
Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Self-Shielded Irradiator Licenses

Final Report

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ABSTRACT

As part of its redesign of the materials licensing process, the Nuclear Regulatory Commission (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. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses," dated October 1998, is the fifth 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 supersedes the guidance found in Regulatory Guide (RG) 10.9, Revision (Rev.) 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators," dated December 1988, and in NMSS Policy and Guidance Directive (P&GD) FC 84-16, Rev. 1, "Standard Review Plan for Applications for Use of Self-Contained Dry Source-Storage Gamma Irradiators," dated January 26, 1989. This final report takes a more risk-informed, performance-based approach to licensing self-shielded irradiators, and reduces the information (amount and level of detail) needed to support an application to use these devices. It incorporates suggestions received during the comment period on draft NUREG-1556, Vol. 5. When published, this final report should be used in preparing self-shielded irradiator license applications. NRC staff will use this final report in reviewing these applications.

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FOREWORD

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, “Consolidated Guidance About Materials Licenses”:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About 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 Irradiators	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiators	Draft for Comment
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope	Draft for Comment
8	Program-Specific Guidance about Exempt Distribution Licenses	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Draft for Comment
10	Program-Specific Guidance about Master Materials License	Draft for Comment
11	Program-Specific Guidance about Licenses of Broad Scope	Draft for Comment

The current document (NUREG-1556, Vol. 5, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiators,” dated October 1998, is the fifth program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It supersedes the guidance for applicants and licensees previously found in RG 10.9, Rev. 1, “Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators,” dated December 1988, the guidance for licensing staff previously found in P&GD FC 84-16, Rev. 1, “Standard Review Plan for Applications for Use of Self-Contained Dry Source-Storage Gamma Irradiators,” dated January 26, 1989, and the documents marked with an asterisk (*) in Appendix A. NUREG-1556, Vol. 5, incorporates the comments received during the comment period on draft NUREG-1556, Vol. 5. See the Addendum for summaries of comments, staff responses, and other changes.

FOREWORD

This report takes a risk-informed, performance-based approach to licensing self-shielded irradiators, i.e., it reduces the amount of information needed from an applicant seeking to possess and use a relatively safe device. These self-shielded irradiators containing sealed sources of radioactive material incorporate features engineered to enhance their safety. NRC's considerable experience with these licensees indicates that radiation exposures to workers are generally low, if the irradiators operate as designed and workers follow basic safety procedures.

A team composed of NRC staff from headquarters and regional offices drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to self-shielded irradiators. A representative of NRC's Office of the General Counsel provided a legal perspective.

NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses," dated October 1998, 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 uniform resource locator (URL):
<<http://www.nrc.gov/NRC/NUREGS/SR1556/V5/index.html>>

The performance-based approach in NUREG-1556, Vol. 5, gives licensees greater flexibility than previously permitted under licenses based on applications prepared according to RG 10.9, Rev. 1. This guidance document permits licensees to make more changes in their radiation safety program without amending their licenses, thus reducing the regulatory burden on licensees and the NRC staff. Accordingly, existing self-shielded irradiator licensees have the option of submitting a complete application using NUREG-1556, Vol. 5, at the time that they file an amendment request. Licensees choosing this option should incorporate the requested change into the complete application, submit it with the appropriate amendment fee, and indicate that the complete revision is an amendment request to take advantage of the new guidance. When the staff has reviewed the request and resolved any outstanding issues, they will amend the license without changing the expiration date.

Licensees wishing to renew their licenses should submit a complete application according to NUREG-1556, Vol. 5. The staff's action will be similar to that described for amendments, but will include an extension of the license's expiration date. By following this procedure, the staff expects all existing self-shielded irradiator licenses to be converted to the more performance-based format within a few years.

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. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses," dated October 1998, 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.

FOREWORD

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

ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
AU	authorized user
bkg	background
BPR	business process redesign
Bq	Becquerel
CaF ₂	calcium fluoride
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	curie
CD-ROM	compact disc-read only memory
C/kg	coulomb/kilogram
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
EDE	effective dose equivalent
FDA	United States Food and Drug Administration
ft	foot
GBq	gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	hour
IN	Information Notice
IP	Inspection Procedure
kg	kilogram
LiF	lithium fluoride
m	meter
MBq	megabecquerel
mCi	millicurie
MeV	million electron volt
mGy	milligray
mo	month
MOU	memorandum of understanding
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Material Safety and Safeguards

ABBREVIATIONS

NRC	United States Nuclear Regulatory Commission
NTIS	National Technical Information Service
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSP	Office of State Programs
P&GD	Policy and Guidance Directive
QA	quality assurance
R	roentgen
Rev.	revision
RG	Regulatory Guide
RQ	reportable quantities
RSO	radiation safety officer
SDE	shallow-dose equivalent
Sr-90	strontium-90
SFPO	Spent Fuel Project Office
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	sealed source and device
std	standard
Sv	Sievert
TAR	technical assistance request
TBq	terabecquerel
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
URL	uniform resource locator
U. S. C.	United States Code
USDA	United States Department of Agriculture
wk	week
yr	year

1 PURPOSE OF REPORT

This report provides guidance to an applicant in preparing a self-shielded irradiator¹ license application as well as NRC criteria for evaluating a self-shielded irradiator license application. It is not intended to address the research and development or the commercial aspects of manufacturing, distribution, and service of self-shielded irradiators and their associated sources. Within this document, the phrases or terms, “self-shielded irradiator,” “self-contained irradiators,” or “irradiators” are used interchangeably.

Irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

- C Irradiating blood or blood products
- C Sterilizing or reducing microbes in medical and pharmaceutical supplies
- C Preserving foodstuffs
- C Studying radiation effects
- C Synthesizing and modifying chemicals and polymers
- C Eradicating insects through sterile male release programs
- C Calibrating thermoluminescent dosimeters (TLDs).

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. In determining basic safety requirements, ANSI divided all gamma irradiators into four general categories. This report deals with the type of irradiator discussed in ANSI Standard N433.1, “Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I).”² This report also uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: “[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration.”

Depending on the design, the radiation source within the irradiator may be in a fixed position or may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position that, during normal use of the irradiators, may cause a radiation hazard to any

¹ Irradiators subject to the requirements of 10 CFR Part 36 are discussed in draft NUREG-1556, Vol. 6, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About 10 CFR Part 36 Irradiators.”

² Copies may be ordered electronically at the following URL: <<http://www.ansi.org>> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (1-800-553-6847).

PURPOSE OF REPORT

individual. Bypassing or failure of an interlock could cause persons to be exposed to high levels of radiation.

Examples of Self-Shielded Irradiators

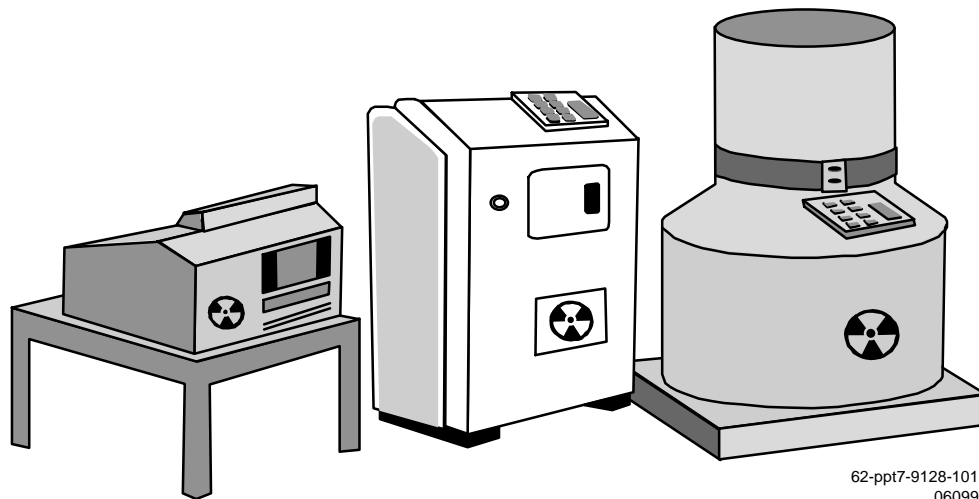


Figure 1.1 Types of Irradiators. *The irradiator on the far left is used to calibrate dosimetry devices, while the other two units are research irradiators.*

Self-shielded irradiators typically contain several hundred to several thousand terabecquerels (TBq) (or curies (Ci)) of cesium-137 (Cs-137) or cobalt-60 (Co-60) and range in weight from several hundred to several thousand kilograms (kg) (or pounds). Other irradiators contain megabecquerel (MBq) (or millicurie (mCi)) quantities of strontium-90 (Sr-90), a beta emitter, and are used primarily for thermoluminescent dosimeter (TLD) calibration.

The NRC's past practice was to issue a separate license to authorize the possession and use of self-shielded irradiators if any of the units exceeded 37 TBq (1,000 Ci). NRC will now authorize self-shielded irradiators on the same license as the licensee's other licensed material.

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

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

- C Regulations—references the regulations applicable to the item;
- C Criteria—outlines the criteria used to judge the adequacy of the applicant's response;
- C Discussion—provides additional information on the topic sufficient to meet the needs of most readers; and

C 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 found for each item on NRC Form 313. NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. For the convenience of applicants and for streamlined handling of self-shielded irradiator applications in the new materials licensing process, use Appendix C to provide supporting information, attach it to NRC Form 313, and submit them to NRC. Appendices D through Q contain additional information on various radiation safety topics. Appendix R is a sample self-shielded irradiator license; it contains the conditions most often found on these licenses, although not all licenses will have all conditions. Appendix S is a checklist that NRC staff uses to review applications and applicants can use to check for completeness. The Addendum contains the comments received on draft NUREG 1556, Vol. 5, and NRC staff's response to each comment.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent (EDE), committed dose equivalent (CDE), committed effective dose equivalent (CEDE), or total effective dose equivalent (TEDE). 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 (R), and the sealed sources used in irradiators emit beta and gamma rays, which means that 1 R = 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, which is available as indicated below.

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 <i>not</i> subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Locations of NRC Offices and Agreement States

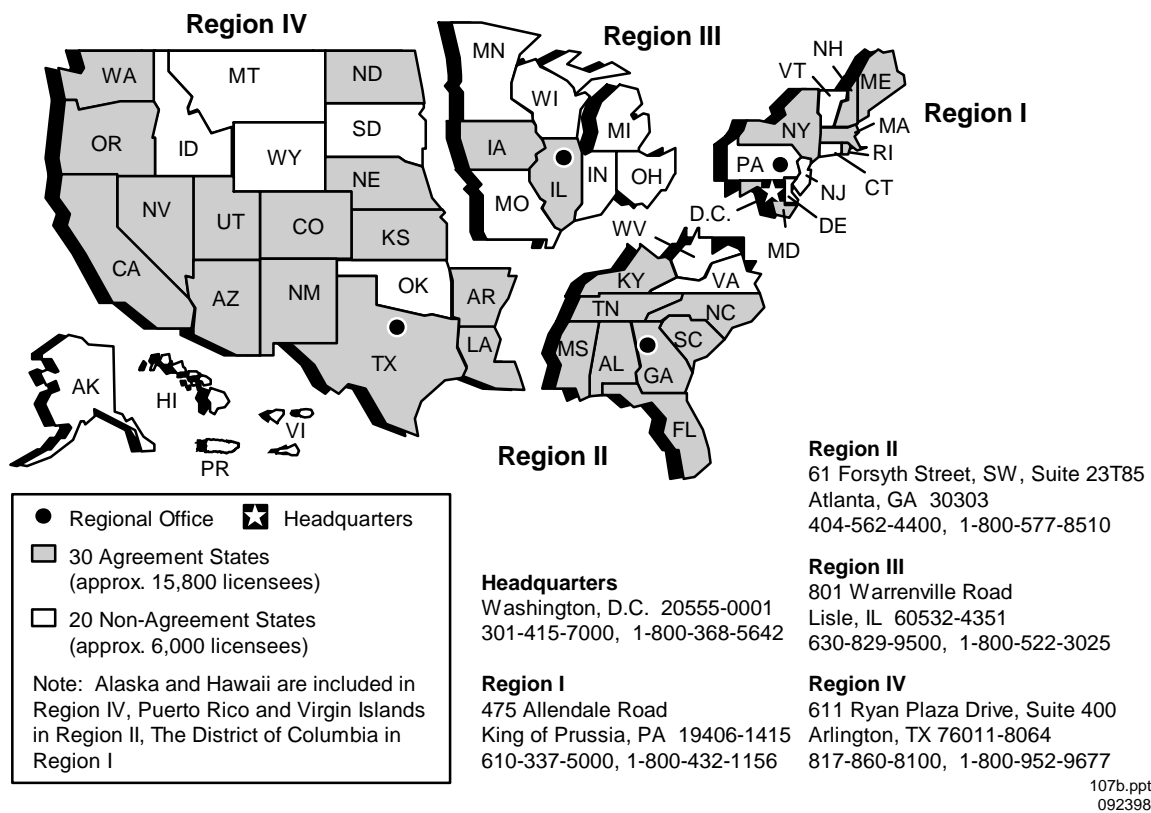


Figure 2.1 U.S. Map. Location of NRC Offices and Agreement States.

References: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available by choosing “Directories” on the NRC Office of State Programs’ (OSP’s) Home Page at <<http://www.hsr.gov/nrc/home.htm>>. As an alternative, request the list from NRC’s Regional Offices.

All Agreement States Letter, SP-96-022, dated February 16, 1996, is available on OSP’s Home Page at <<http://www.hsr.gov/nrc/home.htm>>; choose “NRC-State Communications,” then choose “All of the Above,” and follow the directions for submitting a query for “SP96022.” As an alternative, request the letter from OSP; call NRC’s toll free number (800) 368-5642 and then ask for extension 415-3340.

