Evaluations

The safety performance of each irradiator operator must be evaluated and reviewed at least every twelve months to ensure that regulations, license conditions, and operating and emergency procedures are followed. In addition, the results of the evaluation must be discussed with each operator along with instructions on how to correct any mistakes or deficiencies observed.

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[4] The word "inspections" in 10 CFR 36.51(d)(4) means the "evaluations" performed under 10 CFR 36.51(e).

Individuals, e.g., the RSO or senior operators, conducting these reviews must have adequate training and experience to conduct such evaluations.

Response from Applicant: Describe program for annual safety reviews and performance evaluations of irradiator operators that demonstrates compliance with 10 CFR 36.51(d) and (e).

8.8.3 TRAINING FOR INDIVIDUALS WHO REQUIRE UNESCORTED ACCESS

Regulations: 10 CFR 19.12, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33, 10 CFR 36.51(f).

Criteria: Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for irradiator operators and the RSO, must be instructed and tested in precautions to avoid radiation exposure, procedures listed in 10 CFR 36.53 that they must perform or comply with, and their proper response to alarms.

Discussion: According to 10 CFR 19.12, all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) must receive appropriate instruction on radiation safety. However, in some facilities certain individuals other than irradiator operators may require unescorted access to the radiation room of an irradiator. The applicant should identify those individuals (e.g., individuals who perform inspection and maintenance checks) and train them according to 10 CFR 36.51(f).

Training may include the subjects described in Appendix G. Individuals should be tested on procedures which require unescorted access to conduct. Tests may be given orally. Applicants must develop and implement a program for instructing and testing individuals requiring unescorted access.

Response from Applicant: The applicant's program for instructing and testing unescorted individuals (other than irradiator operators) will be examined during inspections, but should not be submitted in the license application.

8.9 ITEM 9: FACILITIES AND EQUIPMENT

8.9.1 GENERAL DESCRIPTION OF THE FACILITY AND SITE

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.13(e), 10 CFR 36.39(j).

Criteria: Facilities and equipment must be adequate to protect public health and safety and to minimize danger to life or property. The application must include a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

Discussion: A diagram of the facility must be submitted for review with enough detail designating the location of required interlocks and radiation monitors to be used at the facility (e.g., blueprints with interlock and radiation monitor locations identified). See Figure 8.5. In addition, the diagram should include a general layout of the entire facility identifying areas surrounding the irradiator room.

An applicant should provide a schedule for construction activities associated with the irradiator. This will allow the NRC to inspect and ensure construction activities are according to design requirements as described in NRC Manual Chapter 2815 titled "Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators."

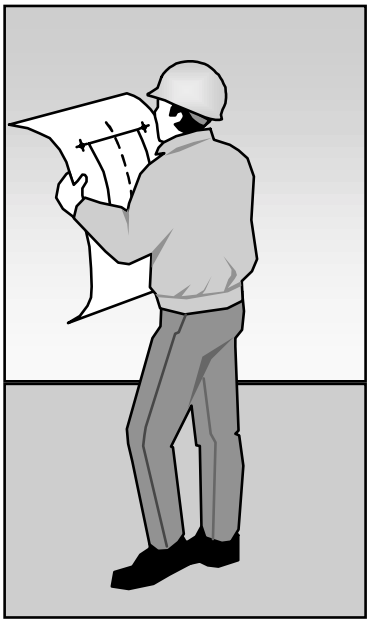

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Figure 8.5 General Description of Facility. *Diagrams, drawings, sketches, or blueprints of facilities are needed for a clear understanding of the facility's design and its relationship to adjacent properties.*

Response from Applicant:

- Describe the irradiator including drawings, diagrams, sketches, and photographs, as appropriate.
- Show locations of safety-related equipment and features as required in 10 CFR Part 36.
- Provide a construction schedule for the irradiator.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain a copy of NRC Manual Chapter 2815 titled "Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators." This standard is also available for purchase from the American Concrete Institute (ACI), P. O. Box 9094, Farmington Hills, Michigan 48333. ACI's telephone number is (248) 848-3700 and its URL is <http://www.aci-int.org>.

8.9.2 ACCESS CONTROL

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.13(e), 10 CFR 36.23, 10 CFR 36.31(a), 10 CFR 36.39(g), 10 CFR 36.41(g).

Criteria: Irradiator facilities must have access controls to prevent inadvertent entry into the radiation room, as required by 10 CFR 36.23.

Discussion: This section discusses two categories of irradiators:

- panoramic irradiators (dry-source-storage, wet-source storage)
- underwater irradiators.

Panoramic Irradiators

The door or barrier that serves as the primary access control system must have devices that will: 1) prevent the source from being moved out of its shielded position if the door or barrier were open; and 2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier

must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

The backup access control system must be able to detect entry while the source is exposed. If entry is detected, the system must: 1) automatically cause the source to return to its shielded position; and 2) activate audible and visible alarms.

Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to alert any individual entering the room to the hazard. The alarm must also alert at least one other individual who is onsite and prepared to render or summon assistance promptly.

A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted entry while the monitor measures high radiation levels must activate the alarm described in 10 CFR 36.23(b). The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam (e.g., an area of the maze that may expose the instrument directly to the irradiator sources when in the unshielded position).

The requirement in 10 CFR 36.23 for a door or other physical barrier applies to each entrance of the radiation room, whether intended for personnel or product entrance or exit. A conveyor system could meet the requirement by providing a clearance large enough for a package, but too small for a person by using barriers that would require unusual exertion to bypass. A photoelectric system cannot be considered a physical barrier. The purpose of this requirement is to prevent someone from carelessly or accidentally entering the radiation room while the sources are exposed.

This section also requires an independent backup access control system to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operating procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The backup system could use photoelectric cells in an entrance maze, pressure mats on the floor, or similar means of detection. The system must also alert another trained person who is onsite and prepared to render or summon assistance.

The mechanism that moves the sources must require a key to actuate it. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any one time, and only irradiator operators or facility management may have access to it. The key must be attached to a calibrated portable radiation survey meter by a chain or cable. In addition, the lock for source control movement must be designed so that the key may not be removed if the sources are in an unshielded position. Also, the door to the radiation room must require the same key to open it. This redundant feature will

ensure that the sources are in the shielded position prior to an individual entering the radiation room. It will also ensure that any individual entering the radiation room will have in his or her possession a calibrated portable radiation survey instrument for monitoring radiation levels in the radiation room in the event the sources were not in the shielded position.

Irradiators can produce ozone in concentrations exceeding those permitted by regulations of the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1000, "Air Contaminants." Nitrogen oxides can also be produced, although concentrations would not be expected to exceed OSHA's limits. To control these gases, irradiators with large sources are typically equipped with ventilation systems to exhaust the gases before personnel entry.

OSHA regulates exposure to ozone and other noxious gases in the workplace, and the U.S. Environmental Protection Agency regulates emissions offsite. If NRC personnel observe problems with noxious gases at an irradiator during an inspection, NRC will notify OSHA of the problem under the terms of the "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities," signed October 21, 1988.

The radiation room must be equipped with a device integrated with the control system ensuring that the sources cannot be exposed unless the access door and other interlocks are engaged within a preset time of activating the control. The irradiator must be equipped with a safety timer that will automatically generate visible and audible warnings to alert personnel in the radiation room that the startup sequence has begun and provide sufficient time to leave the area or operate a clearly identified emergency stop device which will abort the startup sequence. The safety timer must be integrated with the control system so that the source cannot be exposed unless the startup sequence is complete within the preset time and the control console indicates that it is safe to expose the source.

For panoramic irradiators whose construction begins after July 1, 1993, the licensee must verify from the design and logic diagram that the access control system will meet the requirements of 10 CFR 36.23. Before loading sources, the licensee must test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly. For more information see Appendix J, "Construction Monitoring and Acceptance Testing."

Underwater Irradiators

The pool must be within an area surrounded by a personnel access barrier with an intrusion alarm when the facility is not operating. Only operators and facility management may have access to keys to the personnel access barrier. The intrusion alarm must be able to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an

individual (not necessarily onsite) who is prepared to respond or summon assistance when the alarm is activated.

Response from Applicant:

- Submit specific information describing the access control system and how it works that demonstrates compliance with the requirements of 10 CFR 36.23. Specific drawings or sketches should be submitted, as appropriate.
- For panoramic irradiators, describe the facility alarm systems.
- For panoramic irradiators, describe the lock and key system for controlling source movement and discuss how it meets the requirements of 10 CFR 36.31(a).

References: See the Notice of Availability (on the inside front cover of this report) to obtain a copy of the "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities," signed October 21, 1988.

8.9.3 SHIELDING

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.25, 10 CFR 36.39(a), 10 CFR 36.41(a).

Criteria: Irradiator shielding must meet the requirements as described in 10 CFR 36.25 and the requirements of local building codes or other appropriate sources.

Discussion: The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (mSv) (2 millirems (mrem)) per hour at any location 30 centimeters (cm) or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. The maximum dose rate of 0.02 mSv (2 mrem) per hour is considered practical to achieve. Areas where the radiation dose rate exceeds 0.02 mSv (2 mrem) per hour must be locked, roped off, or posted. These may include areas not normally occupied such as the equipment access area on the roof of the irradiator.

The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not exceed 0.02 mSv (2 mrem) per hour when the sources are in the fully shielded position.

The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 mSv (2 mrem) per hour and at 30 cm from the shield may not exceed 0.2 mSv (20 mrems) per hour.

For panoramic irradiators whose construction starts after July 1, 1993:

- If not built in seismic areas, it is acceptable that shielding meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 10 CFR 36.25.
- If built in seismic areas, the applicant must design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.
- ANSI Standard 43.10 (last issued 1984) paragraph 8.25 discusses geologic and seismic site considerations which should be evaluated prior to building a panoramic irradiator.
- The licensee must monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete. See Appendix J, "Construction Monitoring and Acceptance Testing."
- If the irradiator will use more than 2 X 10^{17} becquerels (Bq) (5 million curies) of activity, the applicant must evaluate the effects of heating of the shielding walls by the irradiator sources (e.g., thermal effects on concrete).

Response from Applicant:

- **For panoramic irradiators:**
  - — Describe the shielding to be used and its composition
  - — Submit a diagram showing the configuration of shielding including walls and the ceiling and indicate the thickness of each and penetrations in the shielding
  - — If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 mSv (2 mrem) per hour, identify the areas and explain how access will be controlled
  - — For requests to possess more than 2 x 10^{17} Bq (5,000,000 curies), submit an evaluation of the effects of heating of the shielding walls by the irradiator sources

For underwater irradiators, no response is required from the applicant in a license application.

Note:

- The NRC does not approve irradiator shield designs. Instead, NRC conducts inspections to ensure that the maximum dose rate outside the completed shield is according to NRC requirements.

- For panoramic irradiators whose construction will start after July 1, 1993, the applicant should identify building code requirements to which shielding walls will be built and inspections of the construction that will be performed by local authorities so that the license reviewer can ensure that they do not adversely impact the NRC requirements.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain a copy of the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete." This standard is also available for purchase from the American Concrete Institute (ACI), P.O. Box 9094, Farmington Hills, Michigan 48333. ACI's telephone number is (248) 848-3700 and its URL is <http://www.aci-int.org>.

8.9.4 FIRE PROTECTION

Regulations: 10 CFR 36.27, 10 CFR 36.39(h), 10 CFR 36.41(h).

Criteria: Panoramic irradiators must have smoke and heat detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded to meet the requirements as described in 10 CFR 36.27 and 36.39(h).

Discussion: The radiation room must have heat and smoke detectors that activate an audible alarm capable of alerting a person who can summon assistance promptly. The sources must become fully shielded automatically if a fire is detected.

The radiation room must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

The fire extinguishing system is required because a fire could disable the access control system or could prevent the sources from being shielded, thereby lowering the margin of safety. The fire extinguishing system must be operable without entry into the room. During a fire, there would be no means of assuring that the access control systems and source position indicators or the mechanism that returns the source to the shielded position had operated properly.

For panoramic irradiators whose construction starts after July 1, 1993:

- The applicant must verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The applicant must verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and low characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.
- The licensee must test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. In addition, the licensee must test the operability of the fire extinguishing system. It is not required that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems. For more information see "Radiation Safety Program - Inspection and Maintenance Checks" and Appendix J, "Construction Monitoring and Acceptance Testing."

Response from Applicant:

- For panoramic irradiators, describe:
  - — the type and location of the heat and smoke detectors to be used to detect a fire in the radiation room
  - — the alarms to alert personnel trained to summon assistance
  - — how the sources will automatically become fully shielded if a fire is detected
  - — how the heat and smoke detectors will be tested.

- **For underwater irradiators,** no response is required, since the sources are always underwater and not subject to damage by fire.

8.9.5 RADIATION MONITORS

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.13(e), 10 CFR 36.23(c), 10 CFR 36.29, 10 CFR 36.39(e), 10 CFR 36.41(e), 10 CFR 36.59(b).

Criteria: Irradiator facilities must have radiation monitors to detect radiation levels and sources as described in 10 CFR Part 36.

Discussion: This section will only discuss the evaluation of the location of radiation monitors. For information regarding the calibration, sensitivity, and testing of monitors, see "Radiation Safety Program - Instruments."

For irradiators with automatic product conveyor systems:

The irradiator must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting a trained individual in the facility who is prepared to summon assistance.

For panoramic irradiators:

A monitor must be provided to detect the radiation level in the radiation room when the source is indicated to be in the fully shielded position. The monitor must be integrated with the personnel access door interlocks, as applicable, to prevent room access when the monitor detects an elevated radiation level for which the alarm set point is as low as practical but high enough to avoid false alarms. Room access must also be prevented if the monitor malfunctions or is turned off.

For underwater irradiators that are not in a shielded radiation room:

There must be a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly (e.g., prevent movement of irradiated product out of pool in the event water is contaminated).

For all irradiators whose construction begins after July 1, 1993:

- The licensee must ensure that the location and sensitivity of the monitor used to detect sources carried by the product conveyor system are appropriate
- The licensee must verify that the product conveyor is designed to stop before a source on it could cause a radiation overexposure to any person

For pool irradiators whose construction begins after July 1, 1993:

- If the licensee uses radiation monitors to detect contamination under 10 CFR 36.59(b), the licensee must verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

For all irradiators whose construction begins after July 1, 1993, the licensee must verify the operability of radiation monitors and related alarms and interlocks prior to loading sources. For more information see Appendix J, “Construction Monitoring and Acceptance Testing.”

Response from Applicant:

- Describe the location and type of radiation monitors that will be used to meet the requirements of 10 CFR 36.23(c), 36.29, and 36.59(b).
- Describe the location and types of alarms and those individuals who are trained to respond to those alarms. Diagrams and sketches should be used, as appropriate.
- Discuss the alarm set-points or the methods for establishing the alarm set-points.
- For irradiators whose construction begins after July 1, 1993, describe the evaluation performed to meet 10 CFR 36.39(e) on detector location and sensitivity and the acceptance testing that will be performed to meet 10 CFR 36.41(e).

Note: Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of 10 CFR 36.29.

8.9.6 IRRADIATOR POOLS

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.23(i), 10 CFR 36.33, 10 CFR 36.39(c), 10 CFR 36.39(d), 10 CFR 36.41(c), 10 CFR 36.41(d).

Criteria: Irradiator facilities with pools must be designed and equipped as described in 10 CFR Part 36.

Discussion: For facilities initially licensed after July 1, 1993, NRC requires

EITHER

A water-tight stainless steel liner (or a liner metallurgically compatible with other components in the pool)

OR

Construction preventing substantial leakage and a pool surface designed to facilitate decontamination.

The purpose of the requirement is to reduce the likelihood of the pool leaking water that may be contaminated or used for shielding purposes.

In either case, the licensee must have a method to store the sources safely during repairs of the irradiator pool.

For all licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have breakers to prevent siphoning. Irradiator pools must have a means to replenish water that is lost. The means to replenish the water does not have to be automatic. Irradiator pools must also have a clearly visible indicator to show if the pool water level is above or below the normal low water level.

For all pool irradiators:

- A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations. Also, this ensures compatibility with OSHA requirements and ANSI standards.
- Irradiator pools must be equipped with a purification system capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with enough clarity to allow for inspection of the source and source rack for damage and proper position. The water purification system is needed to minimize the probability of corrosion of the sealed sources and the source rack.
- The 0.02 mSv (2 mrem) per hour limit on the dose rates for poles and long-handled tools to be used in irradiator pools is imposed to prevent radiation streaming. Hollow and low-density poles and tools can have either vent holes to allow shielding water to enter or sufficient bends to prevent radiation levels at handling areas of the tools from exceeding 0.02 mSv (2 mrem) per hour.

For panoramic irradiators whose construction began after July 1, 1993, the licensee must verify that the pool design ensures its integrity as required by 10 CFR 36.39(c) and that the design of the water purification system is adequate. The licensee must also conduct inspections and tests of the pool and water handling systems to meet the requirements of 10 CFR 36.41(c) and (d). See Appendix J, “Construction Monitoring and Acceptance Testing.”

Response from Applicant: Provide the following:

- **For all pool irradiators, describe:**
  - — The high and low water-level indicators and their locations
  - — The purification system for the pool with an explanation of why it is capable of maintaining pool water conductivity less than 20 microsiemens per centimeter
  - — The means to replenish pool water
  - — The barrier used during normal operation to prevent personnel from falling into the pool

— How high radiation doses from radiation streaming will be avoided when using long-handled tools or poles (use sketches if appropriate).

— If the pool has outlets more than 0.5 meter below the surface that could allow water to drain out of the pool, the means of preventing inadvertent excessive loss of pool water (in this context outlets do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools).

- **For irradiators licensed after July 1, 1993, describe:**

— The pool liner. If no water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool is used, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished if necessary.

8.9.7 SOURCE RACK

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.35, 10 CFR 36.39(f), 10 CFR 36.41(f).

Criteria: Systems must be in place to protect the source rack.

Discussion: An important element in a radiation safety program is providing systems to protect the source rack and the mechanism that raises and lowers the sources.

For all irradiators, if the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

For irradiators whose construction begins after July 1, 1993:

- For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source rack that would promote corrosion on a critical area of the source (e.g., crevice corrosion, an inaccessible location in or around the sources or rack with low oxygen concentrations).
- For panoramic irradiators, the licensee must determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. In addition, licensees should review the potential of sealed sources to become dislodged from the source rack when dropped as a result of loss of power, failure of cables, or other alternate means of support.

- For panoramic irradiators, the licensee must review the design of the mechanism that moves the sources to ensure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

For irradiators whose construction begins after July 1, 1993:

- For panoramic irradiators, the licensee must test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.
- For all irradiators with product conveyor systems, the licensee must observe and test the operation of the conveyor system to ensure that the requirements in 10 CFR 36.35 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

See Appendix J, "Construction Monitoring and Acceptance Testing."

Response from Applicant: Submit procedures for ensuring source rack protection. If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack. Provide diagrams or sketches of those systems, if appropriate.

8.9.8 POWER FAILURES

Regulations: 10 CFR 30.33(a)(2), 10 CFR 36.37, 10 CFR 36.39(i), 10 CFR 36.41(i), 10 CFR 36.41(j).

Criteria: If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position. In addition, the lock on the door of the radiation room of a panoramic irradiator must not be deactivated by a power failure.