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 duly authorized management representative must sign the submitted application acknowledging management’s commitments and responsibility for the following:

- C Radiation safety, security and control of radioactive materials, and compliance with regulations
- C Completeness and accuracy of the radiation safety records and all information provided to NRC (10 CFR 30.9)
- C Knowledge about the contents of the license and application
- C Meticulous compliance with current NRC and Department of Transportation (DOT) regulations and the licensee’s operating and emergency procedures
- C Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained
- C Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities
- C Prohibition against discrimination of employees engaged in protected activities (10 CFR 30.7)
- C 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
- C Obtaining NRC’s prior written consent before transferring control of the license
- C 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 the current version of “General Statement of Policy and Procedures for NRC Enforcement Actions,” NUREG-1600, and Inspection Procedure (IP) 87110, Appendix A, “Industrial/Academic/Research Inspection Field Notes.” These documents are available electronically at <<http://www.nrc.gov>>. For hard copies of NUREG-1600 and IP 87110, see the Notice of Availability (on the inside front cover of this report).

MANAGEMENT RESPONSIBILITY

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 self-shielded irradiators:

- C 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- C 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- C 10 CFR Part 20, "Standards for Protection Against Radiation"
- C 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- C 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- C 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- C 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- C 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. Copies of DOT regulations can be ordered from the Government Printing Office (GPO) whose address and telephone number are listed below.

- C 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"
- C 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 the 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:

- C Be sure to use the most recent guidance in preparing an application.
- C Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself.
- C Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C.
- 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.
- C Submit all documents on 8-1/2 x 11 inch paper.
- C Avoid submitting proprietary information unless it is absolutely necessary.
- C Submit an original, signed application and one copy.
- C 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 on "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," 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:

- C Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- C 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**.

HOW TO FILE

- C Choose 12-point or larger font size.
- C Avoid stylized characters such as script, italic, etc.
- C Be sure the print is clear and sharp.
- C 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. You may also call NRC's toll free number (800) 368-5642 and then ask for extension 415-7554.

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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.
<input type="checkbox"/> A. New License	Not Applicable
<input type="checkbox"/> B. Amendment	XX-XXXXXX-XX
<input type="checkbox"/> C. Renewal	XX-XXXXXX-XX

Check box A for a new license request.

Check box B for an amendment³ to an existing license, and provide license number.

Check box C for a renewal³ 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 when 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.

³ See "Amendments and Renewals to a License" later in this document. Licensees may request an amendment to an existing license to add authorization for a self-shielded irradiator.

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: Transferring 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 prior NRC written consent before the transaction is finalized. This is to ensure the following:

- C Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses
- C Materials are properly handled and secured
- C Persons using these materials are competent and committed to implementing appropriate radiological controls
- C A clear chain of custody is established to identify who is responsible for disposition of records and licensed material
- C 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 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, identifies the information to be provided about transferring control.

Notification of Bankruptcy Proceedings

Regulations: 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.

References: INs are available in the “Reference Library” on NRC’s Home Page at <<http://www.nrc.gov>>. For hard copies, see the Notice of Availability (on the inside front cover of this report).

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.

To allow licensees greater flexibility, the applicant should *not* identify the self-shielded irradiator location by room number and should *not* submit drawings of the location within the facility. The acceptability of the irradiator’s location will be reviewed during the inspection process; see section on “Facilities and Equipment” for additional information.

When a new self-shielded irradiator is acquired and will be used at the facility address listed in the license, the license need *not* be amended. An NRC-approved license amendment *is* required before locating an irradiator at an address not already listed on the license, whether that irradiator is an additional unit or a relocation of an existing unit.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed later under “Financial Assurance and Record Keeping for Decommissioning,” licensees do 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 self-shielded irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where each irradiator is used or stored and any information relevant to damaged devices or leaking radioactive sources.

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

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Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, 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. 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 UNSEALED AND/OR SEALED BYPRODUCT MATERIAL

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

Criteria: Applicants must provide the manufacturer’s (or distributor’s) name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: NRC or an Agreement State performs a safety evaluation of self-shielded irradiators before authorizing a manufacturer (or distributor) to distribute the irradiators to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the formalization of the SSD registration process, some older irradiators may have been specifically approved on a license. Licensees can continue to use those units specifically listed on their licenses. Applicants must provide the manufacturer’s (or distributor’s) name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license.

As explained in an “Urgent Notice” with an enclosed Order, both dated July 3, 1984 (see Appendix E), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses that authorize J. L. Shepherd Mark I or Model 81-22 irradiators. Applicants wishing to use either of these models must comply with the Order’s requirements.

Consult with the proposed manufacturer (or distributor) to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination 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. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD Registration Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer (or distributor), by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by NRC, licensees are required to use irradiators according to their respective SSD Registration Certificates. Accordingly, applicants may want to get a copy of the certificate and review it or discuss it with the manufacturer (or distributor).

Response from Applicant:

- C Identify each radionuclide that will be used in each source in the self-shielded irradiators.
- C Provide the manufacturer's (or distributor's) name and model number for each sealed source and device requested.
- C Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State.
- C Confirm that the activity per source and maximum activity in each irradiator will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.

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. For more information about the SSD registration process, see the current version of NUREG - 1556, Vol. 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration." It is available electronically in the "Reference Library" at <<http://www.nrc.gov>>; for a paper copy, see the Notice of Availability (on the inside front cover of this report).

8.5.2 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

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

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Criteria: Self-shielded 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 irradiators are used or stored and to leaking sources. Pursuant to 10 CFR 30.35(g), licensees must transfer these records important to decommissioning to either of the following:

- C The new licensee, before licensed activities are transferred or assigned according to 10 CFR 30.34(b)
- C 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 self-shielded irradiator applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 10 CFR 30.35. The limits for typical self-shielded irradiator sealed sources are shown in Table 8.1. Applicants requesting more than one radionuclide need to use the sum of the ratios method to determine whether financial assurance is needed. See Appendix F for additional information.

Table 8.1 Minimum Inventory Quantity Requiring Financial Assurance

Radionuclide	Activity	
	Gigabecquerel (GBq)	Curie (Ci)
Cs-137	3.7×10^6	100,000
Co-60	3.7×10^5	10,000
Sr-90	3.7×10^4	1,000

In most cases, a licensee would need to possess several irradiators before the financial assurance requirements would apply. Since the standard self-shielded irradiator license does not specify the maximum number of irradiators that a licensee may possess (allowing flexibility in obtaining additional irradiators specifically authorized by the license without amending its license), it contains a condition requiring the licensee to limit its possession of self-shielded irradiators to quantities not requiring financial assurance for decommissioning.

Applicants and licensees wanting to possess self-shielded irradiators or irradiators and other licensed materials exceeding the limits in 10 CFR 30.35 must submit evidence of financial assurance or a decommissioning funding plan (10 CFR 30.35 (b)). RG 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 mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees. See Appendix F for the recommended wording for a Statement of Intent.

NRC will authorize possession exceeding the limits shown in Table 8.1 without requiring decommissioning financial assurance, for the purpose of normal source exchange for no more than 30 days.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All self-shielded irradiator licensees need to maintain records of structures and equipment where each irradiator was used or stored. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees shall substitute appropriate records (e.g., a sketch of the room or building, or a description of the area) concerning the specific areas and locations. If no records exist regarding structure and equipment where self-shielded irradiators were used or stored, licensees shall make all reasonable efforts to create such records based upon historical information (e.g., employee recollections). In addition, if self-shielded irradiator licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For self-shielded irradiator licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each irradiator was used or stored.

Response from Applicant: No response is needed from most applicants. If financial assurance is required, submit evidence as described in RG 3.66.

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

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

OR

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

References: See the Notice of Availability (on the inside front cover of this report) to obtain copies of RG 3.66 and P&GD FC 90-2 (Rev. 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

Regulations: 10 CFR 30.33(a)(1).

Criteria: Proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and irradiators will be used only for the purposes for which they were designed and according to the manufacturer's (or distributor's) recommendations and instructions for use as specified in an approved SSD Registration Certificate. Uses other than those already listed must not compromise the integrity of the source or source shielding or other components of the device critical to radiation safety.

Discussion: Allowed uses normally include irradiation of blood, insects, animals, biological samples, and inanimate objects. Usually prohibited are irradiation of flammable and explosive materials which may harm the shielding or the sealed source containment, or other materials (e.g., unsealed containers of acids or corrosive liquids) which may interfere with the safe operation of the device. Irradiation of food for commercial distribution to the public is subject to regulations of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) and will not be discussed in this document.

Requests to irradiate items not listed or prohibited in the SSD Registration Certificate will be reviewed on a case-by-case basis. Applicants need to submit enough information to demonstrate that irradiation of the proposed items will not compromise the integrity of the source or source shielding, or other components critical to radiation safety of the device. Contact the appropriate NRC Regional Office (see Figure 2.1) for additional case-specific guidance. Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., FDA and USDA regulations about irradiation of food for commercial distribution).

Response from Applicant: If the self-shielded irradiator will be used for the purposes listed on the SSD Registration Certificate, state the following: "The self-shielded irradiator(s) will be used for the purposes described in their respective SSD Registration Certificates." If the self-shielded irradiator will be used for purposes other than those listed on the SSD Registration Certificate, specify these purposes and submit safety analyses (and procedures, if needed) to support safe use.

8.7 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8.7.1 RADIATION SAFETY OFFICER (RSO)

Regulations: 10 CFR 30.33(a)(3).

Criteria: RSOs 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 Radiation Safety Officer, or RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are illustrated in Figure 8.1 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.

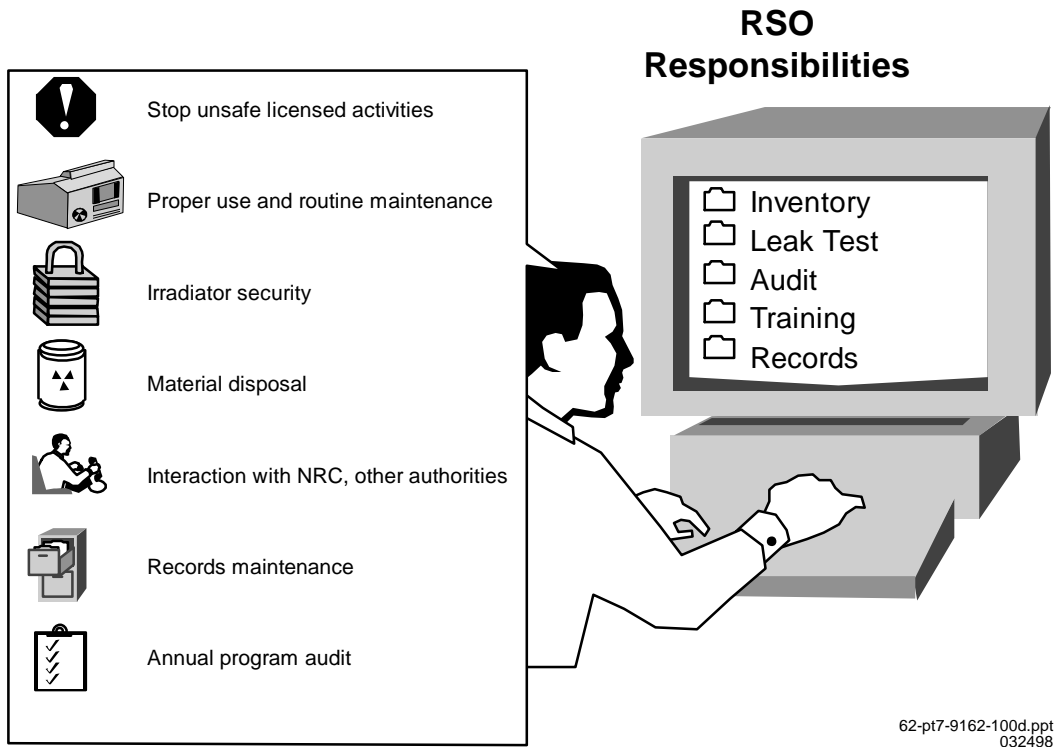


Figure 8.1 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

Response from Applicant: Provide the following:

C Name of the proposed RSO

AND EITHER

C Statement that: “Before obtaining licensed materials, the proposed RSO will have successfully completed training described in Appendix G in NUREG-1556, Vol. 5, ‘Consolidated Guidance

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about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated June 1998”;

AND

- C Statement that: “Before being named as the RSO, future RSOs will have successfully completed training described in Appendix G in NUREG-1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,’ dated June 1998. Within 30 days of naming a new RSO, we will submit the new RSO’s name to NRC to include in our license.”

OR

- C Alternative information demonstrating that the proposed RSO is qualified by training and experience.

Note:

- C It is important to notify NRC, as soon as possible, of changes in the designation of the RSO; such notifications will be handled as administrative amendments not requiring fees as long as the application contains the commitment listed in the third bullet under “Response from Applicant.”
- C Alternative responses will be reviewed using the criteria listed above.

8.7.2 AUTHORIZED USERS (AUs)

Regulations: 10 CFR 30.33(a)(3).

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of training as described in Appendix G is evidence of adequate training and experience.

Discussion: An AU is a person whose training and experience meet NRC criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must ensure the proper use, security, and routine maintenance of self-shielded irradiators containing licensed material. They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of and access to the irradiator, and respond appropriately to accidents and malfunctions.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Response from Applicant: Provide either of the following:

C The statement: “Before using licensed material, authorized users will receive the training described in Appendix G in NUREG-1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,’ dated June 1998.”;

OR

C A description of the training and experience for proposed authorized users.

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

8.8 ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO OCCUPATIONALLY EXPOSED WORKERS AND ANCILLARY PERSONNEL)

Regulations: 10 CFR 19.11, 10 CFR 19.12, 10 CFR 19.13, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.7, 10 CFR 30.9, 10 CFR 30.10, 10 CFR 30.33.

Criteria: Individuals working with, as well as in the vicinity of, a self-shielded irradiator must have adequate training and experience. For those individuals who are not AUs yet work in the vicinity of a self-shielded irradiator and, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) (100 millirem (mrem)), the licensee must provide training as required by 10 CFR 19.12. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Discussion: Licensees need to perform a prospective evaluation to determine radiation doses likely to be received by different individuals or groups. AUs, individuals performing routine maintenance, and individuals performing installations, relocations, non-routine maintenance, or repairs would be most likely to receive doses in excess of 1 mSv (100 mrem) in a year. See the previous section for a discussion of training and experience for AUs.

Individuals, other than AUs (e.g., biomedical engineers), may perform routine maintenance on irradiators. However, they must be trained in radiation safety and in the irradiator manufacturers’

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operating procedures, or they must work under the supervision and in the direct physical presence of someone who has this training.

Some licensees may have specific individuals trained to perform installations, relocations, non-routine maintenance, or repairs. Authorizations for these functions are separate from those for an AU or an individual who performs routine maintenance and will be specifically stated in a license condition. Appendix I contains suggested training for individuals who will conduct non-routine maintenance.

While performing prospective evaluations, a licensee may recognize that some individuals (e.g., housekeeping staff), although not likely to receive doses over 1 mSv (100 mrem), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their involvement with licensed material. For example, housekeeping staff may receive training on the nature and location of the irradiator and the meaning of the radiation symbol, and instructions not to touch the irradiator and to remain out of the room if the irradiator door is open.

Response from Applicant: The applicant's training program will be examined during inspections, but should not be submitted in the license application.

8.9 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 30.33(a)(2).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Self-shielded irradiators incorporate many engineering features to protect individuals from unnecessary radiation exposure. These devices are usually designed for use in a laboratory environment, i.e., inside a building, protected from the weather, and without wide variations of temperature and humidity. For information to help applicants determine the location of irradiators, see the sections on the SSD Registration Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use."

For example, if a proposed location for a self-shielded irradiator is not within the conditions of normal use or the limitations of use, the applicant will need to provide adequate justification. In addition, the applicant will need to take compensatory measures (e.g., increased surveillance and maintenance) to ensure that the irradiator operates as designed and provides the intended level of protection. IN 96-35, "Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training," dated June 11, 1996, discusses an incident resulting from irradiator failure in which the lack of a climate-controlled environment (i.e., loading dock) may

have accelerated the degradation of internal components leading to a failed interlock and excessive dose received by an irradiator operator.

Self-shielded irradiators vary in weight from several hundred to several thousand kilograms (pounds). Before installing an irradiator, licensees need to evaluate whether the floor in the proposed location can support the irradiator. Often licensees locate self-shielded irradiators on a ground floor. Some smaller and lighter irradiators require additional security measures to prevent unauthorized removal (e.g., locked in a room, bolted to the floor). For more information see “Radiation Safety Program - Operating and Emergency Procedures” and “Radiation Safety Program - Public Dose.”

The fire-resistant properties of most irradiators should provide adequate radioactive material containment and shielding integrity in most situations; however, additional protection is desirable for some situations. For example, the room housing the irradiator should be equipped with an automatically-operated fire detection and control system (sprinkler, chemical, or gas). As an alternative, the self-shielded irradiator should be located under conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of firefighting personnel) that ensure a low level of radiation risk attributable to fires.

Response from Applicant: Provide either of the following:

C The statement: “We will ensure that each area where a self-shielded irradiator is located corresponds to the ‘Conditions of Normal Use’ and ‘Limitations and/or Other Considerations of Use’ on the applicable irradiator’s Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.”

OR

C Submit alternative information; be sure to include justification for placing an irradiator in an area that does not correspond to the “Conditions of Normal Use” and the “Limitations and/or Other Considerations of Use.”

Note: Alternative information will be reviewed using the criteria listed above.

References: INs are available in the “Reference Library” on NRC’s Home Page at <<http://www.nrc.gov>>. For hard copies, see the Notice of Availability (on the inside front cover of this report).

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 annually to ensure the following:

- C Compliance with NRC and DOT regulations (as applicable), and the terms and conditions of the license;
- C Occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA) (10 CFR 20.1101); and
- C Records of audits and other reviews of program content are maintained for 3 years.

Discussion: Appendix J contains a suggested audit program that is specific to the use of self-shielded irradiators and is acceptable to NRC. All areas indicated in Appendix J may not be applicable to every licensee 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. Generally, audits are conducted at least once every 12 months.

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 users 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; IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, 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 a notice of violation, refer to the current version of NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

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 follow-up.

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: The documents referenced above are available electronically at <<http://www.nrc.gov>>. For hard copies of NUREG-1600, IN 96-28, and IP 87110, Appendix A, "Industrial/Academic/Research Inspection Field Notes," see the Notice of Availability (on the inside front cover of this report).

8.10.2 RADIATION MONITORING INSTRUMENTS

Regulations: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 30.33(a)(2).

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

Discussion: All licensees possessing self-shielded irradiators should have, or have access to, calibrated radiation detection instruments to determine radiation levels in areas adjacent to the irradiator. Usually, it is not necessary for a licensee to have a survey meter solely for use during irradiator operations, since it is not expected that a survey be performed each time a sample is irradiated. In these cases it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

As explained in an "Urgent Notice" with an enclosed Order, both dated July 3, 1984 (see Appendix E), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism which would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses which authorize J. L. Shepherd Mark I or Model 81-22 irradiators and requires licensee to provide either a calibrated and operable radiation survey meter or room monitor for use with either of these irradiators. Although not required for all licensees possessing moving-source irradiators, it would be prudent for these licensees to use either a calibrated survey meter or room monitor to ensure that the sources are in the shielded position whenever a sample is not undergoing irradiation.

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The NRC requires that survey meter calibrations be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must submit additional information for review. See Appendix K for more information.

Response from Applicant: Provide one of the following:

C A statement that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG-1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,’ dated June 1998. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.”

OR

C A statement that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG-1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,’ dated June 1998. Additionally, we will implement the model survey meter calibration program published in Appendix K to NUREG-1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,’ dated June 1998, and we will ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.”

OR

C A description of alternative equipment and/or procedures for ensuring that interlocks function, as required, to return moving self-shielded irradiator sources to the shielded position and/or determining source shielding integrity after an incident involving the self-shielded irradiator.

Note:

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

C Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in Appendix E. Applicants requesting these irradiators must ensure that their radiation detection instruments meet these requirements.

C Applicants who plan to perform non-routine maintenance that will affect safety-critical components (e.g., sealed source, radiation shielding, source movement control or mechanism, interlocks) will need to possess and use appropriate, calibrated radiation survey meters. Refer

to the section on “Radiation Safety Program - Maintenance,” Appendix I, and Appendix K for more information.

- C Required calibration records must be retained for a minimum of 3 years.

8.10.3 MATERIAL RECEIPT AND ACCOUNTABILITY

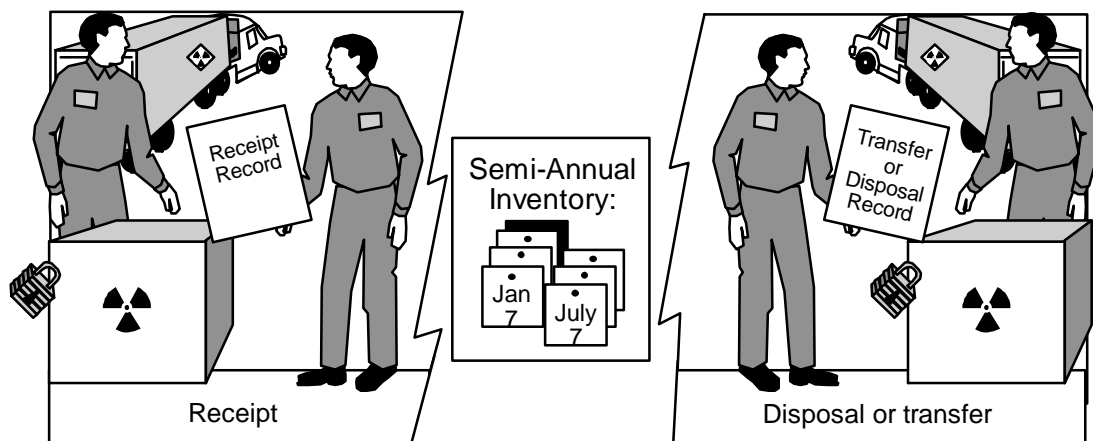
Regulations: 10 CFR 30.34(e), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201, 10 CFR 30.35(g)(2).

Criteria: Licensees must do the following:

- C Maintain accountability for self-shielded irradiators by conducting physical inventories at intervals not to exceed 6 months (or as justified by the applicant) to account for all sealed sources.
- C Maintain records of receipt, transfer, and disposal of self-shielded irradiators.

Discussion: While loss, theft, or misplacement of most self-shielded irradiators is unlikely because of their size and weight, accountability for licensed materials must be ensured; see Figure 8.2. Many licensees record use of self-shielded irradiators in a log book. Licensees are also required to conduct leak tests of irradiator sealed source(s) at the frequency specified in the SSD Registration Certificate. Since both of these activities require that an individual approach the irradiator, records of use and leak tests may be used as part of an accountability program. For more information, see “Radiation Safety Program - Operating and Emergency Procedures” and “Radiation Safety Program - Leak Tests” in this report. However, since some irradiators may not be in use or are used rarely, NRC expects licensees to physically approach and account for all sealed sources at least every 6 months.

Cradle to Grave Accountability



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Figure 8.2 Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal and conduct semiannual physical inventories.

Receipt, transfer, and disposal records must be maintained for the times specified in Table 8.2. Typically, these records contain the following types of information:

- C Radionuclide and activity (in units of becquerels or curies) of byproduct material in each sealed source
- C Manufacturer’s (or distributor’s) name, model number, and serial number (if appropriate) of each device containing byproduct material
- C Location of each sealed source and device
- C 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).

Information on locations where irradiators are used or stored are records important to decommissioning and required by 10 CFR 30.35(g)(2).

Table 8.2 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
Disposal	Until NRC terminates the license

Type of Record	How Long Record Must be Maintained
Important to decommissioning *	Until the site is released for unrestricted use

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

Response from Applicant: Provide either of the following:

C A statement that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."

OR

C A description of procedures for ensuring that no self-shielded irradiator has been lost, stolen, or misplaced and how often this will be done.

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

8.10.04 OCCUPATIONAL DOSE

Regulations: 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.2106.

Criteria: Applicants must do either of the following:

C Perform a prospective evaluation 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 8.3.

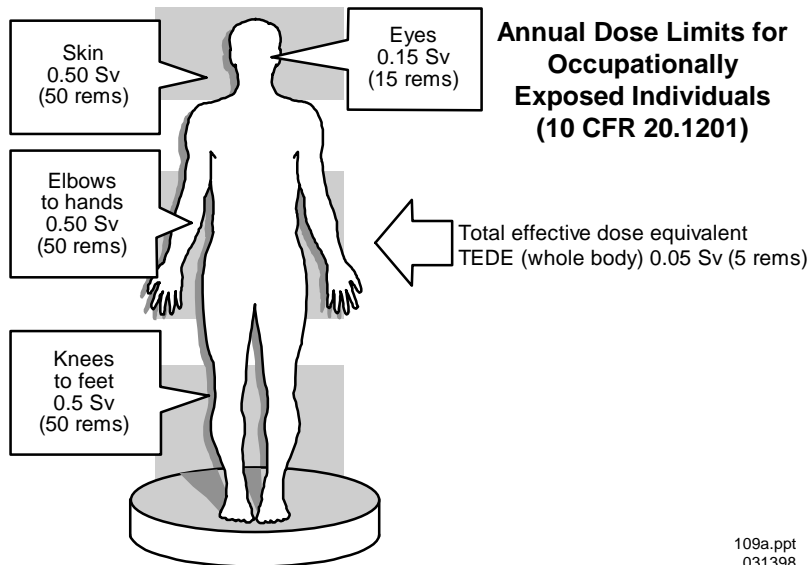
OR

C Provide dosimetry as follows:

- Personnel dosimeters which are processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor and are exchanged at a frequency recommended by the processor; or
- Direct or indirect reading pocket ionization chambers that:
 - P Are assigned to a single individual whose accumulated dose is read, recorded, and the chamber recharged, as appropriate, before the chamber is assigned to another individual
 - P Have a range of 0 to at least 2 mSv (200 mrem)
 - P Are checked at intervals not to exceed one year for correct response to radiation

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- P Read within $\pm 20\%$ of the true radiation exposure
- P Are used under a program that prescribes action to evaluate the individual's dose



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Figure 8.3 Annual Dose Limits for Occupationally Exposed Individuals.

Discussion: Under conditions of routine use and maintenance, the typical self-shielded irradiator user does not require a personnel monitoring device (dosimetry). However, individuals who perform non-routine maintenance do require personnel monitoring devices. Appendix L provides guidance on performing a prospective evaluation demonstrating that self-shielded irradiator users are not likely to exceed 10% of the applicable limits and thus, are not required to have personnel dosimetry.

When personnel monitoring is needed, most licensees use either film badges or 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 licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the criteria above are met. See ANSI N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information.

Response from Applicant: Provide either of the following:

- C A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the Criteria

in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG - 1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated June 1998."

OR

- C A description of an alternative method for demonstrating compliance with the referenced regulations.

Note:

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

References: National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available electronically at <<http://ts.nist.gov/nvlap>>. NIST Publication 810 can be purchased from GPO, whose URL is <<http://www.gpo.gov>>. ANSI N322 may be ordered electronically at <<http://www.ansi.org>> or by writing to ANSI, 1430 Broadway, New York, NY 10018.