Discussion: Automatic source retraction in case of power loss must be accomplished without offsite power. The loss of offsite power may occur at irradiator facilities due to means outside the control of the licensee. In those cases where loss of offsite power occurs, the licensee is responsible for ensuring that the sources automatically return to the shielded position in accordance with 10 CFR 36.37(a). This is normally accomplished by an irradiator design that does not need electrical energy to retract the sources. In addition, 10 CFR 36.37(b) requires that the lock on the door of the radiation room may not be deactivated as the result of a power failure. It also requires that during a power failure, the licensee must ensure that anyone entering the area

of any irradiator where sources are located must use an operable and calibrated radiation survey meter.

The licensee needs to demonstrate how the source rack would be retracted into the shielded position in the event of a power outage and what effects the loss of power would be on the lock of the door to the radiation room that contains the sources. If the locks on the doors did not function as designed and allowed entry into the radiation room, the licensee would need to have procedures in place to ensure that safety features would prevent an individual from being exposed to the sources if they did not retract to the shielded position. Backup power is not required as long as loss of power will cause the source to return to its shielded position, e.g., the source returns to the shielded position due to gravity.

For panoramic irradiators whose construction began after July 1, 1993, the licensee must test the ability of the source rack to return to its shielded position during a power loss greater than 10 seconds. For more information; see Appendix J, "Construction Monitoring and Acceptance Testing."

Response from Applicant:

- **For panoramic irradiators whose construction began after July 1, 1993**, describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds.
- **For all panoramic irradiators**, describe how loss of power will affect the lock on the doors in the radiation room.
- **For underwater irradiators**, no response is required from the applicant in a license application.

8.10 ITEM 10: RADIATION SAFETY PROGRAM

8.10.1 AUDIT PROGRAM

Regulations: 10 CFR 20.1101, 10 CFR 20.2102.

Criteria: Licensees must review the content and implementation of their radiation protection programs at least every 12 months to ensure the following:

- Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101); and

- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Applicants must develop and implement an audit program. Appendix K contains a suggested audit program that is specific to the use of irradiators and is acceptable to NRC. All areas indicated in Appendix K may not be applicable to every licensee and all items may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to their activities, and activities which have not occurred since the last audit need not be reviewed at the next audit.

Currently the NRC's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator operators to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," provides guidance on this subject. The NRC will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the NRC can exercise discretion and may elect not to cite a violation. The NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies. For additional information on NRC's use of discretion on issuing violations, refer to the current version of "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG 1600).

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and followup.

Response From Applicant: The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but should not be submitted in the license application.

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of: Manual Chapter 87100, Appendix F, "Commercial Irradiator Field Notes," the current version of NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996. NUREG-1600 is also available on the Internet. Visit NRC's Home Page <http://www.nrc.gov>, choose "Nuclear Materials," then "Enforcement," "Enforcement Guidance Documents," and then "Enforcement Policy."

8.10.2 INSTRUMENTS

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2), 10 CFR 36.57(c), 10 CFR 36.57(e), 10 CFR 36.81(f), 10 CFR 36.63(b), 10 CFR 36.23(c), 10 CFR 36.27(a), 10 CFR 36.29.

Criteria: NRC requires specific types of instruments to perform radiation surveys and to monitor certain activities.

Survey Instruments

Surveys that are required before and during operation of all types of irradiators require using survey instruments which:

- measure the type of radiation expected
- are calibrated:
  - — at least every 12 months
  - — using a source of radiation similar to that found in the irradiator
  - — after any servicing or repair (other than a simple battery exchange)
  - — to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than ± 20% on each scale
  - — by the instrument manufacturer or person specifically authorized by the NRC or an Agreement State to calibrate survey instruments
- do not saturate and read zero at high radiation dose rates.

Radiation Monitors

The requirements for use of radiation monitors are shown in Table 8.2.

Table 8.2 Requirements for Radiation Monitors

Type of Irradiator	Monitor Required	Purpose of Monitor	Required Checks
Panoramic pool	Gamma sensing integrated with personnel access locks. Must activate alarm if entry is attempted while sensing radiation. 10 CFR 36.23(c)	Detects presence of high radiation in radiation room to prevent room access when rad levels are high	Periodic checks with radioactive check source to confirm operability
All pool types (required unless water is checked daily by analysis of a sample of pool water)	Gamma sensing of pool circulating system. Must activate an alarm set-point as low as practical when pool is contaminated. 10 CFR 36.59(b)	Detects a possible leaking sealed source	Periodic checks with radioactive check source to confirm operability and sensitivity
Underwater type not in a shielded radiation room	Gamma sensing mounted over the pool. Must have an audible alarm capable of alerting an authorized individual. 10 CFR 36.29(b)	Detects abnormal radiation levels	Periodic checks with radioactive check source to confirm operability and sensitivity
Any irradiator using a product conveyor system	Gamma sensing to detect and stop the product conveyor if a source is present. 10 CFR 36.29(a) 10 CFR 36.39(e)	Must stop conveyor before a source on the conveyor can cause a radiation overexposure to any person.	Periodic checks with radioactive check source to confirm operability. The location and sensitivity of the monitor to detect sources carried by the product conveyor must be evaluated.

Discussion: Irradiator licensees must have survey instruments and radiation monitors as shown in Figure 8.6.

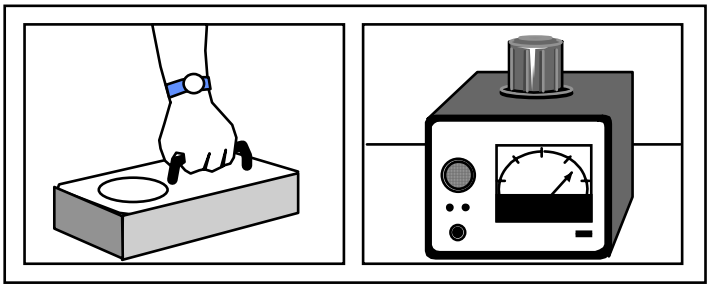

Figure 8.6 Radiation Detection Instruments. *Irradiator licensees must have a variety of radiation detection instruments including portable survey instruments as well as fixed radiation monitors.*

Survey Instruments

The survey instruments should measure at least 0.05 mR through 200 mR per hour (2 mSv) and be checked for functionality with a source of radiation at the beginning of each day of use (e.g., with a check source). Plans to conduct non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the irradiator, sealed source relocation, replacement, and disposal of sealed sources, alignment or removal of a sealed sources from service must include an evaluation of the type of survey instrument to be used because some of these operations may increase the individual's risk of radiation exposure. These operations should be carefully monitored with an appropriate survey meter. Furthermore, proper calibration of a survey meter is important for initial surveys since they can be used as a basis for public dose estimates. For those licensees requesting authorization to calibrate their own survey instruments, Appendix L contains calibration procedures acceptable to the NRC.

Radiation Monitors

Fixed radiation monitors are used to detect the presence of radiation for various purposes at irradiator facilities. They are vital to access control systems because they provide electronic signals used to activate both audible and visual alarms when radiation is present. Monitors that warn individuals of the presence of high radiation or which are integrated with personnel access door locks to prevent room access under high radiation conditions should be designed to provide fail-safe operation, i.e., if the radiation monitor for any reason fails to respond to radiation, the system should provide for a backup warning system.

Response from Applicant:

For Survey Instruments: Provide one of the following:

- A statement that, "We will use survey instruments that meet the Criteria in the section entitled 'Radiation Safety Program - Instruments' in NUREG-1556, Vol. 6, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses,' dated January 1999."

AND ONE OF THE FOLLOWING:

- A statement that, "Each survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations."

OR

- A statement that, "We will implement the model survey meter calibration program published in Appendix L entitled 'Survey Instrument Calibration' in NUREG-1556, Vol. 6, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about 10 CFR Part 36 Irradiator Licenses,' dated January 1999."

OR

- Submit alternative calibration procedures for NRC review.

OR, IN LIEU OF ALL OF THE ABOVE, SUBMIT:

- A description of an alternative method to perform surveys pursuant to 10 CFR 20.1501.

For Radiation Monitors: Describe the type of monitors used to meet the requirements of 10 CFR 36.23(c), 36.29, and 36.59(b). (The location of these monitors and alarm set-points were described in the response to "Facilities and Equipment - Radiation Monitors.")

Notes:

- Alternative responses will be evaluated using the criteria listed above.
- The NRC license will state that survey meter calibrations will be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State to calibrate instruments, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See Appendix L for more information.

- Regardless of whether an applicant is authorized to calibrate survey meters or contracts an authorized firm to perform calibrations, the licensee must retain calibration records for at least 3 years.

8.10.3 MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 30.34(e), 10 CFR 30.35(g), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201.

Criteria: Licensees must do the following:

- Develop, maintain, and implement a procedure to account for licensed material.
- Maintain records of receipt, transfer, and disposal of licensed material (i.e., sealed sources).

Discussion: While loss, theft, or misplacement of licensed material at most irradiator facilities is unlikely because of limited access to sealed sources and the hazards involved with approaching unshielded sources, accountability for licensed materials must be ensured. As illustrated in Figure 8.7, licensed materials must be tracked from "cradle to grave" in order to ensure accountability and ensure that possession limits listed on the license are not exceeded.

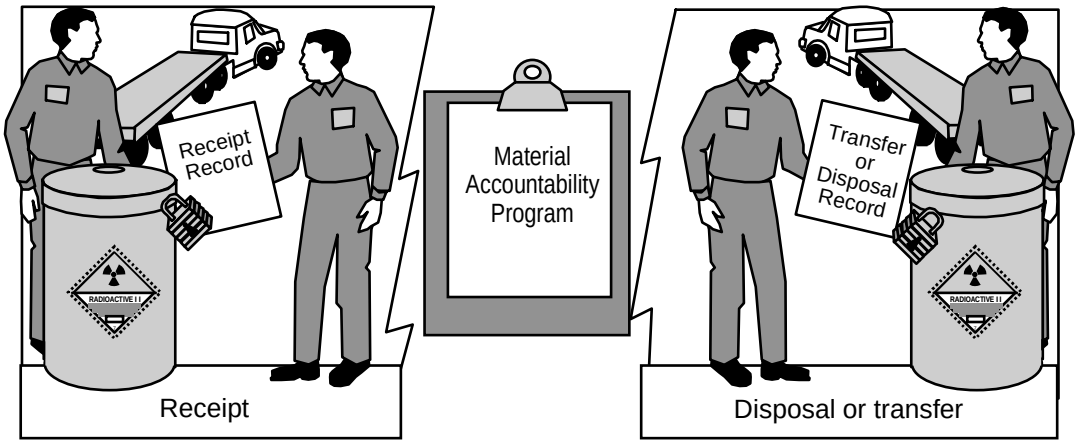

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Figure 8.7 Material Receipt and Accountability. *Licensees must maintain records of receipt, transfer and disposal and implement an accountability procedure.*

Because this report covers various types of irradiators, it is not possible to prescribe a specific procedure for material accountability that will apply to every situation. In developing a licensed material accountability program, the applicant should take into consideration the specific

conditions at its facility. Table 8.3 includes elements that may be included in the accountability procedure for various facilities.

Table 8.3 Elements of Accountability Procedure

Irradiator Type	Items to be Addressed in Accountability Procedure
Pool Irradiator	Verify that no sources have been lost when sources are added to, removed from, or moved within the irradiator or, at a minimum, every 3 years Maintenance of records that include sealed source serial numbers and location of each source
Panoramic Dry-Source-Storage Irradiator (Including Teletherapy Units Converted to Irradiators)	Leak tests Verify that no sources have been lost when sources are added to, removed from, or moved within the irradiator or, at a minimum, every 3 years Maintenance of records that include sealed source serial numbers and location of each source

Receipt, transfer, and disposal records must be maintained for the times specified in Table 8.4. Typically, these records contain the following types of information:

- Radionuclide, activity (in units of becquerels or curies), and date of measurement of byproduct material in each sealed source
- Manufacturer's (or distributor's) name, model number, and serial number of each sealed source containing byproduct material
- Location of each sealed source
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, serial number).

Table 8.4 Receipt, Transfer and Disposal Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer

Type of Record	How Long Record Must be Maintained
Disposal	Until NRC terminates the license
Important to Decommissioning*	Until the site is released for unrestricted use

*See the section entitled "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant: Submit a description of procedure(s) for ensuring material accountability.

8.10.4 OCCUPATIONAL DOSIMETRY

Regulations: 10 CFR 36.55, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501(c).

Criteria: The requirements for occupational dosimetry are shown in Table 8.5.

Table 8.5 Requirements for Occupational Dosimetry

Type of Irradiator	Category of Personnel	Type of Dosimetry Required	When Dosimetry Must Be Worn
Panoramic	Irradiator Operators	Film or TLD (10 CFR 36.55(a))	When operating irradiator
Underwater	Irradiator Operators	Film or TLD (10 CFR 36.55(a))	When in area around pool
Panoramic	Other individuals, including visitors (for groups of visitors, only two must be monitored)	Pocket dosimeter, film, or TLD (10 CFR 36.55(a))	When entering or in radiation room
All	Anyone who could receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in Figure 8.8.*	Pocket dosimeter, film, or TLD (10 CFR 20.1501 and 10 CFR 20.1502)	As directed by the RSO based on 10 CFR 20.1502

* The licensee must maintain, for inspection by NRC, documentation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in Figure 8.8.

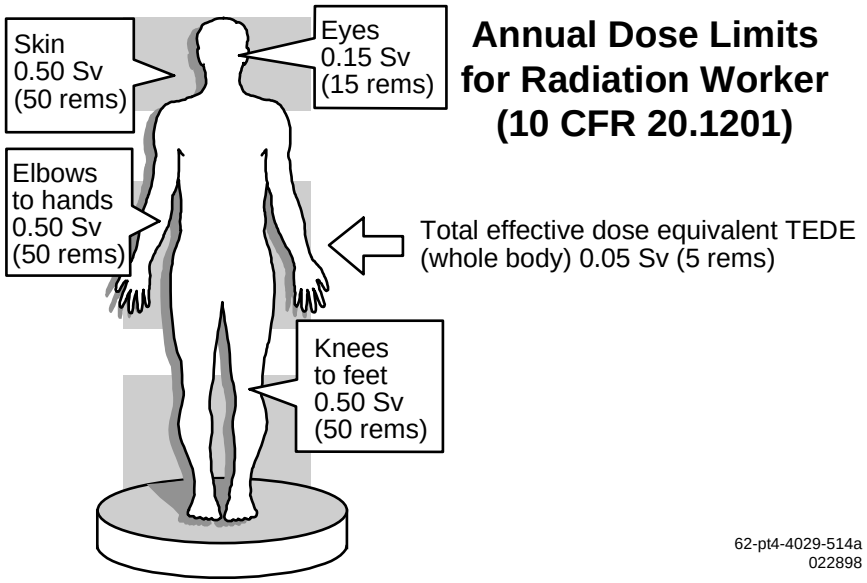

Figure 8.8 Annual Dose Limits for Radiation Workers.

Discussion: The requirements for most individuals are described in Table 8.5. Other individuals who perform certain non-routine operations (e.g., source loading, unloading, and repositioning; troubleshooting the control console; clearing stuck source racks; investigating/remediating removable contamination/leaking sources; (re)installing source cables; and any other activity during which personnel could receive radiation doses exceeding NRC limits) are likely to exceed 10% of the limits as shown in Figure 8.8 (see Appendix I). Applicants will also be required to provide dosimetry (whole body and perhaps extremity monitors) to individuals performing such services.

When personnel monitoring is needed, most licensees use either film badges or thermoluminescent dosimeters (TLDs) that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for TLDs is usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some workers, e.g., package handlers, shipping personnel, and custodial personnel, may work near the irradiator but are not likely to exceed 10% of the limits. Refer to Appendix M for guidance for demonstrating that an unmonitored individual will not exceed 10% of the limits.

Response from Applicant: The applicant's occupational dosimetry program required by 10 CFR Parts 20 and 36 will be examined during inspection, but should not be submitted in the license application.

As of this moment, NRC is considering the use of NAVLAP approved Optically Stimulated Luminescent Dosimeters (OSL). Licensees will be informed of their acceptability via an NRC generic communication.

8.10.5 PUBLIC DOSE

Regulations: 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1003, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2107, 10 CFR 36.25.

Criteria: Licensees must do the following:

- Ensure that irradiators and their sealed sources will be used, transported, and stored in such a way that individual members of the public will not receive more than 1 millisievert (mSv) [100 millirem (mrem)] in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include all persons who are not radiation workers. This includes persons who work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where licensed material is used or stored.

Security procedures described in “Facilities and Equipment - Access Control,” “Radiation Safety Program - Operating Procedures,” and “Radiation Safety Program - Emergency Procedures” should be sufficient to limit the exposure to the public during use or storage. Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., irradiator is locked or located in a locked area) to prevent unauthorized access or use. Irradiator use is usually restricted by controlling access to the keys needed to operate the irradiator and/or to keys to the locked irradiator area. Only authorized users should have access to these keys.

Public dose is also affected by the choice of storage and use locations and conditions. Since an irradiator produces a radiation field, it must be located and constructed so that the dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 0.02 mSv (2 mrem) in any one hour and the dose to an individual does not exceed 1 mSv (100 mrem) in a year. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure. Licensees must determine the radiation levels in unrestricted areas that are normally occupied during operation of an irradiator as specified in Table 8.6.

Table 8.6 Radiation Limits Specified in 10 CFR 36.25

Irradiator Type	Limit	Where Measured	Source Position
Panoramic	0.02 mSv (2 mrem) per hour	30 centimeters or more from the wall (of the room where the sources are exposed) in areas normally occupied	Exposed
Pool irradiator (including panoramic pool irradiators and underwater irradiators)	0.02 mSv (2 mrem) per hour	30 centimeters over the edge of the pool irradiator	Shielded
Dry-source-storage panoramic irradiator	0.02 mSv (2 mrem) per hour	1 meter from the shield of a dry-source-storage panoramic irradiator	Shielded
Dry-source-storage panoramic irradiator	0.2 mSv (20 mrem) per hour	5 centimeters from the shield	Shielded

Doses adjacent to the irradiator location can be determined by direct measurements and calculations using the “inverse square” law to evaluate the effect of distance on radiation levels, and occupancy factor to account for the actual presence of the member of the public.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the shielding of the irradiator, increases the source strength, changes the type or frequency of irradiator use, or changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or a combination of measurement and calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix N for examples of methods to demonstrate compliance.

Response from Applicant: The applicant’s program to control doses received by individual members of the public will be examined during inspection, but should not be submitted in a license application.

8.10.6 OPERATING PROCEDURES

Regulations: 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2203, 10 CFR 30.50, 10 CFR 21.21, 10 CFR 19.11(a)(3), 10 CFR 36.13(c), 10 CFR 36.31, 10 CFR 36.53.

Criteria: The applicant must have and follow written operating procedures for items specified in 10 CFR 36.53(a).

Discussion: Operating procedures must be developed, maintained, and implemented to ensure that irradiators are used only as they were designed to be used, and radiation doses received by occupational workers and members of the public are ALARA. Copies of operating procedures should be provided to all irradiator operators. In addition, the applicant must post current copies of operating procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined.

Improper operation could lead to the damage or malfunction of an irradiator and potentially lethal radiation overexposures to individuals. The applicant will provide summaries of the written operating procedures describing their important radiation safety aspects. The level of detail should be sufficient to demonstrate that regulatory requirements have been addressed.