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.

Criteria: Licensees must do the following:

- C Ensure that licensed self-shielded irradiators will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 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.
- C Control and maintain constant surveillance over self-shielded irradiators that are not in storage and secure stored self-shielded irradiators from unauthorized access, removal, or use.

Discussion: Public dose is defined in 10 CFR Part 20 as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not

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depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of self-shielded irradiators, members of the public include persons who work or may be near locations where self-shielded irradiators are used or 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 stored.

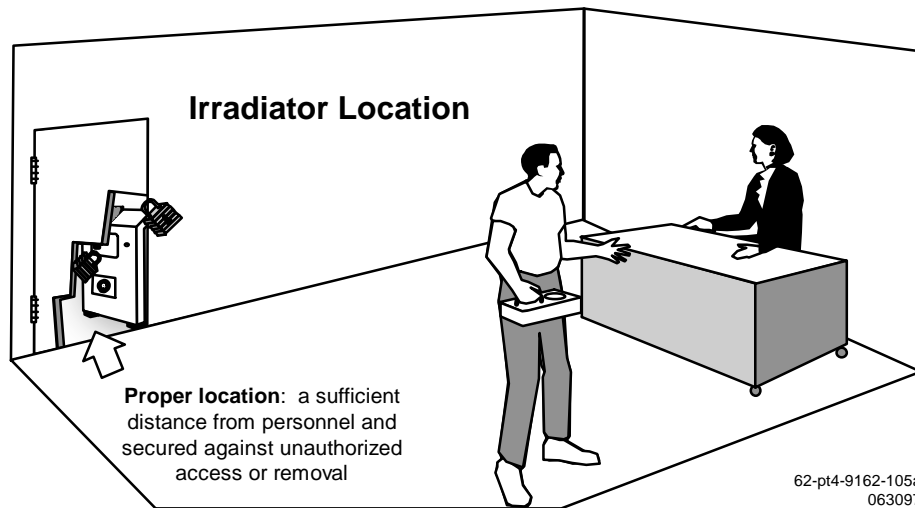


Figure 8.4 Proper Location of Irradiator. *Irradiators should be located away from occupied areas and secured to prevent unauthorized use or removal.*

Security procedures described in “Facilities and Equipment” and “Radiation Safety Program - Operating and Emergency Procedures” should be effective in limiting the exposure to the public during use or storage. See Figure 8.4. Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., located in a locked area) to prevent unauthorized access or use. As shown in Figure 1.1, most self-shielded irradiators are massive [i.e., hundreds of kilograms (pounds) and the size of file cabinets], not likely to be easily removed from their intended location, and may not need to be in a locked area to prevent loss, theft, or unauthorized relocation.

Smaller units, however, such as those used to calibrate TLDs, are more easily moved and should be located in a locked area or bolted in place. 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 a self-shielded irradiator presents a radiation field, it must be located so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. 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 can determine the radiation levels adjacent to the irradiator location either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the irradiator manufacturer (or distributor), the inverse square law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of self-shielded irradiator(s). See Appendix M for an example.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of irradiators, changes the type or frequency of irradiator use, adds self-shielded irradiators, 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 calculation, that the TEDE 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 M for examples of methods to demonstrate compliance.

Response from Applicant: No response is required from the applicant in a license application, but documentation demonstrating compliance will be examined during inspection.

8.10.6 OPERATING AND EMERGENCY PROCEDURES

Regulations: 10 CFR 30.34(e), 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2202, 20.2203, 10 CFR 30.50, 10 CFR 21.21, 10 CFR 19.11(a)(3).

Criteria: Before using an irradiator, licensees must do the following:

C Develop, implement, and maintain model-specific operating and emergency procedures containing the following elements:

- An analysis of each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine if any special safety procedures are needed
- Instructions for using the self-shielded irradiator and performing routine maintenance, according to the manufacturer's (or distributor's) written recommendations and instructions

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- Instructions for maintaining security to prevent unauthorized use, access, or removal of self-shielded irradiators and the associated sealed sources
- Steps to take to keep radiation exposures ALARA
- Steps to maintain accountability
- Steps to control access to a malfunctioning or damaged irradiator
- Steps to take, and whom to contact (e.g., RSO, local officials), when an irradiator malfunctions or has been damaged.

AND

- C Provide copies of operating and emergency procedures to all users.
- C Maintain a current copy of operating and emergency procedures at each irradiator's control panel (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

Discussion: When used as designed, properly functioning self-shielded irradiators pose little radiation safety risk. However, improper maintenance, irradiating material incompatible with an irradiator's design, or operating an irradiator in an environment other than that recommended by the manufacturer (or distributor), could lead to damage or malfunction of an irradiator and elevated exposure rates in the irradiator's immediate vicinity. Operating and emergency procedures should be developed to minimize these risks, while keeping radiation exposures ALARA. These procedures must be model-specific to account for potentially significant differences in irradiator design and construction that lead to manufacturers (or distributors) providing different instructions and recommendations for operating and maintaining irradiators.

Sources contained in many self-shielded irradiators are designed to deliver significant doses in short periods of time. Although self-shielded irradiators are safe when used correctly, unauthorized access to the irradiator or the irradiator's sources by untrained individuals could lead to a life-threatening situation. Therefore, operating procedures will also need to address access control and accountability. Many licensees achieve access control by permitting only AUs or the RSO to have access to the keys for the irradiator and/or the irradiator area. Accountability of an operating irradiator may be ensured by using a log book to record irradiator use, maintenance, service calls, and sealed source leak tests. Each activity requires an individual to interact in some way with the irradiator and thereby verify its presence. For sources contained in irradiators that are not actively used, licensees would need to find other methods to maintain accountability, such as conducting inventories.

Licensees must post current copies of the operating procedures applicable to licensed activities (e.g., at the irradiator control panel). If posting of a document is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

Proper Handling of Incident

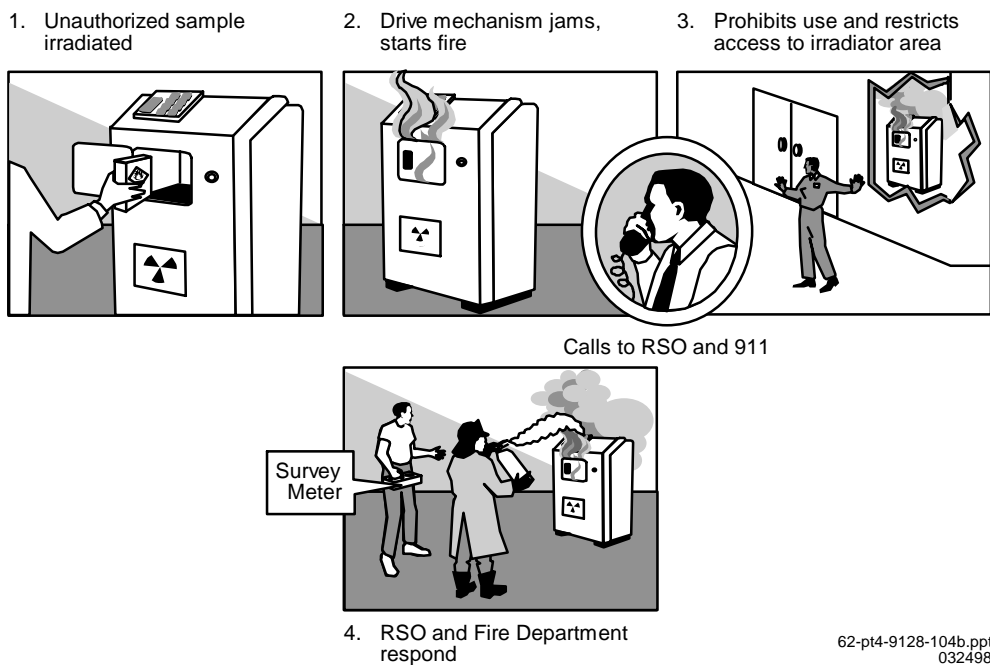


Figure 8.5. Proper Handling of Incident. Licensee personnel implement emergency procedures when a flammable sample catches fire.

Figure 8.5 illustrates proper response to a fire in an irradiator. Emergency procedures should be developed to address a spectrum of incidents (e.g., interlock failure, flood, earthquake). Emergency response procedures should contain the following elements:

- C Leave the irradiator room to reduce radiation exposure
- C Control access (e.g., lock door)
- C Contact the individual responsible for the irradiator program for further instructions and to initiate emergency response. (Telephone numbers for the responsible individual, the irradiator manufacturer (or distributor) or its representative, fire department, or other emergency response organization, and the NRC should be posted or easily accessible.)
- C Survey areas outside the irradiator room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 0.02 mSv (2 mrem) per hour
- C As appropriate, require timely reporting to NRC according to 10 CFR 20.2201, 20.2202, 20.2203, 10 CFR 30.50, and 10 CFR 21.21.

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The NRC must be notified when a self-shielded irradiator is lost, stolen, or other conditions occur. The RSO must be proactive in evaluating whether NRC notification is required. Refer to Appendix N and the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.50, and 10 CFR 21.21) for a description of when and where notifications are required.

Appendix O provides information for applicants to consider when developing their procedures for self-shielded irradiators.

Licensees may change their operating and emergency procedures without amending their licenses if:

- C The changes are reviewed, approved, and documented by licensee management and the RSO
- C Affected licensee staff are trained in the procedures before they are implemented
- C The changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application
- C The changes do not degrade the safety of the program.

Response from Applicant: Do the following:

- C State: “If we change our operating and emergency procedures without amending our license, we will ensure that: the changes are reviewed and approved by licensee management and the RSO; affected licensee staff are trained in the procedures before they are implemented; the changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application; and the changes do not degrade the safety of the program.”

AND EITHER

- C State: “Operating and emergency procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled ‘Radiation Safety Program - Operating and Emergency Procedures’ in NUREG-1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,’ dated June 1998.”

OR

- C Submit alternative procedures.

Note:

- C Alternative procedures will be reviewed using the criteria listed above.
- C Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in Appendix E. Applicants requesting these irradiators must ensure that their operating and emergency procedures address these requirements.
- C Before using a new model irradiator, licensees need to revise operating and emergency procedures to include procedures specific to the new irradiator.

8.10.7 LEAK TESTS

Regulations: 10 CFR 30.53, 10 CFR 20.1501, 10 CFR 20.2103.

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

Discussion: When issued, a license will require performance of leak tests at intervals approved by the NRC or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

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 licensees. In the latter case, the licensee is expected to take the leak test sample according to the self-shielded 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. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Response from Applicant: Do one of the following:

- C State: "Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or 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 self-shielded irradiator manufacturer's (or distributor's) and kit supplier's instructions."

OR

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C State: “Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or 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 self-shielded irradiator manufacturer’s (or distributor’s) and kit supplier’s instructions. As an alternative, we will implement the model leak test program published in Appendix P to NUREG - 1556, Vol. 5, ‘Consolidated Guidance about Materials Licenses: Program-Specific Information about Self-Shielded Irradiators,’ dated October 1998.”

OR

C A description of alternative equipment and/or procedures for determining whether there is radioactive leakage from sources contained in self-shielded irradiators.

Note:

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

C If a self-shielded irradiator is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the irradiator according to the procedures previously approved on its license.

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

8.10.8 MAINTENANCE

Regulations: 10 CFR 20.1101, 10 CFR 30.34(e).

Criteria: Licensees must routinely maintain self-shielded irradiators according to the manufacturer’s (or distributor’s) written recommendations and instructions; see Figure 8.6. For self-shielded irradiators, radiation safety procedures for routine maintenance must consider ALARA and ensure that the irradiator functions as designed and source integrity is not compromised.

In this report, “non-routine maintenance” means any repair, removal, replacement, or alteration involving: electrical and mechanical systems that control source or shielding movement, the irradiator’s shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding NRC limits.

Non-routine maintenance must be performed by the self-shielded irradiator manufacturer (or distributor) or a person specifically authorized by NRC or an Agreement State; see Figure 8.7. Requests for specific authorization to perform non-routine maintenance (see Appendix I) must demonstrate that personnel performing the work do the following:

- C Have adequate training and experience
- C Use equipment and procedures that ensure compliance with regulatory requirements, and consider ALARA
- C Ensure that the self-shielded irradiator functions as designed and that source integrity is not compromised.

Discussion: NRC IN 96-35, “Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training,” dated June 11, 1996, emphasizes the importance of proper maintenance and describes two incidents in which safety interlocks on self-shielded irradiators failed to prevent inadvertent exposure. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- C The tasks to be performed
- C The protocol or procedures to be followed
- C The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- C ALARA considerations
- C Training and experience of personnel performing the work
- C The qualification of parts, components, other materials to be used in the irradiator
- C The tests (to be performed before the irradiator is returned to routine use) to ensure that it functions as designed.

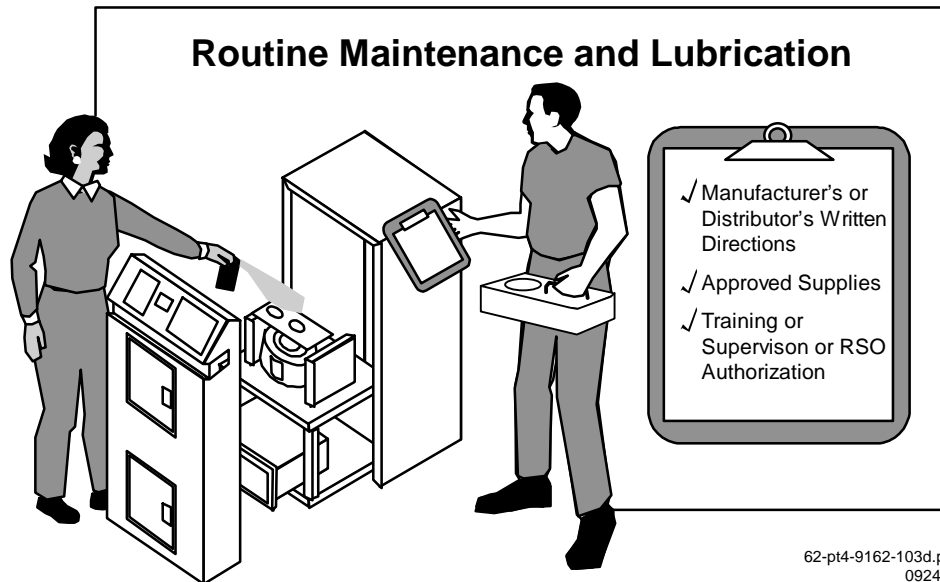
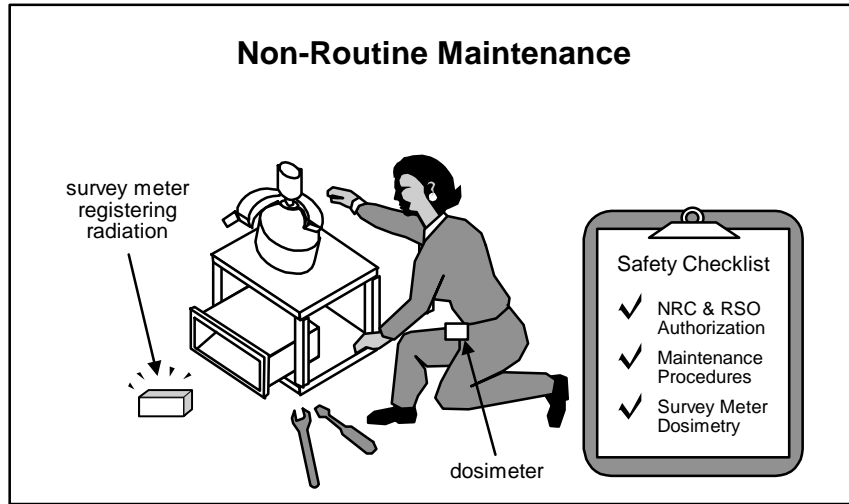


Figure 8.6 Routine Maintenance and Lubrication. *To ensure proper operation of the unit, self-shielded irradiator licensees need to perform routine maintenance according to the manufacturer's (or distributor's) written instructions and recommendations.*

NRC permits self-shielded irradiator licensees to perform routine maintenance of the irradiator provided they follow the self-shielded irradiator manufacturer's (or distributor's) written recommendations and instructions. Although manufacturers (or distributors) may use different terms, "routine maintenance" includes, but is not limited to, cleaning, lubrication, changing batteries, relays or fuses. Routine maintenance does *not* include any activities that involve the source, source drive mechanism, or removing the shielding or source and any other activities during which personnel could receive radiation doses exceeding NRC limits.



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Figure 8.7 Non-Routine Maintenance. *For non-routine maintenance, most licensees rely on the manufacturer, distributor, or other service companies.*

The NRC license will require that non-routine maintenance (as defined above) be performed only by the manufacturer (or distributor) or other persons specifically licensed by the Commission or an Agreement State to perform such services. Most licensees do not perform non-routine maintenance because they must have specialized equipment and technical expertise to perform these activities. Applicants seeking authorization to perform non-routine maintenance must submit specific procedures for review. See Appendix I for more information.

Response from Applicant:

Routine Maintenance: Submit either of the following:

- C A statement that: “We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer’s (or distributor’s) written recommendations and instructions.”

OR

- C Alternative procedures for NRC’s review.

Non-Routine Maintenance: Submit either of the following:

- C A statement that: “We will have the self-shielded irradiator manufacturer (or distributor) or other person authorized by NRC or an Agreement State perform non-routine maintenance.”

OR

C The information listed in Appendix I supporting a request for authorization to perform this work.

Note:

C Alternative procedures for performing routine maintenance will be reviewed using the criteria listed above.

C 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 maintenance.

References: INs are available in the “Reference Library” on NRC’s Home Page at <<http://www.nrc.gov>>. For hard copies, see the Notice of Availability (on the inside front cover of this report).

8.10.9 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, 172, 173, 174, 175, 176, 177, 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. Most self-shielded irradiators contain quantities of radioactive material that require using a Type B package. Before offering a Type B package for shipment, the licensee needs to 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 Rev. 1 of RG 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 OCFO by calling NRC’s toll-free number 800-368-5642 and asking for extension 415-7554.

Some irradiator licensees who rarely ship radioactive material have chosen to transfer possession of radioactive materials to an irradiator manufacturer (or distributor) (or service licensee) with an NRC or Agreement State license who then acts as the shipper. The manufacturer (or distributor)

(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 distributor) (or service licensee):

- C Is authorized to possess the irradiator at temporary job sites (e.g., at the irradiator location)
- C Actually takes possession of the irradiator under its license
- C Uses an approved Type B package
- C Is registered with NRC as a user of the Type B package
- C 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.

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a Memorandum of Understanding (MOU) with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to irradiator licensees. Part 1 of Appendix Q lists major DOT regulations and Part 2 contains a sample bill of lading.

Before the adoption of the requirements of 10 CFR Part 71 in 1966, self-shielded irradiators could be transported without being evaluated under the hypothetical accident conditions that are now incorporated in 10 CFR Part 71. Because pre-1966 irradiators are not certified shipping packages, transporting them may require transferring the sealed source from the irradiator to a certified Type B package or using a certified package for the irradiator containing the sealed sources. Only if these options are not viable will NRC consider a licensee's request for an exemption for a one-time shipment according to 10 CFR 71.8. Exemption requests should contain the information described in Part 3 of Appendix Q. In addition to an NRC exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before offering a Type B package for shipment, 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 (1983 revision)" can be obtained by 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 copies of the MOU or RG.

8.10.10 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 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 SSD Registration Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD Registration Certificate should identify defective sources. Leaking sources must be immediately 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 in the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment," "Radiation Safety Program - Operating and Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Self-Shielded Irradiator Transfer and Disposal."

8.11 ITEM 11: WASTE MANAGEMENT

8.11.1 SELF-SHIELDED IRRADIATOR DISPOSAL AND TRANSFER

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

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 self-shielded irradiators, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the irradiator, 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).

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.

Licensees should promptly dispose of unused irradiators to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Response from Applicant: The applicant does not need to provide a response to this item during the licensing phase. However, the licensee should develop, implement, and maintain self-shielded irradiator transfer and 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.

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.*

CONTENTS OF AN APPLICATION

Note:

- C It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 United States Code (U.S.C.) 1001).
- C 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 may be permitted for operating and emergency procedures), 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:

- C Be sure to use the most recent guidance in preparing an amendment or renewal request.
- C Submit in duplicate, either an NRC Form 313 or a letter requesting amendment or renewal.
- C Provide the license number.
- C 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. As an alternative, describe clearly the exact nature of the changes, additions, and deletions.

The performance-based approach in NUREG-1556, Vol. 5, gives licensees greater flexibility than previously permitted under licenses based on applications prepared according to RG 10.9, Rev. 1. This permits licensees to make more changes in their radiation safety program without amending their licenses, thus reducing the regulatory burden on licensees and the NRC staff. Accordingly, existing self-shielded irradiator licensees have the option of submitting a complete application using NUREG-1556, Vol. 5, at the time that they file an amendment request. Licensees choosing this option should incorporate the requested change into the complete application, submit it with the appropriate amendment fee, and indicate that the complete revision is an amendment request to take advantage of the new guidance. When the staff has reviewed the request and resolved any outstanding issues, the staff will amend the license without changing the expiration date.

Licensees wishing to renew their licenses should submit a complete application according to NUREG-1556, Vol. 5. The staff's action will be similar to that described for amendments, but will include an extension of the license's expiration date. By following this procedure, the staff expects all existing self-shielded irradiator licenses to be converted to the more performance-based format within a few years.

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 71.8). 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:

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

Some licensees with self-shielded irradiators built before 1966 may need an exemption from the requirements in 10 CFR Part 71 in order to transport these irradiators. Part 3 of Appendix Q provides more detailed information about this special situation.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 20.1402, 10 CFR 20.1403, 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:

C 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 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.

C Submit decommissioning plan, if required by 10 CFR 30.36(g).

C Conduct decommissioning, as required by 10 CFR 30.36(h) and 10 CFR 30.36(j).

C 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).

C 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 - Self-Shielded Irradiator Disposal or Transfer.” For guidance on decommissioning records, see the section on “Radioactive Materials - Financial Assurance and Record Keeping for Decommissioning.”

TERMINATION OF ACTIVITIES

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 NRC Documents Considered in The Preparation of This NUREG Report

List of NRC Documents Considered in The Preparation of This NUREG Report

This report incorporates and updates the guidance previously found in the RGs, P&GDs, INs, and TARs listed below. Other NRC documents such as IPs and MOUs were also consulted during the preparation of this report. *The documents marked with an asterisk (*) are superseded by this report and should not be used.*

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

Document Identification	Title	Date
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	06/86
*RG 10.9 (Rev. 1)	Guide for the Preparation of Applications for the Use of Self-contained Dry Source-Storage Gamma Irradiators	12/88
Draft RG FC 412-4	Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services	06/85
Draft RG FC 413-4	Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments	06/85
*P&GD FC 84-16	Standard Review Plan for Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators	10/84
*P&GD FC 84-18	Transportation of Irradiator Units Not Meeting Current Requirements in 10 CFR Part 71	11/84
P&GD FC 90-02 (Rev. 1)	Standard Review Plan for Evaluating Compliance with Decommissioning Requirements	4/30/91
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 89-25 Rev. 1	Unauthorized Transfer of Ownership or Control of Licensed Activities	12/07/94
IN 96-28	Suggested Guidance Relating to Development and Implementation of Corrective Action	05/01/96
*IN 96-35	Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training	06/11/96
IN 97-30	Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises	06/03/97

Table A.3 List of Technical Assistance Requests

No.	Title	TAR Date
*1.	University of Pittsburgh	01/17/91
*2.	University of Wisconsin and Maintenance of J. L. Shepherd Mark I Irradiators	08/08/94

Table A.4 Miscellaneous NRC Documents

Document Identification	Title	Date
IP 87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing	06/11/97
IP 87110, Appendix A	Industrial/Academic/Research Inspection Field Notes	02/03/97
MOU	Memorandum of Understanding with DOT on the Transportation of Radioactive Material	06/06/79

Appendix B

United States Nuclear Regulatory Commission Form 313

United States Nuclear Regulatory Commission Form 313

Replace this page with NRC Form 313.

Appendix C

Suggested Format for Providing Information Requested in Items 5 Through 11 or NRC Form 313

Suggested Format for Providing Information Requested in Items 5 Through 11 or NRC Form 313

Table C.1 Items 5 & 6: Materials to Be Possessed and Proposed Uses

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use As Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cesium-137	Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved Sealed Source and Device Registration Certificate: Sealed source manufacturer's (or distributor's) name and model number: _____ Device manufacturer's (or distributor's) and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis supporting safe use)

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Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use As Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cobalt-60	Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved Sealed Source and Device Registration Certificate: Sealed source manufacturer's (or distributor's) name and model number: _____ Device manufacturer's (or distributor's) and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis supporting safe use)
		Strontium-90	Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved Sealed Source and Device Registration Certificate: Sealed source manufacturer's (or distributor's) name and model number: _____ Device manufacturer's (or distributor's) and model number: _____	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis supporting safe use)

Yes	No	Radioisotope	Manufacturer or Distributor Model No.	Quantity	Use As Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Other (specify)	Sealed source manufacturer or distributor and model number: Device manufacturer or distributor and model number:	Not to exceed either the maximum activity per source or maximum activity per device as specified in Sealed Source and Device Registration Certificate	Yes []	[] Not applicable [] Uses are: (Submit safety analysis supporting safe use)
<i>Financial Assurance Required and Evidence of Financial Assurance Provided</i>						

Table C.2 Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Disposal

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
7. Individual(s) Responsible For Radiation Safety Program And Their Training And Experience	Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Appendix G in NUREG - 1556, Vol. 5, dated October 1998 AND	[]	[]
7.1 Radiation Safety Officer (RSO) Name: _____	Before being named as the RSO, future RSOs will have successfully completed the training described in Appendix G in NUREG - 1556, Vol. 5 dated October, 1998. Within 30 days of naming a new RSO, we will submit the RSO's name to NRC for inclusion in our license.		
7. Individual(s) Responsible For Radiation Safety Program And Their Training And Experience			
7.2 Authorized Users	Before using licensed materials, authorized users will receive the training described in Appendix G in NUREG - 1556, Vol. 5, dated October 1998	[]	[]

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Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
8. Training for Individuals Working in or Frequenting Restricted Areas	The applicant's training program will be examined during inspection, but should not be submitted in the license application.	Need Not Be Submitted with Application	
9. Facilities and Equipment	We will ensure that each area where a self-shielded irradiator is located corresponds to the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath a self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; <i>and</i> each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.	[]	[]
10. Radiation Safety Program 10.1 Audit Program	The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but should <i>not</i> be submitted in the license application.	Need Not Be Submitted with Application	
10. Radiation Safety Program 10.2 Radiation Monitoring Instruments	<p>We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG - 1556, Vol. 5, dated October, 1998. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.</p> <p style="text-align: center;">OR</p> <p>We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG - 1556, Vol. 5, dated October, 1998. Additionally, we will implement the model survey meter calibration program published in Appendix K to NUREG - 1556, Vol. 5, dated October, 1998, and we will ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.</p>	[]	[]