Table 8.7 lists the procedures that must be developed, maintained, and implemented, as well as important radiation safety aspects that should be addressed in the outline (i.e., description) that must be submitted in the application.

Table 8.7 Operating Procedures

Required Procedures	Items to be Addressed in Description of Procedures
Operation of the irradiator, including entering and leaving the radiation room	The description should be detailed enough to show how licensee will comply with 10 CFR 36.67, "Entering and Leaving the Radiation Room," and should describe the initial entry and survey after an irradiation. Describe how the applicant will prevent access to keys by individuals who have not been qualified to be operators, as required by 10 CFR 36.31(a). For panoramic irradiators, when product movement is occurring, the description should address the required presence (10 CFR 36.65) of an irradiator operator and another person who is trained on how to respond and prepared to render or summon assistance if the access alarm sounds. For static irradiations, a person who is trained to respond to alarms must be onsite.‡

Required Procedures	Items to be Addressed in Description of Procedures
Use of personnel dosimeters	See "Radiation Safety Program - Occupational Dosimetry"
Surveying the shielding of panoramic irradiators	See "Facilities and Equipment - Shielding"
Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas	See "Facilities and Equipment - Radiation Monitors"
Leak testing of sources	See "Radiation Safety Program - Leak Tests" and Appendix P
Inspection and maintenance checks required by 10 CFR 36.61	See "Radiation Safety Program - Inspection and Maintenance Checks"
Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and	If these procedures will be performed by the applicant, see Appendix I, "Information Needed to Support Applicant's Request to Perform Non-Routine Operations"
Inspection of movable shielding required by 10 CFR 36.23(h), if applicable.*	Describe inspection of roof plugs or other movable shielding required by 10 CFR 36.23(h), if applicable.*

‡ In 10 CFR 36.65, the term "onsite" is intended to give flexibility to licensees. For example, for a research irradiator at a university, the person onsite could be a guard located on campus but not in the building containing the irradiator, provided the guard would hear the alarm and was trained as required by 10 CFR 36.51(g). The guard would not have to be trained as an irradiator operator.

* If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an *operating procedure requiring inspection of shielding before operating.*

Normally, the manufacturer or a person specifically authorized by NRC or an Agreement State will perform non-routine operations involving, source loading, unloading and repositioning; troubleshooting the control console; clearing stuck source racks; investigating/remediating removable contamination/leaking sources; (re)installing source cables; and other critical operations requiring special skills or the potential for radiation overexposures. If these operations are not performed properly with attention to good radiation safety principles, the irradiator may not operate as designed and personnel performing the operations could receive potentially lethal exposures. If the applicant wishes to perform non-routine operations, the information in Appendix I should be provided.

Repair and Preventive Maintenance

Outlines of maintenance, service, and repair procedures are not required. However, these should be done according to the manufacturer's written instructions, where applicable, by qualified personnel using their knowledge, experience, judgment, and skills to respond to each particular situation.

Improper repairs or maintenance not being performed in a timely fashion was identified as a contributing cause of many of the incidents reviewed in NUREG-1345, "Review of Events at Large Pool-Type Irradiators." Therefore, malfunctions and defects found during inspection and maintenance checks must be repaired *without undue delay*. It is understood that it may be necessary to obtain a special part, piece of equipment, or particular skilled labor that may not be readily available. Licensees are allowed some flexibility in making *noncritical* repairs. As long as a reasonable effort is made, the licensee will meet the intent of the requirement. However, some repairs are *critical* and *not* subject to the latitude in 10 CFR 36.61(b). For example, licensees must make repairs to the access control system before operating the irradiator to ensure compliance with 10 CFR 36.23.

Preventive maintenance should be performed according to the manufacturer's written instructions. If manufacturer's written instructions are not available, the applicant should perform a review of the systems comprising the irradiator in consultation with knowledgeable individuals and determine and implement an appropriate schedule for preventive maintenance.

Security of Licensed Material

NRC considers security of licensed material extremely important and lack of security is a significant violation for which licensees may be subject to enforcement action. Although it is generally difficult to access sealed sources used in most 10 CFR Part 36 irradiators, the applicant should develop, maintain, and implement procedures to prevent unauthorized access, removal, or use of the licensed material. Also, procedures should require that all areas associated with irradiator operations, particularly control and interlock systems, be locked and secured against unauthorized access.

Revision of Procedures

The licensee may revise operating procedures without NRC approval only if all of the following conditions are met:

- The revisions do not reduce the safety of the facility
- The revisions are consistent with the outline or summary of procedures submitted with the license application

- The revisions have been reviewed and approved by the RSO
- The users or operators are instructed and tested on the revised procedures before they are put into use.

Response from Applicant:

For routine operations: Provide an outline that specifically states the radiation safety aspects of the written operating procedures listed in Table 8.7 (i.e., those procedures listed in 10 CFR 36.53(a)). For items where other sections of this guide are referenced, respond to the applicable section.

For non-routine operations: Submit either of the following:

- A statement that: "The irradiator manufacturer or other person authorized by NRC or an Agreement State will perform non-routine operations such as source loading, unloading and repositioning, electrical troubleshooting of the control console, clearing stuck source racks, investigating/remediating removable contamination/leaking sources, (re)installing source cables, and other critical operations requiring special skills or the potential for radiation overexposures."

OR

- The information listed in Appendix I supporting a request to perform this work "in-house."

Note: Information requested in Appendix I will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine operations.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain a copy of NUREG-1345, "Review of Events at Large Pool-Type Irradiators," dated March 1989 or IN 83-09: "Safety and Security of Irradiators," dated March 9, 1983.

8.10.7 PROCEDURE FOR IDENTIFYING AND REPORTING DEFECTS AND NON-COMPLIANCE AS REQUIRED BY 10 CFR PART 21

Regulations: 10 CFR Part 21, 10 CFR 30.50, 10 CFR 36.83.

Criteria: Licensees must notify NRC if defects and failures are found in a basic component that could create a substantial safety hazard.

Discussion: Equipment defects that could create a substantial safety hazard, or equipment failures involving NRC-regulated activities must be reported to NRC. For example, a failure of an access control system such that a person could enter the radiation room during a time when the sources are exposed in a panoramic irradiator, or a defect in an interlock that prevents the operation of a panoramic irradiator in the event a roof plug or other movable shielding is not in place. Operating personnel should be instructed to report any malfunction or defect in irradiator equipment to management so that management can take appropriate action.

Response from the Applicant: None required.

8.10.8 EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 30.50, 10 CFR 36.13(c), 10 CFR 36.37(c), 10 CFR 36.53, 10 CFR 36.67, and 10 CFR 36.83.

Criteria: The licensee must have and follow emergency or abnormal event procedures, appropriate for items listed in 10 CFR 36.53(b). Emergency procedures should include notifying the NRC during and after emergencies and abnormal events.

Discussion: Figure 8.9 illustrates proper handling of one type of incident (i.e., broken source rack cable).

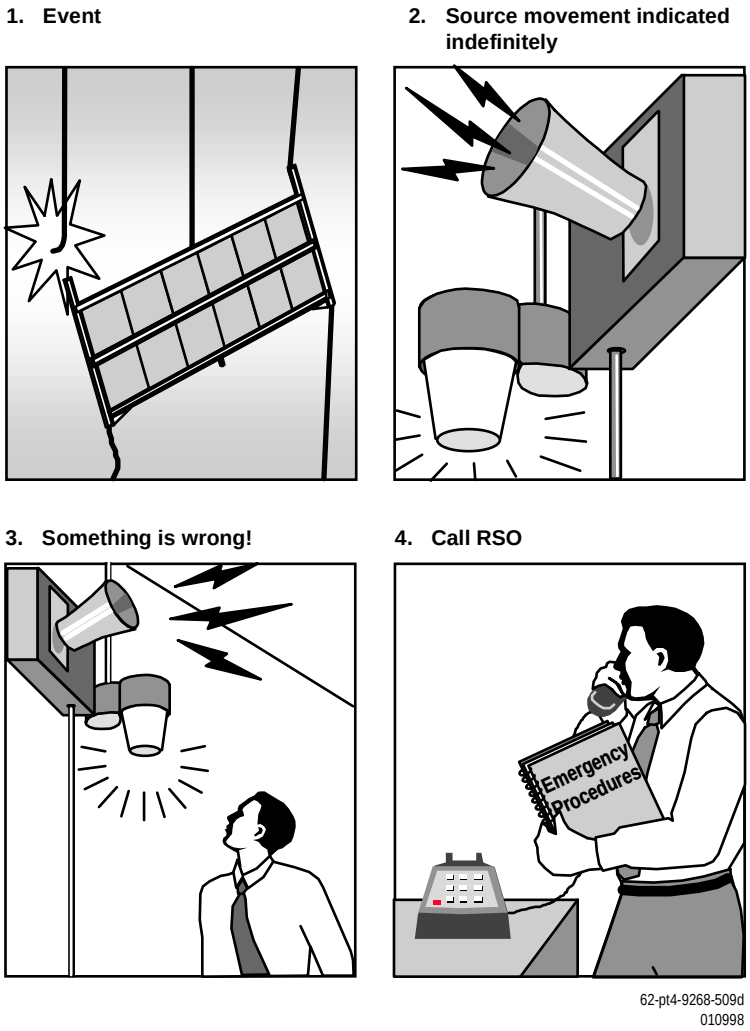

Figure 8.9 Proper Handling of Incident. *Licensee personnel implement emergency procedures when a source rack cable breaks.*

Licensees must have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

- Sources stuck in the unshielded position
- Personnel overexposures
- A radiation alarm from the product exit portal monitor or pool monitor
- Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water (include 10 CFR 36.59(c) requirements)
- A low- or high-water level indicator, an abnormal water loss, or leakage from the source storage pool

- A prolonged loss of electrical power (include 10 CFR 36.37 and 36.67(c) requirements)
- A fire alarm or explosion in the radiation room
- An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area
- Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility
- The jamming of automatic conveyor systems.

The applicant should consider other events which may require emergency or abnormal event procedures (e.g., abnormally high radiation levels indicated by the area radiation monitor, collision with the source(s) or source rack).

Emergency and abnormal event procedures should include who will be notified of the event, the role of the RSO, and what records of the event will be kept. The procedures should clearly identify telephone numbers of the RSO or other individuals who can provide assistance including the irradiator manufacturer (or distributor) and state and local agencies. The procedures should include actions to be taken immediately after discovering the emergency or abnormal event. Emergency procedures should also include notifying the NRC when events specified in Appendix O occur.

The RSO must be proactive in evaluating whether NRC notification is required. Refer to Appendix O and the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.51, and 10 CFR 36.83 for descriptions of when and where notifications are required.

Emergency procedures generally should not include post-emergency corrective actions and repairs, since there will be time to carefully consider such actions on a case-by-case basis after the situation is under control. Copies of emergency procedures should be provided to all irradiator operators. In addition, licensees must post current copies of emergency procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice which describes the documents and states where they may be examined.

Emergency procedures for personnel overexposures, fire alarms, explosion in the radiation room, and natural phenomena may involve emergency responders outside the applicant's organization. The applicant should inform and/or train individuals in these organizations regarding the unique concerns and hazards associated with emergencies at the irradiator facility. For instance, hospitals should be informed about the different radiation accidents that could occur at the facility (i.e., overexposure vs. personnel contamination incident).

The licensee may revise emergency procedures without NRC approval only if all of the following conditions are met:

- The revisions do not reduce the safety of the facility
- The revisions are consistent with the outline or summary of procedures submitted with the license application
- The revisions have been reviewed and approved by the RSO
- The users or operators are instructed and tested on the revised procedures before they are put into use.

Response from Applicant: Provide an outline that specifically states the radiation safety aspects of the written emergency procedures listed in the "Discussion" section (i.e., those procedures listed in 10 CFR 36.53(b)).

8.10.9 LEAK TESTS

Regulations: 10 CFR 36.59, 10 CFR 36.81(h), 10 CFR 36.83.

Criteria: NRC requires testing to determine whether there is any radioactive leakage from the sources in the irradiator. Records of the test results must be maintained.

Discussion:

Dry-Source-Storage Sealed Sources

Each dry-source-storage sealed source must be tested for leakage at 6-month intervals. 10 CFR 36.59(a) prohibits sources from being used unless the licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been performed within 6 months before the transfer.

The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 200 becquerels (0.005 microcurie)[5] of radioactivity and must be performed by a person approved by the NRC or an Agreement State to perform the test. In general, the sensitivity required can be obtained with a thin-window G-M probe.

[5] 10 CFR Part 36 uses one significant figure in converting becquerels to microcurie.

Manufacturers, consultants, and other organizations may be authorized by NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to dry-source-storage licensees. In the latter case, the licensee is expected to take the leak test sample according to the irradiator manufacturer's (or distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. See Figure 8.10 below. Licensees may also be authorized to conduct the entire leak test sequence themselves. Appendix P contains a model leak test program.

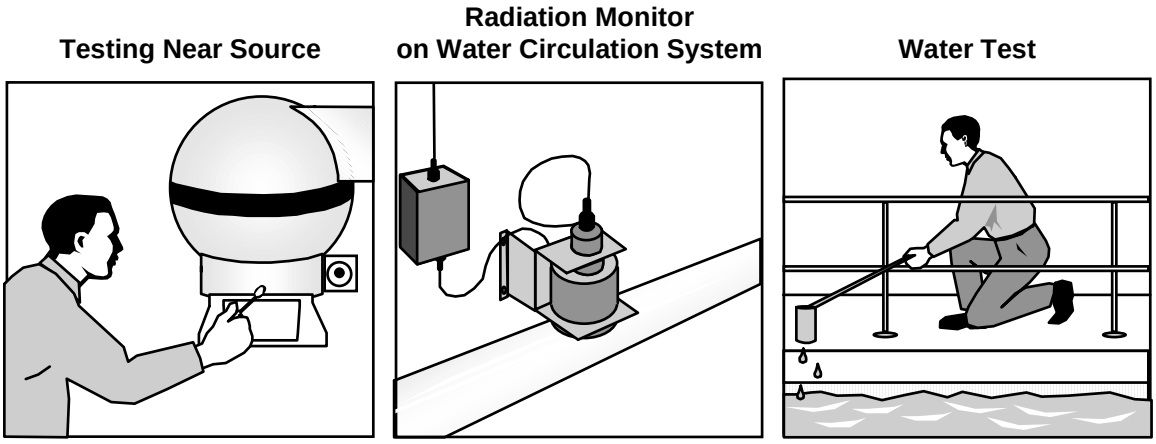

Figure 8.10 Leak Testing. *The panel on the far left illustrates leak testing a dry-source-storage irradiator source, while the other two panels illustrate two ways of monitoring pool water to determine if wet-source-storage sources are leaking.*

Pool Irradiators

For pool irradiators, 10 CFR 36.59(b) prohibits sources from being put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak tests have been performed within 6 months before the transfer. After placing sources in the pool, the water must be checked for contamination each day the irradiator operates. For pool irradiators, leak testing sources by wipe-testing is not highly sensitive or effective. The check may be done either by using a radiation monitor on a pool water circulating system or by analyzing a sample of pool water. If analyzing a sample of pool water, the results must be available within 24 hours. Whether the applicant desires to check for contamination by analyzing a pool water sample daily, or by continuous monitoring, the procedures and sensitivity of the equipment to be used should be detailed in the application. If collecting a pool sample, use a sensitive detector, such as a sodium iodide detector, to verify the absence of detectable contamination in the sample. If using the continuous monitoring method, applicants may use a less sensitive detector such as a G-M detector affixed to a filter/demineralizer where radioactive material would be concentrated.

If the licensee detects a leaking source, the licensee must promptly check personnel, equipment, facilities, and irradiated products for contamination. If any personnel or product are found to be contaminated, decontamination must be performed immediately. If a source is found to be leaking, the licensee must arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If the pool is contaminated, the licensee must arrange to clean the pool until the concentration levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to Part 20. See 10 CFR 30.50 for reporting requirements.

Upon detection of leaking sources, licensees should consider immediately stopping irradiator operations to minimize spread of contamination.

Response from Applicant:

For dry-source-storage irradiators: Submit one of the following three alternatives:

- A statement that: "Leak tests will be performed at intervals not to exceed 6 months. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or 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 irradiator manufacturer's (or distributor's) and kit supplier's instructions. Records of leak test results will be maintained."

OR

- A statement that: "We will implement the model leak test program published in Appendix P to NUREG-1556 Vol. 6, 'Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses,' dated January 1999."

OR

- A description of alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in the irradiator.

For pool irradiators: Submit either of the following:

- A description of equipment, procedures, and sensitivity of method that will be used to check for contamination by *analysis of a sample* of pool water.

OR

- A description of equipment, procedures, and sensitivity of method that will be used to check for contamination by *continuous monitoring.*

Note: Requests for authorization to perform leak testing and sample analysis will be reviewed and, if approved, NRC staff will authorize via a license condition.

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

8.10.10 INSPECTION AND MAINTENANCE CHECKS

Regulations: 10 CFR 20.1101, 10 CFR 36.13(c) and (h), 10 CFR 36.53(a)(6), 10 CFR 36.61.

Criteria: The applicant must have and follow written procedures for inspection and maintenance checks for items specified in 10 CFR 36.61.

Discussion: Applicants must periodically make inspection and maintenance checks to ensure proper operation of the irradiator. The applicant must have and follow procedures for inspection and maintenance checks. The frequency of checks is not stated in the regulations because it will be site-specific depending on the design of the facility. However, the frequency of checks must be specified in the application. In the applicant's description of the procedures, specify the frequency of the following items:

- Operability of each aspect of the access control system required by 10 CFR 36.23
- Functioning of the source position indicator as required by 10 CFR 36.31(b)
- Operability of the radiation monitor for radioactive contamination in pool water required by 10 CFR 36.59(b), using a radiation check source, if applicable
- Operability of the over-pool radiation monitor at underwater irradiators as required by 10 CFR 36.29(b)
- Operability of the product exit monitor required by 10 CFR 36.29(a)
- Operability of the emergency source return control required by 10 CFR 36.31(c)
- Leak-tightness of systems through which pool water circulates (visual inspection)
- Operability of the heat and smoke detectors and extinguisher system required by 10 CFR 36.27 (but without turning extinguishers on)
- Operability of the means of pool water replenishment required by 10 CFR 36.33(c)
- Operability of the indicators of high and low pool-water levels required by 10 CFR 36.33(d)
- Operability of the intrusion alarm required by 10 CFR 36.23(i), if applicable
- Functioning and wear of the system, mechanisms, and cables used to raise and lower sources

- Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 10 CFR 36.35
- Amount of water added to the pool to determine whether the pool is leaking.
- Electrical wiring on required safety systems for radiation damage
- Pool water conductivity measurements as required by 10 CFR 36.63.

The applicant should keep in mind that these are the minimum items to be checked based on requirements in 10 CFR 36.61, and that the licensee should develop and implement procedures for other necessary checks as appropriate (e.g., as recommended by the manufacturer). For instance, if applicable, the applicant should have and follow written procedures for inspection and maintenance checks to ensure that all product positioning system components, product boxes, or carriers continue to meet design specification and are not likely to cause an irradiator malfunction.

Response from Applicant: Describe inspection and maintenance checks, including the frequency of the checks listed in the "Discussion" section (10 CFR 36.61).