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program 10.3 Material Receipt and Accountability	Physical inventories will be conducted at intervals not to exceed 6 months to account for all sealed sources and devices received and possessed under the license.	[]	[]
10. Radiation Safety Program 10.4 Occupational Dose	Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the Criteria in the section entitled “Radiation Safety Program - Occupational Dose” in NUREG - 1556, Vol. 5, dated October, 1998.	[]	[]
10. Radiation Safety Program 10.5 Public Dose	No response is required from the applicant in a license application, but documentation demonstrating compliance will be examined during inspection.	Need Not Be Submitted with Application	
10. Radiation Safety Program 10.6 Operating & Emergency Procedures	<p>If we change our operating and emergency procedures without amending our license, we will ensure that: the changes are reviewed and approved by licensee management and the RSO; affected licensee staff are trained in the procedures before they are implemented; the changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application; and the changes do not degrade the safety of the program.</p> <p style="text-align: center;">AND</p> <p>Operating and emergency procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled, “Radiation Safety program - Operating and Emergency Procedures” in NUREG - 1556, Vol. 5, dated October, 1998.</p>	[]	[]
		[]	

APPENDIX C

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
<p>10. Radiation Safety Program 10.7 Leak Test</p>	<p>Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for 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 manufacturer's (or distributor's) and kit supplier's instructions.</p> <p style="text-align: center;">OR</p> <p>Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the Sealed Source and Device Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for 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 manufacturer's (or distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix P to NUREG - 1556, Vol. 5, dated October, 1998.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p>
<p>10. Radiation Safety Program 10.8 Maintenance</p>	<p><u>ROUTINE MAINTENANCE</u> We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's (or distributor's) written recommendations and instructions.</p> <p><u>NON-ROUTINE MAINTENANCE</u> We will have the self-shielded irradiator manufacturer (or distributor's) or other person authorized by NRC or an Agreement State perform non-routine maintenance.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>	<p style="text-align: center;"><input type="checkbox"/></p> <p><input type="checkbox"/> The information listed in Appendix I supporting a request to perform non-routine maintenance in-house is attached.</p>

Item No. and Title	Suggested Response	Yes	Alternative Procedures Attached
10. Radiation Safety Program 10.9 Transportation	<i>No</i> response is needed from applicants during the licensing phase. However, before offering a Type B package for shipment, 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	
10. Radiation Safety Program 10.10 Minimization of Contamination	The applicant does <i>not</i> need to submit a response to the minimization of contamination section if the applicant's responses meet the criteria for the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment," "Radiation Safety Program - Operating and Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Self-Shielded Irradiator Transfer and Disposal."	Need Not Be Submitted with Application	
11. Waste Management 11.1 Self-Shielded Irradiator Disposal & Transfer	The applicant does <i>not</i> need to provide a response to this item during the licensing phase. However, the licensee should develop, implement, and maintain self-shielded irradiator transfer and 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

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.

APPENDIX D

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 transferring 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.

Appendix E

J. L. Shepherd Order

J. L. Shepherd Order

JULY 3, 1984

UNITED STATES

NUCLEAR REGULATORY COMMISSION

URGENT NOTICE

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid "blinking out" of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

APPENDIX E

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety

Enclosure: Order Modifying License

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D. C. 20555

ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

I

Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the failure of a locking mechanism on a self-shielded irradiator which could have resulted in a radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source remains in a shielded position at all times, both during storage and during irradiations. Therefore, the irradiators need not be placed in a shielded room.)

The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit is operated as follows: (1) With the source in its shielded storage position, the shielded door is opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after irradiation is complete, the source is lowered, and (6) the door is opened for removal of irradiated materials.

The shielded door is interlocked so that it should not open when the radioactive source is in the irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such a situation, an operator who opens the shielded door with the source raised could be subjected to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an interlock similar to the Mark I.

The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore, a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a malfunctioning interlock system. NRC and the Agreement States are studying the problem further to assess its generic implications.

Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a potential radiation hazard warranting immediate preventive action pending further investigation. I have determined, therefore, that the public health, safety, and interest require that the restrictions on the use of such irradiators as prescribed in Section II of this Order should be made immediately effective.

II

Accordingly, pursuant to Sections 81, 116 I, 162 o, and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

1. The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated and operable radiation survey meter or room monitor for use with the irradiator.
2. The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
3. Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.
4. If a room monitor is not installed, a survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.
5. If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.
6. The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section 1 and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

Dated at Bethesda, Maryland
this 3rd day of July, 1984

Appendix F

Guidance on Financial Assurance

Guidance on Financial Assurance

Determining Need for Financial Assurance

If the only radioactive materials possessed are sealed sources in self-shielded irradiators, use Table F.1 to determine if financial assurance is required.

Table F.1 Worksheet for Determining Need for Financial Assurance for Self-Shielded Irradiators

Step No.	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

* For ease of use by most irradiator licensees, this table uses only conventional units. The conversion to SI units is: 1 Ci = 37 GBq.

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit certification of financial assurance or a decommissioning funding plan (10 CFR 30.35(e)). RG 3.66,⁴ "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides sample documents for financial mechanisms. The recommended wording for a Statement of Intent for government licensees is shown below.

⁴ See the Notice of Availability (on the inside front cover of this report) to obtain copies of RG 3.66.

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 Number]. 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]

Attachment: As stated

Appendix G

Model Training Program

Model Training Program

Course Content

Training may be in the form of lecture, videotape, hands-on, or self-study, and emphasizes practical subjects important to the safe use of the self-shielded irradiator:

C Radiation Safety

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Use of radiation detection instruments.

C Regulatory Requirements

- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- License conditions, amendments, renewals
- Transfer and disposal
- Recordkeeping
- Handling incidents
- Licensing and inspection by regulatory agency
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct.

APPENDIX G

C Practical Explanation of the Theory and Operation for Each Irradiator Possessed by the Licensee

- Routine vs. non-routine maintenance
- Operating and emergency procedures
- Prior events involving self-shielded irradiators.

Instructor's Qualifications

The individual preparing and conducting training is qualified as RSO or AU on a self-shielded irradiator license before giving training.

Training Assessment

Management will ensure that potential RSOs and authorized users are qualified to work independently with each type of the licensee's irradiators. This may be demonstrated by written or oral examination or by observation.

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 NRC and DOT regulations and the conditions of the license; see Figure 8.1. Typically, these duties and responsibilities include ensuring the following:

- C Activities involving licensed material that the RSO considers unsafe are stopped
- C Radiation exposures are ALARA
- C Posting of required documents, or a notice where the following documents can be found:
 - Required by 10 CFR 19.11:
10 CFR Parts 19 and 20; license documents; operating procedures; NRC Form 3 "Notice to Employees,"
 - Required by 10 CFR 21.6:
10 CFR Part 21; Section 206 of Energy Reorganization Act of 1974; and procedures adopted pursuant to 10 CFR Part 21
- C Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures
- C Possession, installation, relocation, use, storage, repair, and maintenance of self-shielded irradiators are consistent with the limitations in the license, the SSD Registration Certificate(s), and manufacturer's written recommendations and instructions
- C Safety consequences are analyzed before conducting any activities involving repair, use, maintenance, installation, or relocation, which were never previously analyzed
- C Individuals installing, relocating, using, maintaining, or repairing self-shielded irradiators are trained and authorized (as described in the license application)
- C Prospective evaluations are performed demonstrating that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided
- C When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- C Self-shielded irradiators are properly secured
- C Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in 10 CFR 20.1301
- C Proper authorities are notified of incidents such as damage to or malfunction of self-shielded irradiators, fire, or theft

APPENDIX H

- C Unusual occurrences involving the self-shielded irradiators (e.g., malfunctions or damage) are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- C Radiation safety program audits are performed at least annually and documented
- C When the licensee identifies violations of regulations or license conditions or program weaknesses, the licensee develops, implements, and documents corrective actions
- C Licensed material is transported in accordance with all applicable DOT requirements
- C Licensed material is disposed of properly
- C Appropriate records are maintained
- C Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner

Appendix I

Information Needed to Support Applicant's Request to Perform Non-routine Maintenance

Information Needed to Support Applicant's Request to Perform Non-routine Maintenance

Review the section on "Maintenance" which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine maintenance includes repairs, removal, replacement, or alterations involving:

- C Electrical and mechanical systems and components that control source or shielding movement
- C Self-shielded irradiator's shielding or sealed source(s)
- C Safety interlocks
- C Any other component which may affect safe operation of the device
- C Any other activities during which personnel could receive radiation doses exceeding NRC limits.

See Figure 8.7. If this maintenance or repair is not performed properly with attention to radiation safety principles, the self-shielded irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Non-routine maintenance should be performed only by qualified and specifically authorized individuals. Self-shielded irradiator licensees should conduct these operations only after their procedures have been evaluated and specifically approved by license condition. Also, any non-manufacturer- (non-distributor-) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the irradiator is tested and functions as designed, before the unit is returned to routine use.

Accordingly, applicants wishing to perform non-routine maintenance must provide the following information, as appropriate:

- C Describe the types of non-routine maintenance to 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.

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- C Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance. Adequate training and experience includes the following:
- previous experience in non-routine maintenance and radiation safety training
 - vendor maintenance certification
 - technician(s) using pre-planned procedures with direct health physics supervision.
- C Submit procedures for non-routine maintenance. These procedures should ensure the following:
- doses to personnel and members of the public are within regulatory limits and ALARA
 - the source is secured against unauthorized access or removal
 - appropriate labels and signs are used
 - manufacturer's (distributor's) written instructions and recommendations are followed
 - any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration.
 - before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised.
- C Confirm that individuals performing non-routine maintenance on irradiators will always wear both whole body and extremity monitoring devices.
- C Verify possession of at least one instrument that meets the description for survey meters used with moving-source irradiators in the "Radiation Monitoring Instrument Specifications" section of Appendix K in NUREG-1556, Vol. 5, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-shielded Irradiator Licenses," dated October 1998.
- C Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance 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 (as described above);
 - specify where and when surveys will be conducted during non-routine maintenance; 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

Suggested Self-Shielded Irradiator Audit Checklist

Suggested Self-Shielded Irradiator Audit Checklist

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 the licensee's activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit _____ Date of Last Audit _____

Next Audit _____

Auditor: _____ Date _____
(Signature)

Management Review _____ Date _____
(Signature)

Audit History

- A. Were previous audits conducted annually? [10 CFR 20.1101]
- B. Were records of previous audits maintained? [10 CFR 20.2102]
- C. Were any deficiencies identified during last two audits or two years, whichever is longer?
- D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

A. Radiation Safety Officer

1. If the RSO was changed, was license amended?
2. Does new RSO meet NRC training requirements?
3. Is RSO fulfilling his/her duties?
4. To whom does RSO report?

B. Licensed Material

1. Does the license authorize all of the NRC-regulated radioactive material contained in self-shielded irradiators?
2. Does the total amount of radioactive material possessed require financial assurance?
[10 CFR 30.35(a)]

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- C. Are the self-shielded irradiators as described in the Sealed Source and Device (SSD) Registration Certificate? Have copies of (or access to) SSD Certificates? Have manufacturer's (or distributor's) manuals for operation and maintenance? [10 CFR 32.210]
- D. Are the actual uses of self-shielded irradiators consistent with the authorized uses listed on the license?
- E. If the mailing address or places of use changed, was the license amended?
- F. If control of license transferred or bankruptcy filed, was NRC prior consent obtained or notification made, respectively?

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]? Was refresher training provided, as needed [10 CFR 19.12]?
- B. Did each authorized user and person independently performing routine or non-routine maintenance attend license-required training before working with self-shielded irradiators?
- C. Are training records maintained for each individual?
- D. Did interviews with workers reveal that they know the emergency procedures and repair, maintenance, and relocation limitations?
- E. Did this audit include observations of operators using the self-shielded irradiators? Performing routine or other authorized maintenance?
- F. Did the audit identify any operator error in reporting maintenance and repair or operation issues to the RSO for review before starting work?

Radiation Survey Instruments

- A. Describe the survey instruments possessed:
 - 1. Do they meet the NRC's criteria?
 - 2. Are they appropriate for the source type(s)?
 - 3. Are they checked for function before use?
 - 4. If they are used with moving-source irradiators or during non-routine maintenance, are they calibrated as required? [10 CFR 20.1501]
- B. If the licensee does not possess a survey meter, are specific plans made to have one available?
Location: _____ Location/Operation verified: _____

- C. Are calibration records, if required, maintained? [10 CFR 20.2103(a)]
- D. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition

Self-shielded Irradiator Inventory and Location

- A. Is a record kept showing the receipt of each self-shielded irradiator? [10 CFR 30.51(a)(1)]
- B. Has the location(s) changed since the last audit?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program?
[10 CFR 20.1101(b)]
- B. Were prospective evaluations performed showing that unmonitored users receive #10% of limit? [10 CFR 20.1502(a)]
- C. Did unmonitored users' activities change during the year which could put them over 10% of limit?
- D. If yes to 3. above, was a new evaluation performed?
- E. Is external dosimetry required (user receiving >10% of limit)? Is dosimetry provided to users?
 - 1. If processed dosimetry:
 - a. Is the dosimetry supplier NVLAP-approved? [10 CFR 20.1501(c)]
 - b. Are dosimetry reports reviewed by the RSO when they are received?
 - 2. If self-reading dosimeters:
 - a. Have a range of zero to at least 2 mSv (200 mrem)?
 - b. Are checked at periods not to exceed one year for correct response to radiation?
 - c. Are read within $\pm 20\%$ of the true radiation exposure?
 - d. Are used under a program that prescribes action to evaluate the individual's dose?
- F. Are the dosimeters exchanged or read at the license required frequency?
- G. Are the records NRC Forms or equivalent? [10 CFR 20.2104(d), 10 CFR 20.2106(c)]
 - 1. NRC-4 "Cumulative Occupational Exposure History" completed?
 - 2. NRC-5 "Occupational Exposure Record for a Monitoring Period" completed?

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H. Declared pregnant worker/embryo/fetus

1. If a worker declared her pregnancy, did licensee comply with 10 CFR 20.1208?
2. Were records kept of embryo/fetus dose per 10 CFR 20.2106(e)?

I. Are records of exposures, surveys, monitoring, and evaluations maintained [10 CFR 20.2102, 10 CFR 20. 2103, 10 CFR 20. 2106]

Public Dose

- A. Are self-shielded irradiators located and used 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)?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? [10 CFR 20.1301(a)(2)]
- E. Are self-shielded irradiators being used or stored in a manner that would prevent unauthorized access or removal? [10 CFR 20.1801]
- F. Records maintained? [10 CFR 20.2103, 10 CFR 20.2107]

Operating and Emergency Procedures

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required elements?
- C. Does each operator have a current copy of the operating and emergency procedures? Maintain copy at each irradiator's control panel or post notice indicating where to obtain copy?
- D. Did any emergencies occur?
 1. If so, were they handled properly by operator?
 2. Were appropriate corrective actions taken?
 3. Was NRC notification or reporting required? (10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203)

- E. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition
- F. Were operating or emergency procedures changed since last audit? If so, before new procedures were implemented:
 - 1. Did licensee management and the RSO approve?
 - 2. Did affected staff receive training?
 - 3. Are the changes consistent with license conditions? licensee commitments?
 - 4. Do the changes degrade safety?

Leak Tests

- A. Was each sealed source leak tested every 6 months (or at other license prescribed intervals)?
- B. Was the leak test performed as described in correspondence with NRC and according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was NRC notified?

Maintenance of Self-shielded Irradiators

- A. Are manufacturer's (or distributor's) written procedures followed for routine (not safety critical) cleaning and lubrication and mechanical/electrical maintenance and repair of self-shielded irradiators?
- B. Was non-routine maintenance performed?
- C. If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with dose limits)?
- D. Since the last audit, did operator(s) report a need for non-routine maintenance and repair to the RSO before requesting or conducting the work?

Transportation

- A. Were self-shielded irradiator(s) or sources shipped since the last audit?
- B. If so, were 10 CFR Part 71 requirements followed?
 - 1. 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?

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2. Package performance test records on file? [49 CFR 173.415(a)]
3. Special form sources documentation? [49 CFR 173.476(a)]
4. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 49 CFR 173.441]
5. Package properly marked? [49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324]
6. Package closed and sealed during transport? [49 CFR 173.475(f)]
7. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
8. 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 (SI units required), 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]
9. Secured against movement? [49 CFR 177. 834]
10. Placarded on vehicle, if needed? [49 CFR 172.504]
11. Proper overpacks, if used? [49 CFR 173.25]
12. Any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]
13. Irradiators manufactured before 1966
 - a. Were any shipped?
 - b. Were NRC and DOT exemptions, if needed, received in advance?

Auditor's Independent Survey Measurements (If Made)

- A. Describe the type, location, and results of measurements.
- B. Do any radiation levels exceed regulatory limits?

Notifications and Reports

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

- B. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.50]
- C. Did any overexposures and high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]
- D. If any events (as described in items 1 through 3 above) did occur, what was root cause? Were corrective actions appropriate?
- E. Is the licensee aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]

Posting and Labeling

- A. NRC-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, 10 CFR Part 21]

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 any special license conditions?
- B. Did auditor review any other issues (e.g., non-routine maintenance)?

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. 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 K

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Instrument(s) used with moving-source gamma irradiators must meet the following criteria:

- C The instrument is a survey meter capable of detecting gamma radiation of more than 5×10^{-5} coulombs/kilogram (C/kg) (or up to several hundred milliroentgens (mR)) per hour which is:
- In the licensee's possession
 - Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
 - Calibrated with a source of radiation annually and 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 $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State.

OR

- C The instrument is a room monitor which:
- Is in the licensee's possession
 - Is checked with a source of radiation at the beginning of each day of use to ensure that it will respond accurately to radiation and alarm at 0.02 mSv (2 mrem) per hour
 - Activates a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Is positioned so it will detect any radiation escaping from the irradiator door yet still be visible to the irradiator operator when using the irradiator.

Instrument(s) used with fixed-source gamma irradiators (or beta irradiators) are:

- C A survey meter capable of detecting gamma radiation (or beta radiation, as appropriate)
- C In the licensee's possession or readily accessible in the event of an accident or malfunction which could reduce the shielding for the sealed source(s)
- C Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation

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- C Calibrated with a source of radiation annually and 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 $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State.

Model Survey Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the individual has sufficient classroom and on-the-job training to show competency in performing independent survey instrument calibrations.

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

- C Principles and practices of radiation protection
- C Radioactivity measurements, monitoring techniques, and using instruments
- C Mathematics and calculations basic to using and measuring radioactivity
- C Biological effects of radiation.

Appropriate on-the-job-training consists of:

- C Observing authorized personnel performing survey instrument calibration
- C Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment

- C 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
- C Individuals conducting calibrations will wear assigned dosimetry
- C 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 for Gamma Detection

- C A radioactive sealed source(s) used for calibrating survey instruments 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 $\pm 5\%$ accuracy by NIST
 - Approximate the same photon energy (Cs-137, Co-60) as the environment in which the calibrated device will be employed
 - Be strong enough to give an exposure rate of at least 7.7×10^{-6} C/kg/hr (or 30 mR/hr) at 100 cm [e.g., 3.1 GBq (85 mCi) of Cs-137) or 7.8×10^2 MBq (21 mCi) of Co-60].
- C The inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- C A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a)).
- C 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 $\pm 20\%$.
- C The three kinds of scales frequently used on radiation survey meters are calibrated either as described in ANSI N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments," or as follows:
- Meters on which the user selects a linear scale must be calibrated at not fewer than 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 will be at approximately $1/3$ and $2/3$ of the decade.
- C Readings above 2.58×10^{-4} C/kg/hr (1000 mR/hr) need not be calibrated. However, such scales should be checked for operation and approximately correct response.
- C Survey meter calibration reports will indicate the procedure used and the data obtained. The description of the calibration will include:
- The owner or user of the instrument

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- A description of the instrument including 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 person's name who performed the calibration and the date it was performed

C 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 N323A-1996, "American National Standard Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments." Copies may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018.

See the Notice of Availability (on the inside front cover of this report) to obtain a copy of Draft RG 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 L

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. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective 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 frequent routine maintenance on the irradiator. However, for most new irradiators even these activities result in the individual's receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

The following is an example of an estimate of the dose received by the extremities and whole body of a person performing routine maintenance (cleaning and lubrication) on a self-shielded irradiator rotating drawer drive chain. The estimate is based on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer can provide the following types of information:

- C Time needed to perform the entire procedure (e.g., 20 min)
- C Extremity dose rate received by an individual, associated with the shielded source (e.g., 0.02 mSv/hr [2 mrem/hr] at contact with the shield)
- C Time the hands were exposed to the shielded source (e.g., 3 min)
- C Whole body dose rate received by an individual, associated with the shielded source (e.g., 0.01 mSv/hr [1 mrem/hr] at contact with the shield)
- C Time the whole body is exposed to the shielded source (e.g., 20 min)

From this information, an estimate of the doses that the individual performing this procedure could receive is as follows:

- C 0.001 mSv [0.1 mrem] to the hands
- C Less than 0.0033 mSv [0.33 mrem] TEDE (whole body).

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 mrems) per year. If one of these procedures delivers 0.0033 mSv (0.33 mrem), then

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an individual could perform 1,515 of these procedures each year and remain within 10% of the applicable limit.

The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 mrems) per year. If one of these procedures delivers 0.001 mSv (0.1 mrem), then an individual could perform 50,000 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,515 routine maintenance procedures per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are *not* required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may *not* be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of self-shielded irradiator(s) they intend to use; this information is generally available from the irradiator manufacturer (or distributor) or the SSD Registration Certificate maintained by the NRC and Agreement States.

Table L.1 may be helpful in performing a prospective evaluation.⁵

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new irradiators containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table L.1 Dosimetry Evaluation

Dosimetry Evaluation for _____		Model _____	Self-Shielded Irradiator _____
A.	Time needed to perform the entire routine maintenance procedure.	_____ (minutes/60)	_____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the irradiator while the sealed source is in the shielded position.	_____ mrem/hr	

⁵ For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is: 1 mrem = 0.01 mSv

Dosimetry Evaluation for _____ Model _____ Self-Shielded Irradiator	
C.	Time the <i>hands</i> were exposed to the unshielded source. _____ (minutes/60) _____ hour
D.	Expected extremity dose rate received by the individual, determined using exposure rates measured at the typical distance that the hands would be from the sealed source during the routine maintenance procedure. _____ mrem/hr
Formula: (_____ # hours in Row A) x (_____ mrem/hr in Row B) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem *Whole Body Dose	
Formula: (_____ # hours in Row C) x (_____ mrem/hr in Row D) = (_____ mrem per routine procedure) x (_____ # of routine maintenance procedures each year) = _____ mrem **Extremity Dose	
* Expected Whole Body Doses <i>less than</i> 500 mrem requires no dosimetry	
** Expected Extremity Doses <i>less than</i> 5000 mrem requires no dosimetry	

Appendix M

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:

- C The radiation dose received by individual members of the public does not exceed 1 mSv (100 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 self-shielded irradiator devices are used or 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 stored.

- C 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 self-shielded irradiator facilities, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculational Method⁶

The calculational method takes a tiered approach, going through a three-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 shielded position are taken from either the SSD Registration Certificate, ANSI N433.1,⁷ "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiator (Category I)," or the manufacturer's (or distributor's) literature; and (3) no credit is taken for any shielding found between the irradiator and the unrestricted areas.

⁶ For ease of use by most self-shielded irradiator licensees, 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.

⁷ Copies may be ordered electronically at <<http://www.ansi.org>> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the NTIS, 5285 Port Royal Road, Springfield, VA 22161 1-800-553-6847.

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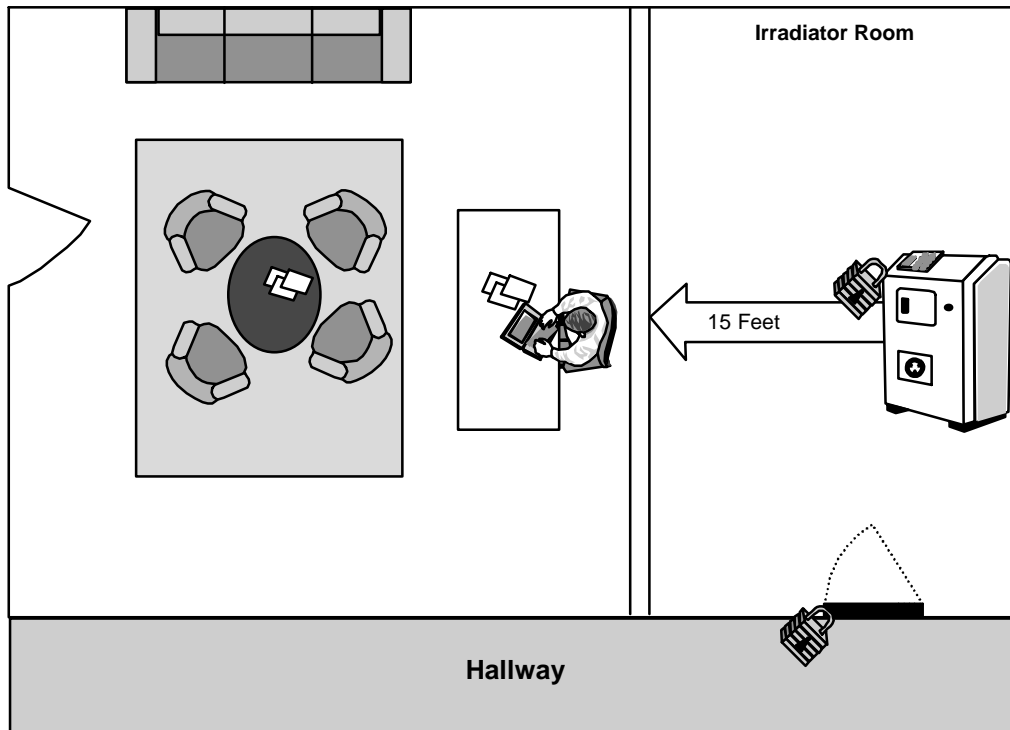
Part 1 of the calculational method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with 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. Part 3 considers the distance, the portion of time and dose rate while the sample is in transit, the portion of time and dose rate while the sample is not in transit, and the portion of time that the affected member of the public is present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculational method through Part 1 or Part 2. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a conservative method for estimating doses which could be received.

Example 1

To better understand the calculational method, we will examine Bugs-Away, Inc., a self-shielded irradiator licensee. Yesterday, the company's president noted that the new irradiator area is close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with NRC's regulations.

The secretary's desk is near the wall separating the reception area from the designated, locked self-shielded irradiator room where the company has located its irradiator. Joe measures the distance from the self-shielded irradiator to the wall and assumes that the irradiator would have the maximum dose rate allowed under ANSI N433.1: 10 mrem per hour at one meter. This is the maximum dose rate permitted while the sample is in transit (i.e., moving into or out of the irradiation position). Figure M.1 is Joe's sketch of the areas in question, and Table M.1 summarizes the information Joe has on the irradiator.

A Bird's Eye View of Office and Irradiator Area



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Figure M.1 Diagram of Office and Irradiator Area. *This sketch shows the areas described in Examples 1 and 2.*

Table M.1 Information Known about the Self-Shielded Irradiator

Description of Known Information	Cs-137 Self-Shielded Irradiator
Dose rate in mrem/hr encountered at specified distance from the irradiator (from ANSI N433.1)	10 mrem/hr at 1 meter (3.28 ft)
Distance in feet to secretary's chair	15 ft

Example 1: Part 1

Joe's first thought is that the distance between the irradiator and the secretary's chair may be sufficient to show compliance with the regulation in 10 CFR 20.1301. So, taking a worst case approach, he assumes: 1) the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit, and 2) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from the self-shielded irradiator as shown in Table M.2 below.