8.10.11 TRANSPORTATION

Regulations: 10 CFR 71.5, 10 CFR 71.12, 10 CFR 71.13, 10 CFR 71.14, 10 CFR 71.37, 10 CFR 71.38, Subpart H of 10 CFR Part 71, 49 CFR Parts 171-178, 10 CFR 20.1101, 10 CFR 30.41, 10 CFR 30.51.

Criteria: Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: The general license in 10 CFR 71.12 provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Transporting licensed materials originating at irradiator facilities normally involves quantities of radioactive material that require a Type B package. Because of the special requirements involved in shipping Type B packages, most irradiator licensees have chosen to transfer possession of radioactive materials to an irradiator manufacturer (or service licensee) with an NRC or Agreement State license who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material at temporary job sites (i.e., at the irradiator location)

- Actually takes possession of the licensed material under its license
- Uses an approved Type B package
- Is registered with NRC as a user of the Type B package
- 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.

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 10 CFR 71.12 general license. For information about QA plans, see Revision 1 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," (dated June 1986). For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number 800-368-5642 and asking for extension 415-8500. For information about associated fees, contact NRC's Office of the Controller by calling NRC's toll-free number 800-368-5642 and asking for extension 415-7554.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a "Memorandum of Understanding with DOT on the Transportation of Radioactive Material" (signed June 6, 1979) to examine and enforce various DOT requirements applicable to irradiator licensees. Appendix Q lists major DOT regulations.

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

References: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials" can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425. See the Notice of Availability (on the inside front cover of this report) to obtain a copy of the "Memorandum of Understanding with DOT on the Transportation of Radioactive Material" and the current version of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material."

8.10.12 MINIMIZATION OF CONTAMINATION

Regulations: 10 CFR 20.1406.

Criteria: Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities so as to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their respective SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in 10 CFR 36.59 should identify defective sources. Leaking sources must be withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria for the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment - Irradiator Pools" (if applicable), "Radiation Safety Program - Operating Procedures," " Radiation Safety Program - Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Sealed Source Transfer and Disposal."

8.11 ITEM 11: WASTE MANAGEMENT

8.11.1 SEALED SOURCE DISPOSAL AND TRANSFER

Regulations: 10 CFR 20.2001, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 30.36, 10 CFR 36.59.

Criteria: Licensed materials must be disposed of according to NRC requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of sealed sources or contaminated items (caused by leaking sources), licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the sources, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

If a product of the irradiator that may have been inadvertently contaminated has been shipped, the licensee must arrange to locate and survey the product for contamination. If contaminated equipment, facilities, or products are found, the licensee must arrange to have them decontaminated or properly disposed of by an NRC or Agreement State licensee authorized to provide these services. If the pool is contaminated, the licensee must arrange to clean up the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to 10 CFR Part 20 (10 CFR 36.59(c)).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in 10 CFR 30.41. In addition, all packages containing radioactive sources must be prepared and shipped according to NRC and DOT regulations. Records of the transfer must be maintained as required by 10 CFR 30.51.

Response from Applicant: The applicant does not need to provide a response to this item during the licensing process. However, the licensee should establish and include waste disposal procedures in its radiation safety program.

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.

The next two items on NRC Form 313 are to be completed on the form itself.

8.12 ITEM 12: FEES

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

An application and required fee must be submitted before start of construction (see 10 CFR 36.15). This will allow regulatory agencies to inspect the construction of the facility as it is being built.

8.13 ITEM 13: CERTIFICATION

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. ***Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant.*** As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. ***NRC will return all unsigned applications for proper signature***.

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

9 AMENDMENTS AND RENEWALS TO A LICENSE

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 (except as permitted by 10 CFR 36.53(c)), the licensee must submit an application for a license amendment before the change takes place. 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 (10 CFR 2.109, 10 CFR 30.36(a))

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request
- Submit in duplicate, either an NRC Form 313 or a letter requesting amendment or renewal
- Provide the license number
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.

10 APPLICATIONS FOR EXEMPTIONS

Various sections of NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11(a), 10 CFR 36.17(a)). These regulations state that NRC may grant an exemption, acting on its own initiative or on an application from an interested person. Key considerations are whether the exemption is authorized by law, will endanger life or property or the common defense and security, and is otherwise in the public interest.

Until NRC has granted an exemption in writing, NRC expects strict compliance with all applicable regulations.

Exemptions are not intended to revise regulations, are not intended for large classes of licenses, and are generally limited to unique situations. Exemption requests must be accompanied by descriptions of the following:

- Exemption and why it is needed
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested
- Alternative methods for complying with the regulation and why they are not feasible.

When NRC codified its requirements in 10 CFR Part 36 for irradiators, NRC recognized the special case of teletherapy-type units converted from human use to use for the irradiation of materials or objects. 10 CFR 36.17(b) permits these licensees to propose alternatives to the requirements of 10 CFR Part 36 provided that there is an adequate rationale and the alternatives provide an adequate level of safety for workers and the public.

For converted teletherapy units, Appendix R lists specific sections of the regulations, the rationale and acceptable alternatives, and the wording of the license condition granting the exemption. The Regions may grant exemption requests shown in Appendix R without consulting NMSS.

Exemption requests other than those described in Appendix R must be coordinated with NMSS.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b), 10 CFR 30.35(g), 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).

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days of:
  - — the expiration of its license
  - — a decision to permanently cease licensed activities at the *entire site* (regardless of contamination levels)
  - — a decision to permanently cease licensed activities in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to NRC requirements
  - — no principal activities having been conducted *at the entire site* under the license for a period of 24 months
  - — no principal activities having not been conducted for a period of 24 months in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to NRC requirements.

- Submit decommissioning plan, if required by 10 CFR 30.36(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and 10 CFR 30.36(j).
- Submit, to the appropriate NRC regional office, completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC regional office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in "Criteria," before a licensee can decide whether it must notify NRC, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

For guidance on the disposition of licensed material, see the section on "Waste Management - Sealed Source Disposal or Transfer." For guidance on decommissioning records, see the section on "Radioactive Materials - Financial Assurance and Record Keeping for Decommissioning."

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. However, when the license expires or at the time the licensee ceases operations, then any necessary decommissioning activities must be undertaken, NRC Form 314 or equivalent information must be submitted, and other actions must be taken as summarized in the Criteria.

Reference: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional Offices. (See Figure 2.1 for addresses and telephone numbers).

Appendix A

List of Documents Considered in Development of this NUREG

List of Documents Considered in Development of this NUREG

This report incorporates and updates the guidance previously found in the NUREG reports, Regulatory Guides (RGs), Policy and Guidance Directives (P&GDs), and Information Notices (INs) listed below. Other NRC documents such as Manual Chapters (MCs), Inspection Procedures (IPs), and Memoranda of Understanding (MOU) were also consulted during the preparation of this report. *The documents marked with an asterisk (*) will be considered superseded and should not be used.*

Table A.1 List of NUREG Reports, Regulatory Guides, and Policy and Guidance Directives

Document Identification	Title	Date
NUREG-1345	Review of Events at Large Pool-Type Irradiators	3/89
RG 3.66	Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72	06/90
RG 7.10 (Rev. 1)	Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material	6/86
*P&GD FC 84-23	Standard Review Plan for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators	12/84
*P&GD FC 84-25	Licensing of Large Irradiators	11/84
P&GD FC 90-02 Rev. 1	Standard Review Plan for Evaluating Compliance with Decommissioning Requirements	04/30/91
P&GD PG 1-26	Processing of Exemptions for Material Licensees	07/25/97
P&GD PG 8-11	NMSS Procedures for Reviewing Declarations of Bankruptcy	08/08/96

Table A.2 List of Information Notices

Document Identification	Title	Date
IN 83-09	Safety and Security of Irradiators	03/09/83

Document Identification	Title	Date
*IN 85-01	Continuous Supervision of Irradiators	01/10/85
IN 85-36	Malfunction of a Dry-Storage, Panoramic, Gamma Exposure Irradiator	05/09/85
IN 89-25 Rev. 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	12/07/97
IN 89-82	Recent Safety-Related Incidents at Large Irradiators	12/07/89
IN 91-14	Recent Safety-Related Incidents at Large Irradiators	03/05/91
IN 94-89	Equipment Failures at Irradiator Facilities	12/28/94
IN 96-28	Suggested Guidance Relating to Development and Implementation of Corrective Action	05/01/96
IN 96-54	Vulnerability of Stainless Steel to Corrosion When Sensitized	10/17/96
IN 97-30	Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises	06/03/97

Appendix B

NRC Form 313

NRC Form 313

Replace this page with NRC Form 313 hardcopy.

Appendix C

Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

Item No.	Title and Criteria	Yes	Description Attached
5	**RADIOACTIVE MATERIAL** **Sealed Sources And Devices** • Identify each radionuclide that will be used in each irradiator. • Identify the manufacturer (or distributor) and model number of each sealed source. • Identify the manufacturer (or distributor) and model number of each irradiator, if applicable. • For dry-source-storage irradiators, specify the maximum activity per source. • Specify the maximum activity per irradiator. • If depleted uranium is used as shielding material, specify the total amount (in kilograms). **Financial Assurance and Record Keeping for Decommissioning** • If financial assurance is required [possession greater than 10,000 curies Co-60 or 100,000 curies Cs-137], submit documentation required by 10 CFR 30.35.		[ ] [ ] [ ] [ ] [ ] [ ] [ ]

Item No.	Title and Criteria	Yes	Description Attached
6	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED** Provide either of the following: • A specific description of use for each type of irradiator requested, e.g., "For use in irradiation of products or food. There will be no irradiation of explosives and no irradiation of more than small quantities of flammable materials with a flash point below 60 degrees C (140 degrees F) without specific written authorization from NRC." **OR** • If the irradiator will be used for purposes other than irradiation of food or products for human or research purposes, description of these purposes and safety analyses (and procedures, if needed) to support safe use.		[ ] [ ]
7	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM** **Radiation Safety Officer (RSO)** **Training and Experience** • State the name of the proposed RSO • Describe the proposed RSO's training and experience specific to the irradiator that the applicant intends to use **Responsibilities and Authorities** • Describe the organizational structure for managing the irradiator. • Specify the radiation safety responsibilities and authorities of the RSO. • Specify other management personnel who have important radiation safety responsibilities and authorities. • Describe who has the authority to stop unsafe operations.		 [ ] [ ] [ ] [ ] [ ] [ ]

Item No.	Title and Criteria	Yes	Description Attached
8	**INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**		
	Initial Training for Irradiator Operators		
	• Before using licensed materials irradiator operators will have successfully completed one of the training courses described in Criteria in the section entitled "Initial Training for Irradiator Operators," in NUREG-1556, Vol. 6, dated January 1999.	[ ]	
	OR		
	• Provide a description of the initial training program for irradiator operators that demonstrates compliance with the requirements of 10 CFR 36.51(a), (b), and (c).		[ ]
	Annual Training Regarding Safety Reviews for Irradiator Operators		
	• Describe program for annual safety reviews and performance evaluations of irradiator operators that demonstrates compliance with 10 CFR 36.51(d) and (e).		[ ]
	Training for Individuals Who Require Unescorted Access		
	• The applicant's program for instructing and testing unescorted individuals (other than irradiator operators) will be examined during inspections, but should not be submitted in the license application.	N/A	N/A
	Training for Individuals Who Must Be Prepared to Respond to Alarms		
	The applicant's program for instructing and testing, as applicable, individuals designated to respond to alarms will be examined during inspections, but should not be submitted in the license application.	N/A	N/A

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT**		
	General Description		
	• Describe the irradiator including diagrams, sketches, and photographs, as appropriate.		[ ]
	• Show locations of safety-related equipment and features as required in 10 CFR Part 36.		[ ]
	• Provide a construction schedule for the irradiator.		[ ]
	Access Control		
	• Submit specific information describing the access control system and how it works that demonstrates compliance with the requirements of 10 CFR 36.23. Specific drawings or sketches should be submitted, as appropriate.		[ ]
	• For panoramic irradiators, describe the facility alarm systems.		[ ]
	• For panoramic irradiators, describe the lock and key system for controlling source movement and discuss how it meets the requirements of 10 CFR 36.31(a).		[ ]
	Shielding for Panoramic Irradiators		
	• Describe the shielding to be used and its composition.		[ ]
	• Submit a diagram showing the configuration of shielding including walls and the ceiling and indicate the thickness of each and penetrations in the shielding		[ ]
	• If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 mSv (2 mrem) per hour, identify the areas and tell how access to those areas will be controlled.		[ ]
	• For requests to possess more than 2×10^{17} becquerels (5,000,000 curies), submit an evaluation of the effects of heating of the shield walls by the irradiator sources [see 10 CFR 36.39(a)].		[ ]
	Note: For underwater irradiators, no response is required from the applicant in a license application.	N/A	N/A

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT *(Cont'd)***		
	Fire Protection for Panoramic Irradiators		
	Describe:		
	• Type and location of the heat and smoke detectors to be used to detect a fire in the radiation room		[ ]
	• Alarms to alert personnel who will be trained to summon assistance		[ ]
	• How the sources will automatically become fully shielded if a fire is detected		[ ]
	• How the heat and smoke detectors will be tested.		[ ]
	***Note*:** For an underwater irradiator, no response is required, since the sources are always underwater and not subject to damage by fire.	N/A	N/A
	Radiation Monitors		
	• Describe the location and type of radiation monitors that will be used to meet the requirements of 10 CFR 36.23(c), 36.29, and 36.59(b).		[ ]
	• Describe the location and types of alarms and those individuals who are trained to respond to those alarms. Diagrams and sketches should be used, as appropriate.		[ ]
	• Discuss the alarm set-points or the methods for establishing the alarm set-points.		[ ]
	• For irradiators whose construction begins after July 1, 1993, describe the evaluation performed to meet 10 CFR 36.39(e) on detector location and sensitivity and the acceptance testing that will be performed to meet 10 CFR 36.41(e).		[ ]
	***Note*:** Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of 10 CFR 36.29.	N/A	N/A

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT *(Cont'd)***		
	Irradiator Pools		
	For irradiators licensed before July 1, 1993, write "Not applicable."	[ ]	
	For irradiators licensed after July 1, 1993, describe:		
	• The pool liner [If no water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool is used, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished if necessary]		[ ]
	• The high and low water-level indicators and their locations		[ ]
	• The purification system for the pool and explain why the purification system is considered capable of maintaining pool water conductivity less than 20 microsiemens per centimeter		[ ]
	• The means to replenish pool water		[ ]
	• The barrier used during normal operation to prevent personnel from falling into the pool		[ ]
	• How high radiation doses from radiation streaming will be avoided when using long-handled tools or poles (use sketches if appropriate)		[ ]
	• If the pool has outlets more than 0.5 meter below the surface that could allow water to drain out of the pool, the means of preventing inadvertent excessive loss of pool water (in this context outlets do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools).		[ ]

Item No.	Title and Criteria	Yes	Description Attached
9	**FACILITIES AND EQUIPMENT *(Cont'd)***		
	Source Rack		
	• Submit procedures for ensuring source rack protection. If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack. Provide diagrams or sketches of those systems, if appropriate.		[ ]
	Power Failures for Panoramic Irradiators		
	• Describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds.		[ ]
	• Describe how loss of power will affect the lock on the doors in the radiation room for a panoramic irradiator.		[ ]
	Note: For underwater irradiators, no response is required from the applicant in a license application.	N/A	N/A
10	**RADIATION SAFETY PROGRAM**		
	Audit Program	Need Not be Submitted with Application	
	The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but should not be submitted in the license application.		

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM**		
	Instruments		
	Survey Instruments		
	• We will use survey instruments that meet the Criteria in the section entitled "Radiation Safety Program - Instruments" in NUREG-1556, Vol. 6, dated January 1999.	[ ]	
	AND ONE OF THE FOLLOWING		
	• Each survey meter will be calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations.	[ ]	
	OR		
	• We will implement the model survey meter calibration program published in Appendix L entitled "Survey Instrument Calibration" in NUREG-1556, Vol. 6, dated January 1999.	[ ]	
	OR		
	• Submit alternative calibration procedures for NRC review.		[ ]
	OR, IN LIEU OF ALL OF THE ABOVE, SUBMIT		
	• A description of an alternative method to perform surveys pursuant to 10 CFR 20.1501.		[ ]
	Radiation Monitors		
	• Describe the type of monitors used to meet the requirements of 10 CFR 36.23(c), 36.29, and 36.59(b).		[ ]
	Material Accountability		
	• Submit a description of procedure(s) for ensuring material accountability.		[ ]

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	Occupational Dosimetry The applicant's occupational dosimetry program required by 10 CFR Parts 20 and 36 will be examined during inspection, but should not be submitted in a license application.	Need Not be Submitted with Application	
	Public Dose The applicant's program to control doses received by individual members of the public will be examined during inspection, but should not be submitted in a license application.	Need Not be Submitted with Application	
	Operating Procedures **Routine Operations** • Provide an outline that specifically states the radiation safety aspects of the written operating procedures listed in 10 CFR 36.53(a)).		[ ]
	Non-Routine Operations Submit either of the following: • The irradiator manufacturer or other person authorized by NRC or an Agreement State will perform non-routine operations such as source loading, unloading and repositioning, electrical troubleshooting of the control console, clearing stuck source racks, investigating/remediating removable contamination/leaking sources, (re)installing source cables, and other critical operations requiring special skills or having the potential for radiation overexposures.	[ ]	
	OR • The information listed in Appendix I in NUREG-1556, Vol. 6, dated January 1999.		[ ]

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	Emergency Procedures		
	• Provide an outline that specifically states the radiation safety aspects of the written emergency procedures listed in the "Discussion" section (i.e., those procedures listed in 10 CFR 36.53(b)).		[ ]
	Leak Tests		
	For Dry-Source-Storage Irradiators		
	Provide one of the following three alternatives:		
	• Leak tests will be performed at intervals not to exceed 6 months. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or 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 irradiator manufacturer's (or distributor's) and the kit supplier's instructions. Records of leak test results will be maintained.	[ ]	
	OR		
	• We will implement the model leak test program published in Appendix P in NUREG-1556, Vol. 6, dated January 1999.	[ ]	
	OR		
	• A description of alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in the irradiator.		[ ]

Item No.	Title and Criteria	Yes	Description Attached
10	**RADIATION SAFETY PROGRAM *(Cont'd)***		
	Leak Tests		
	For Pool Irradiators		
	Submit either of the following:		
	• A description of equipment, procedures, and sensitivity of method that will be used to check for contamination by *analysis of a sample of pool water*.		[ ]
	OR		
	• A description of equipment, procedures, and sensitivity of method that will be used to check for contamination by *continuous monitoring*.		[ ]
	Inspection and Maintenance		
	Describe inspection and maintenance checks, including the frequency of the checks listed in 10 CFR 36.61.		[ ]
	Transportation		
	No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in Type B packages, a licensee needs to have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.	Need Not be Submitted with Application	
	Minimization of Contamination		
	The applicant does not need to provide a response to this item under the following condition. NRC will consider that the criteria have been met if the applicant's responses meet the criteria for the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment - Irradiator Pools" (if applicable), "Radiation Safety Program - Operating Procedures," "Radiation Safety Program - Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Sealed Source Transfer and Disposal."	Need Not be Submitted with Application	

Item No.	Title and Criteria	Yes	Description Attached
11	**WASTE MANAGEMENT** **Sealed Source Disposal and Transfer** The applicant does not need to provide a response to this item during the licensing process. However, the licensee should establish and include waste disposal procedures in its radiation safety program.		Need Not be Submitted with Application

Appendix D

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

NRC has just published Draft Guidance on Bankruptcy and Transfer of Control (January 1999) in NUREG 1556, Vol. 15. NRC will inform licensees of the availability of the Final Guidance via generic communication.

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. The new name of the licensed organization. If there is no change, the licensee should so state.

2. The new licensee contact and telephone number(s) to facilitate communications.

3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.

4. An indication of whether the transferor will remain in non-licensed business without the license.

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).

7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.

8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.

9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.

10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license terminations.

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36, and 70.25. Include information about how the transferee and transferor propose to divide the transferor's assets, and responsibility for any cleanup needed at the time of transfer.

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 10 CFR 30.35(g); implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

    With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

    With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

14. Documentation that the transferor and transferee agree to transfer control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program, to ensure compliance with the license and regulations.

Reference: The information above is contained in IN 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities." See the Notice of Availability (on the inside front cover of this report) to obtain copies.

Appendix E

Suggested Wording for a Statement of Intent for a Government Licensee

Suggested Wording for a Statement of Intent for a Government Licensee

[DATE]
TO: U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 [or appropriate regional address]

STATEMENT OF INTENT

As [Title] of [Licensee Name] I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by U.S. Nuclear Regulatory Commission Material License No. [License No.]. This authority is established by [Name of Document(s) Governing Control of Funds]. Within this authority, I intend to have funds made available when necessary in an amount up to [Dollar Amount] to decommission [Description of Facilities]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [Name of Documents] is attached as evidence that I am authorized to represent [Licensee Name] in this transaction.

[SIGNATURE]
[NAME]
[TITLE]

Appendix F

Irradiation of Explosive Materials or Greater Than Small Quantities of Flammable Materials

Irradiation of Explosive Materials or Greater Than Small Quantities of Flammable Materials

Explosive Materials

Irradiation of explosive materials is prohibited under 10 CFR Part 36 unless the applicant has received prior written authorization from the NRC. If an applicant requests authorization to irradiate explosive materials, he or she must be able to demonstrate that detonation of the explosive would not rupture the irradiator sealed sources, injure personnel, damage safety systems, or cause radiation overexposure of personnel.

Greater Than Small Quantities of Flammable Materials

Prior written authorization from NRC is required by 10 CFR 36.69(b) before irradiation of more than small quantities of flammable materials with a flash point below 60°C (140°F) in a panoramic irradiator. As defined in the National Fire Code NFPA 30, "Flammable and Combustible Liquids Code," published by the National Fire Protection Association[6], the flash point is "the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid…" According to the NFPA 30 classification system, Class I and Class II liquids have flash points below 60°C (140°F). The flash points of many substances are tabulated in National Fire Code NFPA 325M, "Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids."[6] Flash points are also specified on the Material Safety Data Sheets for industrial chemicals, when applicable. Examples of common flammable liquids with a flash point below 60°C (140°F) are acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, turpentine, and any flammable gas.

NRC is concerned about irradiating flammable materials which may cause an explosion. If the flash point of a flammable liquid is exceeded, the concentration of the vapor in air could exceed the flammable limit and the potential for an explosion could exist.

The NRC considers that compliance with the requirements in 10 CFR 36.21, 36.27, 36.35, 36.39(h), 36.41(h), and 36.53(b)(7) will provide adequate protection against radiological impacts arising from a fire. With an energetic explosion, however, applicants should consider the possibility of direct damage to the source encapsulation or to the source rack preventing it from being lowered to the shielded position.

A "small quantity" of flammable material can be defined as a quantity of flammable material that, when dispersed evenly throughout the radiation room with no loss to ventilation, would have a concentration below the lower flammable limit concentration. Although local

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[6] Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 9146, Quincy, MA 02269-9959 (Telephone No. 1-800-344-3555).

concentrations could exceed the average room concentration, the movement of air into and out of the radiation room provides a margin of safety. In addition, the time required to vaporize all the material also adds to the margin of safety. Further, small pockets of flammable vapor will contain quantities of energy too small to provide a force strong enough to significantly damage the irradiator. Given these factors, the definition of small quantity is considered to be conservative enough to ensure safe operation of an irradiator.

Special precautions must be taken when irradiating cryogenic material. The hazard from cryogenic irradiation occurs when air condenses or freezes (possibly insidiously without detection) on cold surfaces during irradiation. While the exact details are uncertain, oxygen in the air is converted by the radiation to ozone. Under certain circumstances (often during a subsequent warm-up), the ozone decomposes or reacts with other agents explosively. If cryogenic material is to be irradiated the applicant must submit procedures for ensuring the safe handling of such material.[7]

Example of determining a small quantity of flammable material:

This example considers the irradiation of isopropyl alcohol in a radiation room whose total volume is 100 m^3. NFPA 325M states that the lower flammable limit for isopropyl alcohol is 2% by volume, the specific gravity of the liquid is 0.8, and the vapor density relative to that of air is 2.1. The density of air is 1.293 kg/m^3. The volume of isopropyl alcohol in the room at the lower flammable limit will be 2% of 100 m^3, which is equal to 2 m^3. The weight will be 2 m^3 x 1.293 kg/m^3 x 2.1 (density relative to air) = 5.43 kg. With a specific gravity of 0.8, the volume of the liquid isopropyl alcohol would be 6.79 liters. If the liquid mixture were 70% isopropyl alcohol and 30% water, the volume of a small quantity would be 6.79/0.7 = 9.7 liters. Thus, in a radiation room with a volume of 100 m^3, a volume less than 9.7 liters of 70% pure isopropyl alcohol (exposed to the direct radiation beam) can be considered a small quantity because the flammable limit could not be reached in any significant volume even if there were no ventilation.

If the applicant irradiates small quantities of flammable material, the licensee's records should demonstrate that the above criterion for small quantities has been met, including how the licensee limited the quantity of flammable material in the radiation room at one time.

If the quantity to be exposed to the direct beam at any one time would exceed a small quantity, it is necessary to consider whether the concentration of flammable vapor in the room air could exceed the lower flammable limit. If product movement through the irradiator stopped and the radiation sources could not be returned to the shielded position, the temperature of the irradiated product would rise, the vapor pressure of the flammable material would increase, and that pressure might cause the containers to leak and release flammable vapor into the room air. If

[7] This information was taken from Oak Ridge National Laboratory Report ORNL/M-260, DE87 002877, "Safety Analysis Report for the National Low-Temperature Neutron Irradiation Facility (NLTNIF) at the ORNL Bulk Shielding Reactor (BSR)," June 1986.

ventilation were insufficient, the flammable vapor concentration might exceed the lower flammable limit and a spark could cause the mixture to explode.

Requests for approval to irradiate more than small quantities of flammable material:

The applicant must demonstrate that it is unlikely that the concentration of flammable vapor in air in a significant volume of the room would exceed the lower flammable limit. There are two methods to do this. The first method is to demonstrate that no single failure would be likely to cause the product to become immobilized in the radiation room and prevent the sources from being returned to the shielded position. Such a situation theoretically might arise if the product carriers became jammed and pushed into the source rack preventing its return to the shielded position. The second method is to demonstrate that even if the product became immobilized and the source rack could not be returned to the shielded position, the ventilation system would prevent the concentration of flammable vapor in a significant volume of the room air from reaching the lower flammable limit.

If an applicant is applying for authorization to irradiate more than a small quantity of flammable material, the application should include all of the following information:

- Name of the flammable material that has a flash point below 60°C (140°F) and its flash point
- Its flammable limit as percent by volume in air
- Its specific gravity as a liquid
- Its vapor density relative to that of air
- Maximum quantity to be in the direct radiation beam in the radiation room at any one time
- Description of the packaging for the product.

In addition, the application should:

EITHER

Describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position.

OR

Describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position. If this second approach is taken, the applicant should also provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should also identify the means to detect ventilation system failure.

Appendix G

Training for Radiation Safety Officers and Irradiator Operators

Training for Radiation Safety Officers and Irradiator Operators

Course Content

Instruction may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of irradiators:

- Radiation Safety:
  - — External radiation vs. radioactive contamination
  - — Internal vs. external exposure
  - — Biological effects of radiation (e.g., why large radiation doses must be avoided)
  - — Units of radiation dose
  - — Types and relative hazards of radioactive material possessed
  - — ALARA concept
  - — Use of time, distance, and shielding to minimize exposure (e.g., how shielding and access controls prevent large doses)
  - — Proper use of survey meters and personnel dosimeters.

- Regulatory Requirements:
  - — Applicable regulations
  - — NRC dose limits
  - — License conditions, amendments, renewals
  - — Locations of use and storage of radioactive materials
  - — Material control and accountability
  - — Annual audit of radiation safety program
  - — Transfer and disposal
  - — Record keeping
  - — Case histories of accidents or problems involving irradiators
  - — Handling incidents
  - — Recognizing and ensuring that radiation warning signs are visible and legible
  - — Licensing and inspection by regulatory agency
  - — Need for complete and accurate information (10 CFR 30.9)

  - — Employee protection (10 CFR 30.7)
  - — Deliberate misconduct (10 CFR 30.10).

- Practical Explanation of the Theory and Operation for Irradiators:
  - — Basic function of the irradiator
  - — Radiation safety features of an irradiator
  - — Operating and emergency procedures which the individual is responsible for performing
  - — Routine vs. non-routine maintenance
  - — Lock-out procedures
  - — How an irradiator is designed to prevent contamination.

On-the-job or simulator training must be done under the supervision of a qualified irradiator operator:

- Supervised Hands-on Experience Performing:
  - — Operating procedures which the individual is responsible for performing
  - — Test runs of emergency procedures which the individual is responsible for performing
  - — Routine maintenance
  - — Lock-out procedures.

- Training for an RSO should include at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

Course Examination

- Written examination designed to verify an individual's competency and understanding of the subject matter (e.g., 25 to 50 question, closed-book written test with 70% as passing grade

Emphasis on radiation safety of irradiator operations and maintenance, licensee operating and emergency procedures that the individual will be responsible for performing, and other operations necessary to safely operate the irradiator without supervision

Review of correct answers to missed questions with prospective irradiator operators immediately following the scoring of the test.

Training Assessment

Management will ensure that potential RSOs and authorized operators are qualified to work independently with irradiators. This must be demonstrated by written examination and by direct observations.

Course Instructor Qualifications

Instructor should have either:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of an irradiator manufacturer's course for users (or equivalent)
- Successful completion of an 8 hour radiation safety course AND
- 8 hours hands-on experience with irradiators

OR

- Successful completion of an irradiator manufacturer's course for users (or equivalent)
- Successful completion of 40 hour radiation safety course; and
- 30 hours of hands-on experience with irradiators.

Note:

- Licensees must maintain records of training (10 CFR 36.81(b)).
- Additional training is required for those applicants intending to perform non-routine operations such as source loading and unloading. See Appendix I, "Non-Routine Operations."

Appendix H

Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with both NRC regulations and the conditions of the license. Typically, the RSO's duties and responsibilities include:

- Stopping activities that the RSO considers unsafe
- Keeping exposures ALARA
- Developing, maintaining, distributing, and implementing up-to-date operating and emergency procedures
- Ensuring that individuals associated with irradiator operations are properly trained and evaluated
- Ensuring that non-routine operations (See Appendix I) for irradiators are consistent with the limitations in the license, the Sealed Source and Device Registration Certificate(s), and the manufacturer's written recommendations and instructions
- Analyzing potential safety consequences of non-routine operations before conducting any such activities that have not been previously analyzed
- Ensuring non-routine operations are performed by the manufacturer or person specifically authorized by the NRC or an Agreement State to perform those operations
- Ensuring that personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained by the licensee
- Maintaining documentation that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or provide personnel monitoring devices
- Notifying proper authorities of incidents such as damage to or malfunction of irradiators, fire, loss or theft of licensed materials (See also Appendix O)
- Investigating emergencies and abnormal events involving the irradiators (e.g., malfunctions or damage), identifying cause(s), implement appropriate and timely corrective action(s)
- Performing radiation safety program audits at least every 12 months and developing, implementing, and documenting timely corrective actions
- Ensuring transport of licensed material according to all applicable DOT requirements
- Ensuring proper disposal of licensed material
- Maintaining appropriate records associated with irradiator operations
- Maintaining an up-to-date license and timely submission of amendment and renewal requests

- Ensuring that when the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented

Appendix I

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Information Needed to Support Applicant's Request to Perform Non-Routine Operations

Non-routine operations may include the following:

- Source loading, unloading and repositioning
- Troubleshooting the control console
- Clearing stuck source racks
- Investigating/remediating removable contamination/leaking sources
- (Re)installing source cables
- Any other activity during which personnel could receive radiation doses exceeding NRC limits.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive lethal radiation doses.

Applicants wishing to perform non-routine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, personnel dosimetry). Accordingly, provide the following information:

- Describe which non-routine operations will be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform non-routine operations and their training and experience applicable to these operations. Acceptable training would include manufacturers' courses for non-routine operations or equivalent.
- Submit procedures for non-routine operations. These procedures should ensure the following:
  - — doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielding and adequate planning when working with unshielded sources)
  - — manufacturer's written instructions and recommendations are followed
  - — planned special exposure requirements (10 CFR 20.1206), if applicable, are met
  - — operations involving source loading, unloading, and repositioning include recording the rack position of each source and surveying all empty or loaded source transport containers for removable contamination to prevent the introduction of radioactive contaminants into the irradiator.

- Confirm that individuals performing non-routine operations will wear whole body radiation dosimetry, if appropriate.
- Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed 10 CFR 20.1301 limits. For example, applicants can do the following:
  - — commit to performing surveys with a survey instrument;
  - — specify where and when surveys will be conducted during non-routine operations; and
  - — commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by 10 CFR 20.2103.

Appendix J

Construction Monitoring and Acceptance Testing

Construction Monitoring and Acceptance Testing

To ensure that irradiators and their components are built and installed as designed, 10 CFR 36.41 requires that, for irradiators whose construction began after July 1, 1993, licensees conduct monitoring and acceptance testing before loading sealed sources. Figure J.1 illustrates this point and Table J.1 correlates the components to be checked and the types of tests with the type of irradiator to which the requirement applies.

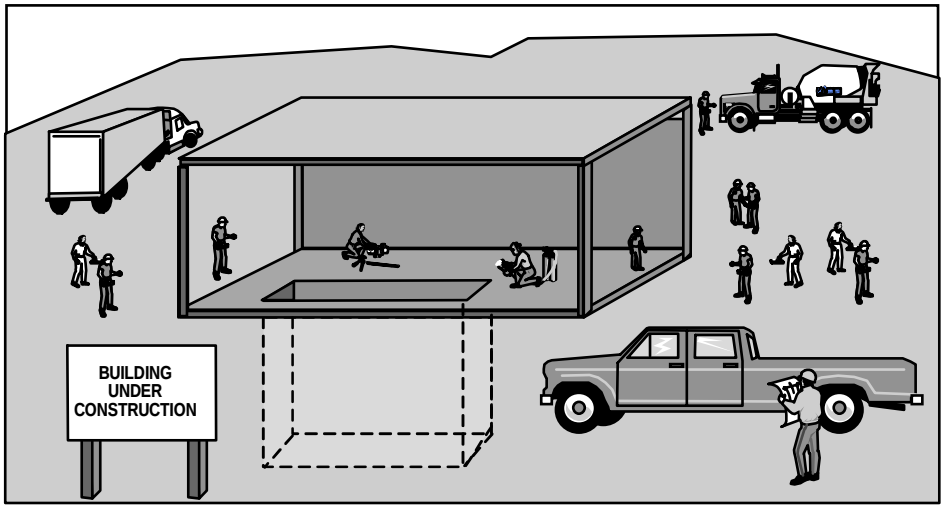

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Figure J.1 Construction Monitoring and Acceptance Testing. *Before loading sealed sources, irradiator licensees must ensure that the as-built irradiator meets design criteria.*

Table J.1 Construction Monitoring and Acceptance Testing

Irradiator Elements	Irradiator Type	Licensee Requirement
Shielding	Panoramic	Monitor the construction of the shielding to make sure that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
Foundations	Panoramic	Monitor the construction of the foundations to verify that their construction meets design specifications.
Pool Integrity	Pool	Verify that the pool meets design specifications including requirements in 10 CFR 36.33(a) and test the integrity of the pool. Verify that outlets and pipes meet the requirements of 10 CFR 36.33(b).

Irradiator Elements	Irradiator Type	Licensee Requirement
Water Handling System	Pool	Verify that the water purification system, the conductivity meter, and the water level indicators operate properly (water level controls should be checked, if installed).
Radiation Monitors	All	Verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 10 CFR 36.29(a).
	Pool	Verify the proper operation of the radiation monitors and the related alarm if used to meet 10 CFR 36.59(b).
	Underwater	Verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 10 CFR 36.29(b).
Source Rack	Panoramic	Test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power.
	Irradiator with Product Conveyor Systems	Observe and test the operation of the conveyor system to ensure that the requirements in 10 CFR 36.35 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.
Access Control	Panoramic	Test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly.
Fire Protection	Panoramic	Test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee must test the operability of the fire extinguishing system. It is not necessary that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems.
Source Return	Panoramic	Demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

Irradiator Elements	Irradiator Type	Licensee Requirement
Computer Systems	Panoramic, that use a computer system to control the access control system	Verify that the access control system will operate properly if offsite power is lost and verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
Wiring	Panoramic	Verify that the electrical wiring and electrical equipment that were installed meet the design specifications (e.g. radiation-resistant wiring installed in appropriate locations and according to code).

Appendix K

Suggested Audit Checklist for 10 CFR Part 36 Irradiators

Suggested Audit Checklist for 10 CFR Part 36 Irradiators

Note: **All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit**. For example, licensees do not need to address areas which do not apply to their activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Licensee's name: _____ License No. _____

Date of This Audit _____

_____ Date _____
(Auditor Signature)

_____ Date _____
(Management Signature)

Audit History

A. Last audit of this location conducted on (date) _____

B. Were previous audits conducted at intervals not to exceed least every 12 months? [10 CFR 20.1101]

C. Were records of previous audits maintained? [10 CFR 20.2102]

D. Were any deficiencies identified during last two audits or two years, whichever is longer?

E. Were corrective actions taken? (Look for repeated deficiencies).

Organization And Scope of Program

A. If the mailing address or places of use changed, was the license amended?

B. If ownership changed or bankruptcy filed, was NRC prior consent obtained or was NRC notified?

C. Radiation Safety Officer

   1. If the RSO was changed, was license amended?

   2. Does new RSO meet the licensee's training requirements?

3. Is RSO fulfilling his/her duties?
4. To whom does RSO report?

D. If the designated contact person for NRC changed, was NRC notified?

E. Sealed Sources and Devices

1. Does the license authorize all of the NRC regulated radionuclides contained in irradiators?
2. Have copies of (or access to) SSD Certificates?
3. Are the sealed sources, and if applicable, devices in accordance with the description in the Sealed Source and Device (SSD) Registration Certificates? [10 CFR 32.210]
4. Have manufacturers' manuals for operation and maintenance?
5. Are the actual uses of the irradiator consistent with the authorized uses listed on the license?
6. Are the sealed sources used under conditions specified in the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD Registration Certificates?

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per [10 CFR 19.12]? Refresher training provided, as needed? Records maintained?

B. Did each individual permitted to operate the irradiator without a supervisor present, receive instruction according to the license commitments and 10 CFR 36.51 before operating the irradiator?

C. Are records of training, tests, safety reviews, and annual evaluations maintained for each authorized irradiator operator? [10 CFR 36.81(b), (c)]

D. Did individuals who perform non-routine operations receive training before performing these operations?

E. Did interviews reveal that individuals know the emergency procedures?

F. Did this audit include observations of irradiator operations?

G. Do workers know requirements for the following:

1. the radiation safety program
2. annual dose limits
3. new Form NRC 4 and 5

4. 10% monitoring threshold
5. dose limits to embryo/fetus and declared pregnant worker
6. grave danger posting?

Radiation Survey Instruments And Radiation Monitors

A. Are all portable survey meters calibrated at least annually to an accuracy of ± 20% for the gamma energy of the sources in use? [10 CFR 36.57(c)]

B. Are portable survey meters of a type that does not saturate and read zero at high dose rates? [10 CFR 36.57(c)]

C. Are calibration records maintained?

D. Are all operable survey instruments able to detect 0.5 microsievert (0.05 mrem) per hour?

E. Has the licensee evaluated the location and sensitivity of the radiation monitor to detect sources carried by the product conveyor system for automatic conveyor systems? [10 CFR 36.29(a)]

F. Has the licensee tested the operability and sensitivity of monitor used to detect the presence of high radiation levels in the radiation room before personnel entry at frequency specified in license application?

G. Has the licensee tested the operability and sensitivity of monitor used to detect contamination of pool water due to leaking sources? (frequency of checks as specified in license application?)

H. For underwater irradiators not in a shielded radiation room, has the licensee tested the operability and sensitivity of monitor used to detect abnormal radiation levels? (frequency of checks as specified in license application?)

Conductivity Meters

A. Are appropriate operable conductivity meters possessed and used?

B. Are conductivity meters calibrated at least annually? [10 CFR 36.63(b)]

Sealed Source Accountability Program

A. Are records maintained showing the receipt, location, transfer, and disposal of each sealed source? [10 CFR 30.51(a)(1)]

B. Is material accountability program as described in application being implemented?

Personnel Radiation Protection

A. Are ALARA considerations incorporated into the radiation protection program? [10 CFR 20.1101(b)]

B. Is documentation kept showing that unmonitored individuals receive ≤10% of limit? [10 CFR 20.1502(a)]

C. Did unmonitored individuals' activities change during the year which could put them over 10% of limit?

D. If yes to C above, was a new evaluation performed?

E. Is external dosimetry provided to individuals as required by 10 CFR 36.55 and to individuals likely to receive >10% of limit?

   1. Irradiator Operators: Is the dosimetry supplier NVLAP approved? [10 CFR 20.1501(c)]
   2. Are the dosimeters exchanged monthly for film badges and quarterly for TLDs?
   3. Are dosimetry reports reviewed by the RSO upon receipt?
   4. Are dosimeters provided to persons who enter the radiation room of a panoramic irradiator? [10 CFR 36.55(b)]
   5. Annual checks of accuracy of pocket dosimeters performed? [10 CFR 36.55(b)]
   6. Are the records NRC Forms or equivalent? [10 CFR 20.2104(d), 10 CFR 20.2106(c)]
      a. NRC-Form 4 "Cumulative Occupational Exposure History" completed?
      b. NRC-Form 5 "Occupational Exposure Record for a Monitoring Period" completed?
   7. Declared pregnant worker/embryo/fetus
      a. If a worker declared her pregnancy, did licensee comply with [10 CFR 20.1208]?
      b. Were records kept of embryo/fetus dose per [10 CFR 20.2106(e)]?

F. Are records of exposures, surveys, monitoring, and evaluations maintained [10 CFR 20.2102, 10 CFR 20. 2103, 10 CFR 20. 2106, 10 CFR 36.57(a)]

Public Dose

A. Is public access controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? 10 CFR 20.1301(a)(1)]

B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

C. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? [10 CFR 20.1301(a)(2)]

D. Is access to sealed sources controlled in a manner that would prevent unauthorized use or removal? [10 CFR 20.1801]

E. Records maintained? [10 CFR 20.2103, 10 CFR 20.2107]

Operating And Emergency Procedures

A. Have operating and emergency procedures been developed? [10 CFR 36.53]

B. Do they contain the required elements?

C. Does each individual working with the sealed sources have a current copy of the operating and emergency procedures (including emergency telephone numbers)?

D. Did any emergencies occur?

1. If so, were they handled properly?
2. Were appropriate corrective actions taken?
3. Was NRC notification or reporting required? [10 CFR 20.2201, 2202, 2203, 10 CFR 30.50 and 10 CFR 36.83]

Leak Tests

A. Were sealed sources leak tested at prescribed intervals? 10 CFR 36.59

B. Was the leak test performed according to regulatory requirements? 10 CFR 36.59

C. Are records of results retained with the appropriate information included?

D. Were any sealed sources found leaking and if yes, were appropriate actions taken and was NRC notified? [10 CFR 20.2201,10 CFR 20.2203, 10 CFR 21.21, 10 CFR 30.50, 10 CFR 36.59,10 CFR 36.83]

Inspection and Maintenance Checks

A. Are all procedures for maintenance of the irradiator being followed where applicable?

B. Are all checks to determine proper functioning and wear of the source movement systems performed at frequencies as specified in the license application?

C. Are labels, signs, and postings clean and legible?

D. Are checks for operability as required by 10 CFR 36.61(a) (not included in item 4.) performed at frequencies and according to procedures described in license application:

   1. Each aspect of the access control system
   2. Emergency source return control
   3. Heat/smoke detectors, extinguisher system
   4. Pool water replacement system high and low water indicators
   5. For underwater irradiators, was the intrusion alarm tested for operability? (frequency of checks as specified in license application?

E. Are checks for functioning and condition of equipment performed at required frequencies and according to procedures described in license application:

   1. Assessment of the condition and operability of the source rack protector are performed at the required frequencies [10 CFR 36.61(a)].
   2. Assessment of water added to the pool to determine if there is pool leakage are performed at required frequencies as required by [10 CFR 36.61(a)(14)].
   3. Assessment of radiation damage to electrical wiring are performed at required frequencies as required by [10 CFR 36.61(a)(15)].
   4. Water conductivity and analysis are performed at required frequencies [10 CFR 36.63]
   5. Confirmation that water circulation system is leak tight. [10 CFR 36.61(a)(7)]
   6. Functioning of the source position indicator [10 CFR 36.61(a)(2)]
   7. Leak tightness of water circulation system, visual inspection [10 CFR 36.61(a)(7)]

Repair and Preventive Maintenance

A. Are repair and maintenance of components related to the radiological safety of the irradiator performed by the manufacturer or person specifically authorized by the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 10 CFR 20.1301 limits)?

B. Malfunctions and defects found during inspection and maintenance checks are repaired without undue delay.

Transportation

Note: This section will not apply if you have not transported sealed sources during the period covered by this audit.

A. Were sources shipped since the last audit?

B. If so, were 10 CFR Part 71 requirements followed?

C. DOT-Type A or Type B packages used? [10 CFR Part 71, 49 CFR 173.415, 49 CFR 173.416(b)] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? NRC-approved QA program?

D. Package performance test records on file? [49 CFR 173.415(a)]

E. Special form sources documentation? [49 CFR 173.476(a)]

F. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 49 CFR 173.441]

G. Package properly marked? [49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324]

H. Package closed and sealed during transport? [49 CFR 173.475(f)]

I. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]

J. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} [49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604]

K. Secured against movement? [49 CFR 177. 834]

L. Placarded on vehicle, if needed? [49 CFR 172.504]

M. Proper overpacks, if used? [49 CFR 173.25]

N. Any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]

Auditor's Independent Survey Measurements

A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits [10 CFR 20.1501(a) & 1502(a)]?

Notification and Reports

A. Was a telephone report made within 24 hours as described in 10 CFR 36.83(b),10 CFR 30.50(c)(1), and a written report within 30 days as described in 10 CFR 30.50(c)(2) of any of the following:

   1. Source stuck in an unshielded position

2. Any fire or explosion in a radiation room
3. Damage to the source rack
4. Failure of the cable or drive mechanism used to move the source racks
5. Inoperability of the access control system
6. Detection of radioactive contamination attributable to licensed radioactive material
7. Detection of radioactive contamination attributable to licensed radioactive material
8. Structural damage to the pool liner or walls
9. Abnormal water loss or leakage from the source storage pool
10. Pool water conductivity exceeding 100 microsiemens per centimeter.

B. Was any radioactive material lost or stolen? Were reports made? [10 CFR 20.2201, 10 CFR 30.50]

C. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.50]

D. Did any overexposures and high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]

E. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?

F. Is the management/RSO/shift foreman licensee aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]

Posting and Labeling

A. NRC-Form 3 "Notice to Workers" posted? [10 CFR 19.11]

B. NRC regulations, license documents posted or a notice posted? [10 CFR 19.11, 10 CFR 21.6]

C. Other posting and labeling? [10 CFR 20.1902, 10 CFR 20.1904]

According to 10 CFR 36.23(g), the radiation room of a panoramic irradiator must be posted as a "high radiation area." However, 10 CFR 20.1902(c) requires that the area be posted as a "very high radiation area." There has been an oversight in not adopting in 10 CFR Part 36 the "very high radiation area" concept that is contained in 10 CFR Part 20. The NRC plans to change 10 CFR 36.23(g) to require posting as a "very high radiation area." In the meantime, the preferred posting is "very high radiation area," and irradiators posted in this manner will not be subject to enforcement action under 10 CFR 36.23(g).

Record Keeping for Decommissioning

A. Records kept of information important to decommissioning? [10 CFR 30.35(g)]

B. Records include all information outlined in [10 CFR 30.35(g)]?

Bulletins And Information Notices

A. NRC Bulletins, NRC Information Notices, NMSS Newsletters, received?

B. Appropriate training and action taken in response?

Special License Conditions or Issues

A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?

Deficiencies Identified in Audit; Corrective Actions

A. Summarize problems/deficiencies identified during audit.

B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? Include date(s) when corrective actions are implemented.

C. Provide any other recommendations for improvement.

Evaluation of Other Factors

A. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (RSO) oversight?

B. RSO has sufficient time to perform his/her radiation safety duties?

C. Licensee has sufficient staff to support the radiation protection program?

Appendix L

Model Survey Instrument Calibration Program

Model Survey Instrument Calibration Program

Training

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

- Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:
  - — Principles and practices of radiation protection
  - — Radioactivity measurements, monitoring techniques, and the use of instruments
  - — Mathematics and calculations basic to using and measuring radioactivity
  - — Biological effects of radiation.

- On-the-job-training will be considered complete if the individual has:
  - — Observed authorized personnel performing survey instrument calibration, and
  - — Conducted survey meter calibrations under the supervision, and in the physical presence of an individual already authorized to perform calibrations.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present
- Individuals conducting calibrations will wear assigned dosimetry
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

1. A radioactive sealed source(s) will be used for calibrating survey instruments, and this source will:

   - Approximate a point source
   - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ± 5% accuracy by National Institutes of Standards and Technology (NIST)

- Contain a radionuclide which emits photons of identical or similar energy as the sealed sources that the instrument will measure
- Be strong enough to give an exposure rate of at least 30 mR/hour (7.7 microcoulomb/kilogram per hour) at 100 cm [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of Co-60].

2. Inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.

3. A record must be made of each survey meter calibration.

4. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than ±20%.

5. There are three kinds of scales frequently used on radiation survey meters. They are calibrated as follows:

   - Meters on which the user selects a linear scale must be calibrated at not fewer that two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
   - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.
   - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

6. Readings above 200 mR/hour (50 microcoulomb/kilogram per hour) need not be calibrated. However, higher scales should be checked for operation and approximately correct response.

7. Survey meter calibration reports will indicate the procedure used and the results of the calibration. The reports will include:

   - The owner or user of the instrument
   - A description of the instrument that includes the manufacturer's name, model number, serial number, and type of detector
   - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure

- For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
- The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument)
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument
- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
- The exposure rate from a check source, if used
- The signature of the individual who performed the calibration and the date on which the calibration was performed.

8. The following information will be attached to the instrument as a calibration sticker or tag:

- The source that was used to calibrate the instrument
- The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
- The date of calibration and the next calibration due date
- The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org>.

See the Notice of Availability (on the inside front cover of this report) to obtain copies of Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

Appendix M

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in 10 CFR 20.1201. However, irradiator operators are required by 10 CFR 36.55(a) to wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. Also, other individuals who enter the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. When groups of visitors enter the radiation room at least two people must wear dosimeters. In those instances where pocket chambers are used instead of film badges or TLDs, a check of the response of the dosimeters to radiation must be made at least annually. Acceptable dosimeters must read within plus or minus 30% of the true radiation dose. To demonstrate that dosimetry is *not* required for other workers, a licensee needs to have available, for inspection, an evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing work near the irradiator shield or areas of cable or equipment penetration of the shield of the irradiator. However, for most irradiators even these activities result in the individual receiving minimal doses. A licensee will need to evaluate the doses which its workers might receive in performing these tasks to assess whether dosimetry is required. The evaluation may be done by carefully measuring the dose rates when the source is in the irradiate position using techniques similar those as described in Appendix N. An evaluation of the actual time workers spend in the area can provide the information needed to estimate the annual dose of the workers.

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 millirems) per year.

Example: A careful measurement of the highest dose rate at the face of the shield of a panoramic irradiator is found to be 0.015 mSv/hr (1.5 mrem/hr). An individual is expected to spend no more than 3 hours per week in the area near the shield. Based on the dose rate, assuming the source is continuously in the irradiate position while the work is being performed, the annual dose is expected to be less than 2.34 mSv (234 mrem) (i.e., 3 hr/wk x 1.5 mrem/hr x 52 wk/yr). Based on the above specific information, no dosimetry is required if the individual performs work in the area less than 6.4 hours per week.

Appendix N

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

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

Members of the public include persons who live, work, or may be near locations where an irradiator is used or where the sealed sources for the irradiator are stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or sources stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both portions of the regulation. For areas around irradiator facilities, a combination of calculations and measurements (e.g., using an environmental TLD) is often used to prove compliance.

Combined Measurement - Calculational Method[8]

These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a "work year" of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

[8] For ease of use, the examples in this Appendix use conventional units. The conversions to SI units are as follows: 1 ft = 0.305 m; 1 mrem = 0.01 mSv.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs[9] in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

The combined measurement-calculational method may be used to estimate the maximum dose to a member of the public. Since 10 CFR Part 36 irradiators are designed so that the maximum dose rate in any public area is less than 0.02 mSv (2 mrem) in any one hour, the licensee will generally be able to show by calculation that the maximum dose to an individual will be less than the 1 mSv/yr (100 mrem/yr) limit. The combined measurement-calculational method takes a tiered approach, going through a two-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source; (2) typical radiation levels encountered when the source is in the unshielded position; and (3) no credit is taken for any shielding found between the irradiator shield and the unrestricted areas. The method is only valid for the source activity at the time of measurement and must be repeated if the source strength or shielding is changed.

Even though most large irradiators approximate a planar source, the results obtained from a point source assumption will be conservative and therefore may be used.

Part 1 of the combined measurement-calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. Part 2 considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a method for estimating conservative doses which could be received.

[9] TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF_2 that are used for environmental monitoring.

Example

To better understand the combined measurement-calculational method, we will examine Food-Safe, Inc., an irradiator licensee. Yesterday, the company's president noted that the shield of the new irradiator area is close to an area used by workers whose assigned duties do not include the use of licensed materials and he asked Leslie, the Radiation Safety Officer (RSO), to determine if the company is complying with NRC's regulations.

The area in question is near the wall which constitutes the primary shield of the irradiator. Leslie measures the distance from the shield to the center of the area in question and, using a calibrated survey instrument, measures the highest dose rate at one foot from the shield, to be 2 mrem per hour.

Table N.1 summarizes the information Leslie has on the irradiator.

Table N.1 Information Known About Dose at the Shield of the Irradiator

Description of Known Information	Co-60 Panoramic Irradiator
Dose rate encountered at 1 foot from the face of the shield, in mrem/hr.	2 mrem/hr.
Distance from the face of the shield to the nearest occupied work area, in ft.	4 ft

Example: Part 1

Leslie's first thought is that the distance between the irradiator shield and the area in question may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst case approach, he assumes: 1) the irradiator is constantly in use (i.e., 24 hr/d), and 2) the workers are constantly in the unrestricted work area (i.e., 24 hr/d). Leslie proceeds to calculate the dose the workers might receive hourly and yearly from the irradiator as shown in Table N-2 below.

Table N.2 Calculational Method, Part 1: Hourly and Annual Dose Received from Irradiator

Step No.	Description	Input Data	Results
1	Multiply the measured dose rate measured at 1.0 ft from the face of the shield wall in mrem/hr by the square of the distance (ft) at which the measurement was made (e.g., 1 foot from the face of the shield)	$2 \times (1)^2$	2
2	Square of the distance (ft) from the face of the shield to the nearest unrestricted area, in ft^2	$(4)^2$	16

Step No.	Description	Input Data	Results
3	Divide the result of Step 1 by the result of Step 2 to calculate the dose received by an individual in the area near the shield. **HOURLY DOSE RECEIVED FROM IRRADIATOR**, in mrem in an hour	2/16	**0.125**
4	Multiply the result of Step 5 by 40 hr/work week x 52 weeks/year = **MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR**, in mrem in a year	0.125 X 40 X 52	**260**

Note: The result in Step 3 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the result in Step 4 exceeds 100 mrem/yr, proceed to Part 2 of the calculational method.

At this point, Leslie is pleased to see that the total dose that an individual could receive in any one hour is only 0.125 mrem in an hour, less than the 2 mrem in any one hour limit but notes that an individual could receive a dose of 260 mrem in a year, higher than the 100 mrem limit.

Example: Part 2

Leslie reviews the assumptions and recognizes that the workers are not in area near the shield all of the time. A realistic estimate of the number of hours the workers spend in the area is made, keeping the other assumptions constant (i.e., the irradiator is in constant use (i.e., 24 hr/d). The annual dose received is then recalculated.

Table N.3 Calculational Method, Part 2: Annual Dose Received from a 10 CFR Part 36 Irradiator

Step No.	Description	Results
5	A. Average number of hours per day an individual spends in area of concern (e.g., a non-radiation worker spends 1.5 hr/day in the area near the shield; the remainder of the day the workers are away from the area assigned to jobs unrelated to radiation. (painting, grounds keeping, desk jobs, etc.)	1.5
	B. Average number of days per week in area	5
	C. Average number of weeks per year in area (e.g., full time workers)	52

Step No.	Description	Results
6	Multiply the results of Step 5.A. by the results of Step 5.B. by the results of Step 5.C. = **AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR**	1.5 x 5 x 52 = **390**
7	Multiply the results in Step **3** by the results of Step 6 = **ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN**, in mrem in a year	0.125 x 390 = **49**

Leslie is pleased to note that the calculated annual dose received is significantly lower, and does not exceed the 100 mrem in a year limit.

Since most irradiators are in use a majority of the time, and down time is usually unpredictable, generally no additional allowance for irradiator duty cycle is made.

Leslie is glad to see that the results in Step 7 show compliance with the 100 mrem in a year limit. Had the result in Step 7 been higher than 100 mrem in a year, then Leslie could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding[10] located between the irradiator shield and the public area — such calculation is beyond the scope of this Appendix

Take corrective action (e.g., change work patterns to reduce the time spent in the area near the shield) and perform new calculations to demonstrate compliance

Designate the area inside the use area as a restricted area and the workers as occupationally exposed individuals. This would require controlling access to the area for purposes of radiation protection and training the workers as required by 10 CFR 19.12

Note that in the example, Leslie evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations

[10] National Council on Radiation Protection and Measurements (NCRP) Report No. 49, " Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV," contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

(e.g., adding sources to the irradiator, changing the work habits of the workers, or otherwise changing the estimate of the portion of time spent in the area in question) and to perform additional evaluations, as needed.

RECORDKEEPING: 10 CFR 20.2107 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Appendix O

Typical NRC Incident Notifications Required for Irradiator Licensees

Typical NRC Incident Notifications Required for Irradiator Licensees

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
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 (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
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)
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)
Source stuck in an unshielded position	24 hours	30 days	10 CFR 36.83(a)(1)
Any fire or explosion in a radiation room	24 hours	30 days	10 CFR 36.83(a)(2)
Damage to the source racks	24 hours	30 days	10 CFR 36.83(a)(3)

Event	Telephone Notification	Written Report	Regulatory Requirement
Failure of the cable or drive mechanism used to move the source racks	24 hours	30 days	10 CFR 36.83(a)(4)
Inoperability of the access control system	24 hours	30 days	10 CFR 36.83(a)(5)
Detection of radiation source by the product exit monitor	24 hours	30 days	10 CFR 36.83(a)(6)
Detection of radioactive contamination attributable to licensed radioactive material	24 hours	30 days	10 CFR 36.83(a)(7)
Structural damage to the pool liner or walls	24 hours	30 days	10 CFR 36.83(a)(8)
Abnormal water loss or leakage from the source storage pool	24 hours	30 days	10 CFR 36.83(a)(9)
Pool water conductivity exceeding 100 microsiemens per centimeter	24 hours	30 days	10 CFR 36.83(a)(10)

Note: Telephone notifications shall be made to the NRC Operations Center at 301-951-0550 except as noted.

Appendix P

Model Leak Test Program For Dry-Source-Storage Irradiator Sealed Sources

Model Leak Test Program For Dry-Source-Storage Irradiator Sealed Sources

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and the use of instruments
- Mathematics and calculations basic to the use and measurement of radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- A NaI(Tl) well counter system with a single or multichannel analyzer will be used to count samples from sealed sources containing gamma-emitters (e.g., Cs-137, Co-60).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at least every 6 months.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.[11]
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 200 becquerels (0.005 microcurie)[12] of the radionuclide.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ±5% of the stated value and traceable to a primary radiation standard such as those maintained by the National Institutes of Standards and Technology (NIST).
- Calculate efficiency.

For example: $\frac{\text{[(cpm from std) - (cpm from bkg)]}}{\text{activity of std in Bq}}$ = efficiency in cpm/Bq

where: cpm = counts per minute
std = standard
bkg = background
Bq = Becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example: $\frac{\text{[(cpm from wipe sample) - (cpm from bkg)]}}{\text{efficiency in cpm/Bq}}$ = Bq on wipe sample

- Sign and date the list of sources, data and calculations. Retain records for 3 years.

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[11] Prepare one swipe per irradiator, if more than one source is contained in the same enclosure.

[12] 10 CFR Part 36 uses one significant figure in converting becquerels to microcurie.

- If the wipe test activity is 200 becquerels (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify NRC.

Appendix Q

Transportation

Transportation

Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of licensed materials used in irradiators are as follows:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities
- Shipping Papers 49 CFR 172.200-204: general entries, description, additional description requirements, shipper's certification
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.800, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.415, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A_1 and A_2…, table of A_1 and A_2 values for radionuclides, radiation level limit, requirements for USNRC-approved packages (Type B), quality control requirements prior to each shipment…, approval of special form radioactive materials

- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Appendix R

Exemptions for Teletherapy Units Converted to Non-Human Use

Exemptions for Teletherapy Units Converted to Non-Human Use

The following are technical justifications and commitments which are acceptable to exempt licensees from specific sections of 10 CFR Part 36. The Regions may grant the exemptions shown below without prior coordination with NMSS. Acceptable license conditions are also shown below.

1. 10 CFR 36.23(a) - "The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources."

   For converted teletherapy units, the use of a single key or even several keys on a key-ring may be impractical. The key-switch on many control panels is a 3-position switch which controls electrical power to the teletherapy unit. The key can only be inserted/removed in the "off" position, and in this position the main power and control circuits are without electrical power. Power is required to move collimators, activate field lights, align system, etc. Requiring a single key would not allow the licensee to operate these powered systems.

   Therefore, a licensee may be exempted from this requirement, provided that the licensee commits to have the operator present for the entire period of time that the key is in the control panel.

   The following license condition should be used:

   "Notwithstanding the requirements of 10 CFR 36.23(a), the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter/application dated _____ ."

2. 10 CFR 36.23(b) - "…each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while sources are exposed."

   The licensee may be granted an exemption from this requirement provided that the licensee has an electrical interlock system meeting all of the conditions specified in 10 CFR 35.615(b) on each entrance to the radiation room. Alterations of the electrical interlocks of the teletherapy unit to meet the requirements of 10 CFR 36.23(b) may cause the interlock system to function incorrectly. A working electrical interlock system on each entrance suffices to prevent personnel entry while the source is exposed. The licensee should commit in its application to each of the conditions of 10 CFR 35.615(b). In addition, the licensee should commit to having an operator present during the entire irradiation who can visually observe the entrance, and to having a radiation monitor that can be read before entering the radiation area.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from having an independent backup access control to detect personnel entry while sources are exposed based on the commitments described in the letter/application dated _____ ."

3. 10 CFR 36.23(c) - "…The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high."

   Alteration of the interlock system to meet this requirement would prevent entry to the treatment room to remove a patient in the event of a stuck source. The region may grant the licensee an exemption from this requirement provided that the licensee has an electrical interlock system which will retract the source, upon opening access doors to the radiation room and commits to its use. In addition, the licensee must commit to having an operator present and having a radiation monitor in the room as described above.

   The following license condition should be used:

   "Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from having the monitor integrated with personnel access door locks to prevent room access when radiation levels are high based on the commitments described in the letter/application dated _____ ."

4. 10 CFR 36.23(d) - "…visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position."

   An acceptable justification is that an audible alarm within the treatment room may cause undue distress to the patients (human or animal). If the licensee commits to having a visual alarm provided on the outside of the treatment room, and to having the operator visually check the room before starting treatments, the regions may grant the licensee an exemption.

   The following license condition should be used:

   "Notwithstanding the requirements of 10 CFR 36.23(d), the licensee is exempt from having an audible alarm within the treatment area, based on the commitments described in the letter/application dated _____ ."

5. 10 CFR 36.23(f) - "Each radiation room at a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door…has been closed within a preset time…"

   Exemptions may be granted to licensees having teletherapy units that are being used for irradiation of materials only (no patients), provided that the licensee commits to the operator visually verifying that the room is not occupied before closing the door, and that

the converted teletherapy unit (irradiator) activates a visual and audible alarm in the teletherapy room for at least 15 seconds before moving the source from the shielded position. This visual/audible alarm must be interlocked with the teletherapy unit such that the source will not move to the exposed position until the visual/audible alarm has been activated and is finished alarming. The use of a visual/audible alarm in a patient treatment room may cause anxiety for patients. Therefore, licensees having teletherapy units that are being used for both patient treatment (human or animal) and object or material irradiation may be authorized an exemption from 10 CFR 36.23(f) without the need to have a visual/audible alarm, if the licensee commits to having an operator visually verify that the room is not occupied before closing the door and if the licensee has a means of visually observing the area as required in 10 CFR 35.615(e). If the unit is not used for patients, then the audible/visible alarm described above is required.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.23(f), the licensee is exempt from having a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time based on the commitments described in the letter/application dated _____ ."

6. 10 CFR 36.27(a) - "…The sources must automatically become shielded if a fire is detected."

   10 CFR 36.27(b) - "…be equipped with a fire extinguishing systems capable of extinguishing a fire without entry of personnel. The system must have a shutoff valve to control flooding into unrestricted areas."

   The Statements of Consideration state that the purpose of the fire extinguishing system is to prevent a fire from damaging the access control system or preventing the sources from being shielded. Most converted teletherapy units are designed to retract the source when the electrical power fails, as may occur during a fire. The licensee may be granted an exemption from these requirements provided that the licensee commits to the following:

   - Having smoke detectors, fire extinguishers and a fire alarm at the site to detect and fight small fires
   - Alerting authorities of the fire
   - Having a means of measuring the radiation levels in the radiation room during an electrical failure
   - Instructing the operators to retract the source before exiting for a fire involving major portions of the facility, provided this action does not jeopardize the operator's safety.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.27(a) and (b), the licensee is exempt from (*as requested by the licensee*) based on the commitments described in letter/application dated _____ ."

7. 10 CFR 36.31(a) - "The key must be attached to a portable radiation survey meter by a chain or cable… The door to the radiation room must require the same key."

Converted teletherapy units require that the source activation key be inserted in the console to provide power to the unit to activate field lights and align the head. Therefore, the region may grant the licensee an exemption from this requirement provided that the licensee commits to having administrative controls in place to ensure that personnel entering the radiation room use a portable survey meter to verify that the source has retracted. The licensee must also commit to attach the survey meter to the exposure room door key.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirement to have console key attached to a portable survey meter by a chain or cable and that the door to the radiation room require the same key, based on the commitments described in the letter/application dated _____ . The radiation room door key shall be attached to the portable survey meter."

8. 10 CFR 36.31(b) - "…The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in…transit."

In converted teletherapy units the source is moved nearly instantaneously from the shielded to the exposed position. Most teletherapy units are designed with two indicator lights — green indicates the source is in the fully shielded position, red indicates the source is exposed. During transit both lights are "on" indicating that the source is in transit. To require that the licensee install an electronic system to indicate "in transit" for the period of time the source is in transit, less than a second, does not provide any additional protection. Therefore, the region may grant this exemption provided the licensee submits a description of its device indicators.

The following license condition should be used:

"Notwithstanding the requirements of 10 CFR 36.31(b), the licensee is exempt from the requirement to have a separate position indicator to indicate when the source is in transit, in accordance with letter/application dated _____."

9. 10 CFR 36.67(b)(2) - "…the irradiator operator…must activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control."

   Because of the risk of malfunction associated with alterations to the existing electrical interlocks of the teletherapy unit, and considering the licensee's commitment to administratively control access to the room to meet the intent of this regulation, the region may grant this exemption, if the licensee demonstrates that a retrofit to install such a control would not be possible with the teletherapy unit and a licensee commits to the following:

   The operator will close the doors immediately upon completion of the visual inspection required by 10 CFR 36.67(b)(1).

   The operator will verify that each door has locked automatically before stepping to the control panel.

   The following license condition should be used:

   "Notwithstanding the requirements of 10 CFR 36.67(b)(2), the licensee is exempt from the requirement to have a control in the radiation room which must be activated prior to irradiation which would not allow the source to be moved from the shielded position unless the door to the radiation room is locked within a preset time, based on the commitments described in the letter/application dated _____ ."

Appendix S

Sample Licenses for 10 CFR Part 36 Irradiators

Sample Licenses for 10 CFR Part 36 Irradiators

This appendix contains examples of irradiator licenses that the NRC would issue to an applicant who meets the requirements in 10 CFR Part 36. The three types are:

- Dry-source-storage panoramic
- Wet source-storage panoramic
- Underwater type irradiator.

The authorizations in the sample licenses do not necessarily reflect those normally provided to an applicant. For example, any authorizations for exemptions to 10 CFR Part 36 would require the applicant to have specific procedures approved by the NRC, following a specific request for an exemption.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Best Research Institute	3. License No. 19-12345-01
2. 1234 Main Street Anywhere, USA 20000	4. Expiration date September 30, 2007
	5. Docket No. 030-12345 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt - 60	A. Sealed sources contained in (XYZ Capsule Type X-145)	A. 2,000 curies

9. Authorized use

A. For use in XYZ Pinto-22 teletherapy unit to perform irradiation studies on cell cultures and small animals, excluding explosives, flammables, or corrosives.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 432 Main Street, Anywhere, USA.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the last use of licensed material by the individual.

B. The Radiation Safety Officer for this license is Enrico Foomie.

12. Sealed sources containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

13. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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SUPPLEMENTARY SHEET

License Number
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Docket or Reference Number
030-12345

Amendment No.

14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

15. Licensed material shall not be used in or on human beings.

16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

17. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated September 1997

Date _____ By _____

John Q. Reviewer, Health Physicist
Nuclear Materials Licensing Branch
NRC Region
City, State 54321

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. UnderWater Irradiator Inc.	3. License No. 08-12345-01
2. 1234 Main Street Anywhere, USA 20000	4. Expiration date April 30, 2007
	5. Docket No. 030-12345 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt-60	A. Sealed sources (XYZ Sources Inc. DWG A2002)	A. 80,000 curies
B. Cobalt-60	B. Sealed sources (ZYX Inc. Dwg. 10-C935 hollow, solid, or clad sources encapsulated per ZYX Dwg. A 20007)	B. 2,000,000 curies
C. Cobalt-60	C. Sealed sources (ABC Inc. Model 34W)	C. 50 millicuries

9. Authorized use

A. and B. For irradiation of materials other than explosives or corrosive materials.
C. For use in the calibration of the licensee's radiation detection equipment.

CONDITIONS

10. A. Licensed material may be used at the licensee's facilities located at 1234 Main Street, Anywhere, U.S.A.

11. A. Licensed material shall be used by, or under the supervision of individuals who have satisfactorily completed the training and examination described, in the application dated January 29, 1997 and have been designated in writing, by the Radiation Safety Officer. The licensee shall maintain

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 08-12345-01

Docket or Reference Number 030-12345

Amendment No.

records of individuals designated as users for 3 years following the last use of licensed material by the individual.

B. The Radiation Safety Officer for this license is A. Loyd Webber.

12. A. Sealed sources containing licensed material specified in item 6.C shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years. **[Note: The calibration source is not covered by the leak test requirement in 10 CFR 36.59]**

B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately remove the source from service, to report to the Nuclear Regulatory Commission according to 10 CFR 30.50(b)(2) and (c)(1), and have the source decontaminated, repaired, or disposed of according to Commission regulations. The licensee shall file a written report according to 10 CFR 30.50(c)(2).

E. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

13. Sealed sources containing licensed material shall not be opened.

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030-12345

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14. The licensee shall implement the material accountability program described in letter dated March 8, 1997, to account for all sealed sources containing licensed material received and possessed under the license

15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material,"

16. Irradiation and distribution of foods for human consumption shall be in accordance with the rules and regulations of the Food and Drug Administration and the U.S. Department of Agriculture.

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated January 29, 1997
    B. Letter received March 8, 1997

For the U.S. Nuclear Regulatory Commission

Date _____ By _____

John Q. Reviewer, Health Physicist
Nuclear Materials Licensing Branch
NRC Region
City, State 54321

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Really Big Irradiator Inc.	3. License No. 19-1234-01
2. 1234 Main Street Anywhere, USA 20000	4. Expiration date September 30, 2005
	5. Docket No. 030-12345 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt-60	A. Sealed sources (XYZ Sources DWG A2345)	A. 3,000,000 curies

9. Authorized use

   A. For use in an XYZ Model D-230 irradiator for irradiation of materials except explosives, flammables, or corrosives.

10. Licensed material may be used only at the licensee's facilities located at 1234 Main Street, Anywhere, USA.

11. A. Licensed material shall be used by, or under the supervision and in the physical presence of individuals who have satisfactorily completed the training and examination described in Item 8 of application dated January 28, 1997 and have been designated in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual

    B. The Radiation Safety Officer for this license is Jayson M. Rutherford.

12. Sealed sources containing licensed material shall not be opened by the licensee.

13. The licensee shall implement the material accountability program described in letter dated June 28, 1997 to account for all sealed sources containing licensed material received and possessed under the license.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
08-12345-01

Docket or Reference Number
030-12345

Amendment No.

15. Irradiation and distribution of foods for human consumption shall be in accordance with the rules and regulations of the Food and Drug Administration and the U.S. Department of Agriculture.

16. The licensee is authorized to make modifications to the source rack as requested in letter dated August 27, 1997. The licensee shall test the movement of the source rack for proper operation in accordance with 10 CFR 36.41(f) and (i) prior to source loading.

17. Except as specif
ically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated June 28, 1997
B. Letter dated August 27, 1997

Date _____ By _____

John Q. Reviewer, Health Physicist
Nuclear Materials Licensing Branch
NRC Region
City, State 54321

Appendix T

Addendum: Response to Comments on Draft NUREG - 1556, Vol. 6, Dated March 1998

Addendum: Responses to Comments on Draft NUREG - 1556, Vol. 6, Dated March 1998

Table T.1 Mark Smith, Corporate Manager of Technical Services, Sterigenics International, Dated May 18, 1998

Section	Page	Paragraph	Comment
8.6	8-9	3rd from end of page	The prohibition against cryogenic materials is not in current regulations and is not well defined at this point. Referring to Appendix F gives more information, but is still extremely limited. Considering that the NRC and Agreement States will use this guidance in reviewing license applications, more guidance is necessary. For example, define the temperature of concern or specific conditions under which the effect is noted. Some irradiator applications, such as tissue irradiation, use dry ice to maintain low temperatures and maintain integrity of the product. Broad use of the term "cryogenic" could result in prohibitions against this application, even though it would appear not to be included in the temperatures of concern (based on condensation of air). Imposing prohibitions that are not in the regulations through license application review is not a good method to ensure consistency in applying the interpretation. A better approach would be to propose adding the cryogenic prohibition in the regulations, presenting the appropriate data and making a final decision on the risks associated with the practice, including considering the probability and mechanisms of occurrence.

Section	Page	Paragraph	Comment

NRC Staff Response: As recognized in the comment, irradiated cryogenic material may or may not become explosive dependent upon numerous factors some of which are not clearly understood. The guidance in Section 8.6 and Appendix F does not prohibit use of cryogenic materials in irradiators. In the text the guidance states that cryogenic materials are an example of materials not listed in the SSD registration certificate. The prohibition of irradiation of explosive material is contained in 10 CFR 36.69 and provides for NRC review on a case by case basis. The guidance provided is intended to alert licensee's to the fact that under certain conditions, irradiated cryogenic materials can explode. As stated in the guidance in Appendix F, the exact details of the phenomenon is uncertain. It is believed that oxygen in the air is converted by the radiation to ozone. Under certain circumstances (often during a subsequent warm-up), the ozone decomposes or reacts with other agents explosively. Since the details of the conditions required for this phenomenon are uncertain but may lead to serious consequences, the licensee should carefully analyze any proposed irradiation of cryogenic material, design adequate safeguards and/or procedures, and submit its analysis for review by the NRC.

The staff has for clarification, made minor revisions to the original text in Item 6: Purpose(s) for Which Licensed Material will be Used.

8.8.03	8-18	2nd (titled: "Discussion")	The requirement is given for training all personnel who work in or frequent restricted areas. This does not agree with the current version of 10 CFR 19.12 (e.g., limited to those likely to receive annual occupational dose of 100 mrem).

NRC Staff Response: The first sentence in the first paragraph under "Discussion" in Item 8.8.03 has been revised and now states: "…According to 10 CFR 19.12, all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1mSv) must receive appropriate instruction in radiation safety…"

Section	Page	Paragraph	Comment
8.9.01	8-19	1st under "Discussion"	Considering the shielding requirements and the low probability of any offsite consequences from irradiator operations, the general layout of properties adjacent to building should be of no particular interest. It should be sufficient for the licensee to verify that the facility is located in accordance with the local zoning restrictions (i.e., "...in an area zoned industrial."). [This requirement is repeated on page 8-20.]
NRC Staff Response: The last sentence in the first paragraph under "Discussion" and the third bullet under "Response from Applicant" in Item 8.9.01 have been removed. As a reminder, it should be noted that as defined in 10 CFR 36.1(a) and Item 8.3, an NRC license does not relieve the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.			
8.9.01	8-19	last on page	Using the phrase "…any construction activities not yet completed…" is inaccurate for new facility licenses, since 10 CFR 36.15 states that the application has to be submitted prior to starting irradiator construction. The guidance should be to provide "…a schedule for construction of the irradiator." (It is stated correctly on page 8-20.)
NRC Staff Response: The first sentence in the second paragraph under "Discussion" in Item 8.9.01 has been revised and now states: "…An applicant should provide a schedule for construction activities associated with the irradiator…"			
8.9.02	8-21	last on page	The term "direct radiation beam" is used. For a panoramic irradiator, which is what most of those covered by this guidance are, the concept needs to be explained. For example, does this mean that portion of the room that has no materials interposed between the sources and the area under consideration? The concept of a "beam" does not apply to panoramic irradiators in the traditional interpretation of the term. An operational definition as to how that concept is to be applied would be useful in this guidance.

Section	Page	Paragraph	Comment
NRC Staff Response: The NRC staff agrees with this comment; however, 10 CFR 36.23(c) specifically states the sentence using the term "direct radiation beam." In order to clarify this, the last sentence in the fifth paragraph under "Panoramic Irradiators" in Item 8.9.02 has been revised and now states: "…The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam (e.g., an area of the maze that may expose the instrument directly to the irradiator sources when in the unshielded position…"			
8.9.02	8-22	last	This paragraph is unclear. I was unable to determine exactly what requirement was being considered and what the stated rationale was for it. This radiation monitor appears to be the one required under 10 CFR 36.23(b), but that was addressed on the previous page. If that was what was intended, then this paragraph should be deleted, as the pertinent requirements are covered earlier. If that is not what was intended, this paragraph would then appear to be imposing a requirement for an additional radiation monitor not called for in either the pertinent ANSI documents or the NRC regulations.
NRC Staff Response: The ninth paragraph under "Panoramic Irradiators" in Item 8.9.02 has been deleted.			

Section	Page	Paragraph	Comment
8.9.03	8-24	1st under "Discussion"	The guidance should clarify what effects are expected from heating in shield walls (i.e., how can an individual reviewing a license application determine if the NRC concerns have been adequately addressed ?). The only reasonable concern from the NRC perspective should be for compromising radiation shielding or structural stability in the walls. Since these facilities with more than 5 MCi are typically constructed with 6 feet (or more) of concrete, it is hard to imagine any scenario in which heating from the sources would compromise either the shielding or structure. However, since the requirement is in the regulations, it must be addressed in the guidance. As a minimum, the guidance should give direction to the license reviewer and applicant as to what evaluation should be done and provide references to which either can go to find additional information…such as maximum temperature tolerances for concrete and an explanation of the likely effects from exceeding those temperatures.

NRC Staff Response: The criteria for this requirement was based on industry standards and consensus at the time the final rule was amended to the regulations. Thermal effects are a concern because of its effects on shielding (e.g., deterioration of concrete walls when exposed to high temperatures). As a result, licensees should conduct this evaluation to determine what impact thermal effects would have on the type of shielding used at their facility. Licensees should submit what additional engineering controls or designs that need to be implemented to prevent thermal effects that may damage shielding. In order to clarify this matter, the fourth bullet under the first box in Item 8.9.03 has been revised and now states:

- If the irradiator will use more than 2 X 10^{17} (Bq) (5 million curies) of activity, the applicant must evaluate the effects of heating of the shielding walls by the irradiator sources (e.g., thermal effects on concrete)…

Section	Page	Paragraph	Comment
8.9.03	8-25	last	The guidance document says that possession limits of more than 5 MCi requires the licensee provide a description of how cooling the shield walls will be done. The requirement of 10 CFR 36.39(a) is that, at that activity level, the licensee must evaluate possible heating effects. Cooling may not be required until much higher activity levels are loaded into the irradiator.
NRC Staff Response: The fourth bullet under "Response from Applicant: • For Panoramic Irradiators… to Item 8.9.03 has been revised and now states: "…For requests to possess more than 2 X 10^{17} Bq (5,000,000 curies), submit an evaluation of the effects of heating of the shield walls by the irradiator sources…"			
8.9.04	8-27	1st	The last sentence of this paragraph is unclear. Whether the source position indicators, access control system, and source return system operate properly in a fire does not relate to having the fire extinguishing system operable without entering the radiation room. The best approach would be to delete that sentence, as it adds nothing to the interpretation of the regulatory requirement.
NRC Staff Response: The subject matter regarding fire protection was discussed in the "Statements of Consideration" when 10 CFR Part 36 was made into a final rule. The sentence the commenter was referring to in the new guidance was the NRC's position regarding fire protection at the time the final rule was amended to the regulations. Based on this position, the guidance document was not revised in response to this comment.			

Section	Page	Paragraph	Comment
8.9.05	8-28	last	10 CFR 36.59 does not require that the water monitoring system be continuous. Later in the same paragraph, the statement is made that "Each time the irradiator operates, the licensee should measure for radioactive contamination in the pool water…" 10 CFR 36.59(b) states that monitoring is required "…each day the irradiator operates…"The irradiator may be operated several times in one day (assuming a batch system) or in a continuous mode. The guidance should be changed to read "each day."
NRC Staff Response: The second sentence in the bullet "For pool irradiators:" under "Discussion" in Item 8.9.05 has been revised and now states: "…The system should be equipped with a radiation monitoring device with an alarm which will stop all pool water recirculation should the radiation reach a preset alarm level…" The third sentence in the bullet "For pool irradiators:" under the "Discussion" in Item 8.9.05 has been revised and now states: "…Each day the irradiator operates,…"			
8.9.06	8-30	sentence directly above the box	This states that the purpose for maintaining pool liner integrity is to minimize the probability of contaminated water leakage. In the absence of contamination, it is still desirable to minimize the possibility of large leaks, since the water provides shielding for the sources.
NRC Staff Response: The second sentence under "Discussion" in Item 8.9.06 has been revised and now states: "…The purpose of the requirement is to reduce the likelihood of the pool leaking water that may be contaminated or used for shielding purposes…"			
8.9.06	8-30	next-to-last	The phrase "prevent corrosion" is much too strong, considering recent debate as to whether conductivity alone is an adequate indicator of pool water quality. Better wording would be "…minimize the probability of corrosion…"
NRC Staff Response: The last sentence in the fifth paragraph under "Discussion" in Item 8.9.06 has been revised and now states: "…The water purification system is needed to minimize the probability of corrosion of the sealed sources and the source rack…"			
8.9.07	8-32	2nd paragraph	The statement regarding "no crevices" needs to be clarified, i.e., what constitutes a crevice?

Section	Page	Paragraph	Comment
NRC Staff Response: The first sentence in the third paragraph under "Discussion" in Item 8.9.07 has been revised and now states: "…For pool irradiators, the licensee must verify that there are no crevices on the source or between the source and source rack that would promote corrosion on a critical area of the source (e.g., crevice corrosion, an inaccessible location in or around the sources or rack with low oxygen concentrations).			
8.9.07	8-32	2nd	An additional concern should also be expressed regarding the potential for sources to be dislodged from the source rack during these drops.
NRC Staff Response: The third sentence in the second paragraph under "Discussion" in Item 8.9.07 has been added and now states: "…In addition, licensees should review the potential of sealed sources to become dislodged from the source rack when dropped as a result of loss of power, failure of cables or other alternate means of support…"			
8.10.01	8-34	under "Response from Applicant"	According to this sentence, the license application is supposed to address reviewing the "…content and implementation…" of the program. No guidance is given on criteria for reviewing content, only for implementation.
NRC Staff Response: The first two pages of Appendix K provide guidance on reviewing the content of the program. Based on this, the guidance document was not revised.			
8.10.02	8-37	under "Survey Instruments"	The guidance says that individuals performing source manipulations should be monitored with a survey instrument. This implies that they should be checked for personnel contamination. A better way to state this would be to say that the "operations" must be monitored.
NRC Staff Response: The staff agrees with the comment and changes have been made to the text to indicate that operations must be monitored.			
8.10.02	8-37	last	This defines fail-safe radiation monitors as "a backup warning system." That is the definition for "redundant,"not 'fail safe." Redundancy is not required for monitors, nor should it be. However, a fail-safe system is and should be required, with the definition being that failures of the system cause the same response as detection of a high radiation level. (e.g., the door remains locked)

Section	Page	Paragraph	Comment
NRC Staff Response: The last sentence under the second heading of "Radiation Monitors" in Item 8.10.02 has been revised and now states: "…Monitors that warn individuals of the presence of high radiation or which are integrated with personnel access door locks to prevent room access under high radiation conditions should be designed to provide fail-safe operation, i.e., if the radiation monitor for any reason fails to respond to radiation, the door to the irradiator room remains locked until it has been determined that the sources are in the shielded position and safe for individuals to enter the room…"			
Table 8.3	8-40		A semiannual visual inspection is of extremely limited value in terms of source accountability. The only determination that could be made under such a procedure would be that sources are still in the source rack.
NRC Staff Response: A 6-month general visual inspection would be of little use in determining accountability of sources stored in the irradiator since the licensee would be unable to see if individual sources were missing. The concern that the team attempted to address with the 6-month general visual inspections was that the licensee should be able to verify that no sources have been lost. Sources are added to many pool irradiators on an approximately annual basis. As an alternative, it was thought that it would be reasonable to have the licensee verify that no sources have been lost during source loadings. The team felt that, for licensees that do not have sources loaded annually, it would be reasonable to verify that no sources have been lost at least every three years. The following was added as an item to be addressed in accountability procedures: "verify that no sources have been lost each time sources are added to, removed from, or moved within the irradiator or, at a minimum, every three years."			
Table 8.3	8-40		The phrase "irradiator location (if more than one irradiator is authorized)" should be replaced with "location of each source."
NRC Staff Response: Table 8.3 has been amended as suggested.			
Table 8.3	8-40		The irradiator use log is also of limited value in terms of source accountability.
NRC Staff Response: Table 8.3 has been amended to remove "Irradiator use log books" as an element of accountability procedures for Panoramic Dry-Source-Storage Irradiators.			

Section	Page	Paragraph	Comment
Table 8.3	8-40		A semiannual physical inventory in a dry-source-storage irradiator should not be a requirement, considering the difficulty in conducting such an inventory in a typical production model irradiator, where the source rack remains within its shield when not in operation and is not accessible during operations. However, it would be easy to conduct a physical inventory for teletherapy units converted to non-human use.
NRC Staff Response: Table 8.3 has been amended to remove "6-month physical inventory" as an item to be addressed in accountability procedures. This is do to the fact that it is not practical to visually observe sealed sources installed in Panoramic Dry-Source-Storage Irradiators.			
8.10.06	8-45	1st paragraph under "Discussion"	The requirement should be to provide copies of procedures "for" each operator, not "to" each operator. Since internal procedures are typically controlled documents under ISO 9001/9002 registrations, having each operator of a production irradiator, particularly with multiple irradiator locations, results in too many controlled copies and increases the probability that outdated copies would be in circulation. Same comment applies on page 8-51, sect. 8.10.07.
NRC Staff Response: Section 8.10.06, "Operating Procedures," has been changed as suggested.			
8.10.08	8-45	1st	Guidance should be provided on when to consider that a source may be leaking. The traditional action level is 0.005 μCi, which is of course not applicable to pool water monitoring. Some guidelines for licensees as to what levels are considered indicative of source leakage would be beneficial.
NRC Staff Response: Due to constant improvements in radiation detection technology, the staff determined that additional guidance as to what levels are considered indicative of source leakage in a pool type irradiator is not warranted at this time. In effect any increase in the radioactivity in the pool water should alert the licensee to a possible leaking source or sources. Based on this position, the guidance was not revised in response to the comment.			

Section	Page	Paragraph	Comment
Appendix F	F-1	3rd	The statement is made that the concern is for explosion during irradiator operations. However, the "small quantity" discussion uses the lower flammable limit as the defining value. If explosion is of concern, then the lower explosive limit should be used instead.
NRC Staff Response: With regards to the subject matter on flammable materials, the use of "lower explosive limits" as suggested by the cementer would not be appropriate in this case, in that, the lower flammable limit is appropriate when used in discussing this subject matter. After careful consideration by the staff it was determined that if such terminology were used in that context, it could be construed that it would be appropriate for licensees to irradiate materials under conditions conducive for explosive conditions. The intent of this statement was that when irradiating flammable liquids as allowed by the regulations, licensees must evaluate products to ensure that when irradiated the flash point or lowest temperature at which the vapor of the liquid would ignite to create an environment susceptible to explosion. Based on this position, the guidance document was not revised in response to the comment.			
Appendix O	O-2	3rd row of Table	"product" is misspelled: "Detection of radiation source by the prodect [sic] exit monitor"
NRC Staff Response: The first column in the 17th row under Table O.1 in Appendix O has been revised and now states: "…Detection of radiation source by the product exit monitor…"			
Appendix P	P-2	3rd bullet Item	Using a separate wipe for each source not practical in many dry source storage configurations.
NRC Staff Response: The staff agrees with the comment and has changed the text to read, "Prepare one swipe per irradiator, if more than one source is contained in the same enclosure."			

Table T.2 Joseph G. Klinger, Chief, Division of Radioactive Materials, State of Illinois Dated July 8, 1998

Section	Page	Paragraph	Comment
N/A	N/A	N/A	Many of the items discussed are already required by 10 CFR Part 36. Applicants should not have to submit information that is adequately covered by regulation.
NRC Staff Response: Since no specific examples were given by the cementer of information that should not be required of the licensee when filing a license application, it is difficult to respond directly to this suggestion. In general, the NRC appreciates the time and effort required to prepare license applications. Therefore, only information necessary to adequately evaluate a license application is requested. Document has not been revised in response to this comment			
8.7.01	8-11		In Section, page three months does not seem to be enough practical experience to be named as an RSO for an irradiator facility. This should be increased to at least six months.
NRC Staff Response: Staff experience indicates that three months is an adequate amount of practical experience to be named as an RSO at an irradiator facility. To date, no adverse outcomes have arisen from approving a RSO with three months of practical experience. Document has not been revised in response to this comment.			
8.9			Section 8.9 discusses requirements for facilities constructed after July 1, 1993, but does not clearly indicate if these requirements are applicable to facilities existing prior to this date. Obviously structural changes may be impossible, but systems such as radiation monitors, fire protection, access control, etc. should be updated.
NRC Staff Response: The cementer's suggestion is derived from the document's handling of the design requirements in 10 CFR 36.39 for irradiators whose construction begins after July 1, 1993. Section 8.9.03 was changed to specify the requirements that to clearly indicate that those design requirements that are applicable to irradiators whose construction begins after July 1, 1993. The cementer also addresses the issue of backfitting existing irradiators to the new standards. Since 10 CFR Part 36 does not address the issue of backfitting existing irradiators to the new standard, it is not addressed in this guide.			

Section	Page	Paragraph	Comment
8.9.03	8-25		Section 8.9.03, page 8-25, should clarify that diagrams showing the configuration of shielding and the thickness specifically for ceilings should be included. This information should also be added to page C-4.
NRC Staff Response: Section 8.9.03 has been amended to request diagrams showing the configuration of shielding including walls and the ceiling, and the thickness specifically for ceilings.			
8.9.04			Section 8.9.04 appears to contain conflicting information as to whether the fire extinguishing systems must actually be tested (e.g., with water spray and/or chemicals). Page 8-27 and Appendix J indicate testing of the fire extinguishing system is required, but page 8-55 indicates the fire extinguisher should not be turned on during the test.
NRC Staff Response: It is not required that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems. Section 8.9.04 and Appendix J have been amended to make this clear.			
8.9.06	8-30		Section 8.9.06, page 8-30 discusses pool water quality and the 20 microsiemens limit. Most of the manufacturers also require through their contracts for sale/warranties that the pH and chloride content also be monitored. These should be investigated for use in place of or in addition to the 20 microsiemen limit.
NRC Staff Response: Currently conductivity is the only regulated measure of pool water quality for irradiators (10 CFR 36.63). The NRC is concerned about the possible corrosion problems that may be caused by dissolved chlorides in pool water and the effects of low pH on sealed sources and irradiator components . However, since there are currently no regulatory limits for chloride content or pH, no monitoring of these qualities is suggested in this guidance document. Document has not been revised in response to this comment.			

Section	Page	Paragraph	Comment
8.10.02	8-37		Section 8.10.02, page 8-37 indicates survey instruments should measure at least 0.3 mR/hr through 200 mR/hr. 10 CFR 36.57 requires survey instruments to be capable of measuring a minimum of 0.05 mR/hr.
NRC Staff Response: Section 8.10.02, page 8-37 has been changed as suggested.			
N/A	N/A		A section should be added to the document which discusses limiting the cask activity limits and the length of time casks can be loaded at the maximum activity to ensure the manufacturer's recommended temperatures are not exceeded. Additionally, if the manufacturer's specifications for transport containers have not been determined, tests should be performed to establish these limits.
NRC Staff Response: As discussed in Section 8.10.10, "Transportation," transporting licensed materials originating at irradiator facilities normally involves quantities of radioactive material that require a Type B package. Because of the special requirements involved in shipping Type B packages, most irradiator licensees have chosen to transfer possession of radioactive materials to an irradiator manufacturer (or service licensee) with an NRC or Agreement State license who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 10 CFR 71.12 general license. Requirements for the issues identified by the cementer are normally found in Certificates of Compliance for Type B packages. QA plans are required to be implemented to assure that the requirements of Certificates of Compliance are met. Section 8.10.10, "Transportation," discusses guidance documents that adequately address QA Plans. Therefore, these issues have been adequately addressed in Section 8.10.10, "Transportation," especially when one considers that irradiator licensees do not normally transport licensed materials in Type B containers. Document has not been revised in response to this comment.			

Section	Page	Paragraph	Comment
Appendix J			Appendix J indicates what steps during pool irradiator construction the regulating agency should perform inspections to ensure the irradiator facility is being built to specifications. However, the time frames and critical construction points to be observed should be specified (i.e., inspections for voids during pours of shielding walls vs. after pours, etc.).

NRC Staff Response: This comment has already been addressed in Item 9: Facilities and Equipment. In the discussion, the applicant is directed to submit a construction schedule to allow the NRC to inspect such activities. The staff recognized the cementer's concern but after review determined that such activities vary from facility to facility based on designs and construction and would best be reviewed on a case-by-case basis. Providing the NRC a construction schedule would allow the NRC or other regulatory agency to make their own determinations as to when activities required inspection oversight. The document was not revised in response to this comment.