Table M.2 Calculational Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator

Step No.	Description	Input Data	Result
1	Dose received in an hour at known distance from irradiator (e.g., from ANSI N433.1), in mrem/hr	10	10
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3.28) ²	10.8
3	Square of the distance (ft) from the irradiator to the secretary's desk in an unrestricted area, in ft ²	(15.0) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	10 x 10.8	108 (rounded to 110)
5	Divide the result of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in an hour	110/225	0.48
6	Multiply the result of Step 5 by 24 hr/d x 366 (leap year) d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in a year	0.48 x 24 x 366	4200

Note: The result in Step 5 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumptions change. If the result in Step 6 exceeds 100 mrem/yr, proceed to Part 2 of the calculational method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.48 mrem, but notes that an individual could receive a dose of 4,200 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit). He then recalculates the annual dose received.

Table M.3 Calculational Method, Part 2: Annual Dose Received from Self-Shielded Irradiator

Step No.	Description	Result
7	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/d; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5.0
	B. Average number of days per week in area (e.g., secretary is part time and works 3 d/wk)	3.0
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
8	Multiply the results of Step 7.A. by the results of Step 7.B. by the results of Step 7.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5.0 \times 3.0 \times 52 =$ 780
9	Multiply the results in Step 5 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN , in mrem in a year	$0.48 \times 780 =$ 370
<i>Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the calculational method.</i>		

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again Joe reviews his assumptions and recognizes that the irradiator is not constantly in use nor is the sample continuously in transit during an irradiation cycle when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

Table M.4 Calculational Method, Part 3: Summary of Information

Step No.	Description	Input
10	Dose rate while the irradiator is idle, in mrem/hr at 3.28 ft from the irradiator	2.0
11	Dose rate while the sample is in transit, in mrem/hr at 3.28 ft from the irradiator	10.
12	Dose rate while sample is irradiated, in mrem/hr at 3.28 ft from the irradiator	2.0

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Step No.	Description	Input
13	Maximum number of irradiations per hour	5.0
14	Maximum irradiation time, in min	3.0
15	Time that the sample is in transit, in min per irradiation cycle	0.20
16	From Table M.1, distance from irradiator to secretary, in ft	15.
17	From Step 8, average number of hours that secretary is in area of concern, per year	780

Table M.5 Calculational Method, Part 3: Annual Dose Received from Irradiator

Step No.	Description	Result
18	[60 minus the input from Step 13 multiplied by (the input from Step 14 plus the input from Step 15)] divided by 60 = $[60. - 5.0 \times (3.0 + 0.20)] / 60. = [60. - 16.] / 60 =$ FRACTION OF TIME THE IRRADIATOR IS IDLE	0.73
19	(The input from Step 13 multiplied by the input from Step 15) divided by 60 = $(5.0 \times 0.20) / 60 = 1/60 =$ FRACTION OF TIME THE SAMPLE IS IN TRANSIT	0.017
20	1.0 minus the result from Step 18 minus the result from Step 19 = $1 - 0.73 - 0.017 =$ FRACTION OF TIME THE IRRADIATOR IS IN USE	0.253
21	(The input from Step 10 multiplied by the result from Step 18) plus (the input from Step 11 multiplied by the result from Step 19) plus (the input from Step 12 multiplied by the result from Step 20) = $(2.0 \times 0.73) + (10. \times 0.017) + (2.0 \times 0.253) = 1.46 + 0.17 + 0.506 =$ AVERAGE DOSE RATE ENCOUNTERED AT 3.28 FEET FROM THE IRRADIATOR , in mrem in an hour.	2.136
22	The result from Step 21 multiplied by (3.28 squared divided by the input from Step 16 squared) = $2.136 \times (3.28^2 / 15^2) = 2.136 \times (10.8 / 225) =$ AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY . in mrem per hour.	0.10
23	The result from Step 22 multiplied by the input from Step 17 = $780 \times 0.10 =$ ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATES OF TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND IRRADIATOR USAGE , in mrem in a year.	78.

Note: If the result in Step 23 is greater than 100 mrem/yr, the licensee must take corrective actions.

Joe is glad to see that the results in Step 23 show compliance with the 100 mrem in a year limit. Had the result in Step 23 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- C Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- C Calculate the effect of any shielding⁸ located between the irradiator area and the secretarial workstation — such calculation is beyond the scope of this Appendix
- C Take corrective action (e.g., move irradiator within the use area, move the use area, move the secretarial workstation) and perform new calculations to demonstrate compliance
- C Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary.

Note that in the example, Joe 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 (e.g., moving the self-shielded irradiator closer to the secretarial workstation, adding a second irradiator, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) 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.

Combination Measurement-Calculational Method

This method, which allows the licensee to take credit for shielding between the irradiator and the area in question, begins by measuring radiation levels in the areas, as opposed to using ANSI-N433.1 or manufacturer- (or distributor-) supplied rates at a specified distance from each irradiator. 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.

⁸ 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.

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

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 TLDs⁹ 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.

Example 2

As in Example 1, Joe is the RSO for Bugs-Away, Inc., a self-shielded irradiator licensee. The company has one irradiator in a designated, locked area that adjoins an unrestricted area where a secretarial work station is located. See Figure M.1 and Table M.2 for information. Joe wants to see if the company complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table M.6 Combination Measurement-Calculational Method

Step No.	Description	Input Data and Results
Part 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hr/d x 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 = HOURLY DOSE RECEIVED , in mrem in an hour	100/720 = 0.14

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 CaF₂ that are used for environmental monitoring.

Step No.	Description	Input Data and Results
4	Multiply the results of Step 3 by 366 d/yr [leap year] x 24 hr/d = 8784 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR , in mrem in a year	366 x 24 x 0.14 = 8784 x 0.14 = 1230

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations.

Part 2

At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.

Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he may have to consider moving the self-shielded irradiator or the secretary's desk, or adding shielding to the wall.

Appendix N

Typical NRC Incident Notifications Required for Self-Shielded Irradiator Licensees

Typical NRC Incident Notifications Required for Self-Shielded Irradiator Licensees

Table N.1 Typical NRC Incident Notifications Required for Self-Shielded 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)
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at <i>entire site</i>	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any <i>separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>at the entire site</i>	none	60 days	10 CFR 30.36(d)

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Event	Telephone Notification	Written Report	Regulatory Requirement
No principal activities conducted for 24 months <i>in any separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
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)

Note: Telephone notifications shall be made to the NRC Operations Center at 301-816-5100 or 301-951-0550.

Appendix O

Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Elements of Operating Procedures Applicable to All Types of Self-Shielded Irradiators

- C Analyze each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine whether special procedures in addition to those given by the manufacturer (or distributor) are required to ensure the safe operation of the irradiator.
- C Prepare model-specific instructions for routine inspections, test procedures, and maintenance to ensure that all interlocks, devices, and components critical to the safe operation of the irradiator are functioning properly. (Prohibited actions such as changing the safety control system or removing the source should be stated.)
- C Develop methods to maintain accountability (e.g., log book to record irradiator use) and to ensure that only authorized persons will use or have access to the irradiator (e.g., control access to the irradiator's keys or control access to the area where the irradiator is located).
- C Define steps to take to keep radiation exposures ALARA.
- C For each model irradiator, define step-by-step procedures on how to operate the irradiator and how to perform routine maintenance. Information may be extracted from the manufacturer's (or distributor's) manual.

Specific Operating Procedures Applicable to Moving-Source Irradiators¹⁰

- C The irradiator should not be used unless the licensee provides a calibrated and operable radiation survey meter or a room monitor for use with the irradiator.
- C The irradiator door should not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
- C Each room monitor should:
 - be operable at all times when the irradiator is in use
 - activate a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mem) per hour
 - be located to detect any radiation escaping from the irradiator door
 - be located so that it is visible to the irradiator user when next to the irradiator.

¹⁰ These procedures are required for licensees authorized for J. L. Shepherd Mark I or Model 81-22 irradiator.

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C If a room monitor is not installed, a survey meter should be used to:

- determine the radiation level at the irradiator door when the door is closed
- check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators should position themselves to minimize exposure to any radiation escaping from the open door.
- If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee should stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the RSO, and determine if a report to NRC is required.
- The licensee should not attempt to repair or authorize others to attempt to repair the irradiator except as specifically authorized in a license issued by NRC.

Elements of Emergency Procedures Applicable to All Types of Self-Shielded Irradiators

- C Leave the irradiator area (to reduce radiation exposure).
- C Control access to the area (e.g., lock door).
- C Contact responsible individuals (e.g., names, phone numbers of RSO, irradiator manufacturer (or distributor), emergency response organizations such as fire department, NRC).
- C Take additional steps, dependent on the specific situations (e.g., surveys).
- C As appropriate, require timely reporting to NRC

Changes to Operating and Emergency Procedures Without a License Amendment

Licensees may change their operating and emergency procedures without amending their licenses if:

- C The changes are reviewed and approved by licensee management and the RSO
- C Affected licensee staff are trained in the procedures before they are implemented
- C The changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application
- C The changes do not degrade the safety of the program.

Copies of operating and emergency procedures should be provided to all users. Post a current copy at each irradiator's control panel. If posting the procedures is not practicable, post a notice describing the document(s) and where it may be examined.

Appendix P

Model Leak Test Program

Model Leak Test Program

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, hands-on, or self-study and will cover the following subject areas:

- C Principles and practices of radiation protection
- C Radioactivity measurements, monitoring techniques, and using instruments
- C Mathematics and calculations basic to using and measuring radioactivity
- C Biological effects of radiation.

Appropriate on-the-job-training consists of:

- C Observing authorized personnel collecting and analyzing leak test samples
- C 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

- C To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- C Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed. If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{2.71 \text{ } \% \text{ } 4.65 / (B_R \times t)}{t \times E} \text{ , } \textit{Minimum Detectable Activity}$$

where MDA = activity level in disintegrations per minute
 B_R = background rate in counts per minute

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t = counting time in minutes
E = detector efficiency in counts per disintegration

For example:

B_R = 200 counts per minute
E = 0.1 counts per disintegration (10% efficient)
t = 2 minutes

$$MDA = \frac{2.71\% \cdot 4.65 / (200 \times 2)}{2 \times 0.1} = \frac{2.71\% \cdot 4.65 / (400)}{0.2}$$

$$= \frac{2.71\% \cdot 4.65 (20)}{0.2} = \frac{2.71\% \cdot 9}{0.2} = \frac{11.71}{0.2}$$

$$= \frac{59 \text{ disintegrations}}{\text{minute}}$$

$$\text{becquerels (Bq)} = \frac{1 \text{ disintegration}}{\text{second}}$$

$$Bq = \frac{59 \text{ disintegrations}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 0.98 = 1 Bq$$

C A NaI(Tl) well counter system with a single or multi-channel analyzer will be used to count samples from irradiators containing gamma-emitters (e.g., Cs-137, Co-60).

C A liquid scintillation or gas-flow proportional counting system will be used to count samples from irradiators containing beta-emitters (e.g., Sr-90).

Frequency for Conducting Leak Tests of Sealed Sources

C Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

C For each source to be tested, list identifying information such as self-shielded irradiator serial number, radionuclide, activity.

C If available, use a survey meter to monitor exposure.

- C Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- C Number each wipe to correlate with identifying information for each source.
- C Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- C Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide in the irradiator.
- C Using the selected instrument, count and record background count rate.
- C Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to primary radiation standards such as those maintained by NIST.
- C Calculate efficiency.

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

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

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

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

- C Sign and date the list of sources, data, and calculations. Retain records for 3 years (10 CFR 20.2103(a)).
- C If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify NRC.

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

Appendix Q
Transportation

Transportation

Part 1 Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of typical self-shielded irradiators that are shipped as Type A or Type B quantities are as follows:

- C 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
- C Shipping Papers 49 CFR 172.200-204: general entries, description, additional description requirements, shipper's certification
- C 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 packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- C 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
- C 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
- C 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
- C Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements
- C Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.800, etc.
- C 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 173.433, 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 U.S. NRC-approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials

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C 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.

Part 2 Sample Bill of Lading

A Sample Bill of Lading appears on the following page.

Intentionally left blank: Replace this page with Sample Bill of Lading

Part 3 Irradiators Built Before 10 CFR Part 71 Regulation Implementation

Before the adoption of the requirements of 10 CFR Part 71 in 1966, irradiators could be transported without being evaluated under the hypothetical accident conditions now incorporated in 10 CFR Part 71. Unlike most post-1966 irradiators, pre-1966 irradiators are not certified shipping packages. Transport of pre-1966 units may require transferring the sealed source from the irradiator to a Type B package or the use of a certified package for the irradiator containing the sealed sources.

NRC will consider a licensee's request for an exemption for a one-time shipment according to 10 CFR 71.8 *only* if these options are not viable.

An exemption may be granted if the request is authorized by law and will not endanger life or property or the common defense and security. In this case, an exemption request should demonstrate the need for the exemption, describe why alternatives considered are not viable, specify from what requirement(s) an exemption is requested and the period for which the exemption is requested, and describe steps taken to ensure that the shipment will not endanger life or property or the common defense and security (e.g., steps to minimize accident risk and to respond to a transportation accident). Typically, approved requests are for a limited period (e.g., 30 days).

Circumstances vary, but additional information supporting an exemption request may include the following:

- C Manufacturer's (or distributor's) name and model number of the irradiator, the type and activity of radioactive material to be transported, and brief description of proposed trip (starting and ending points and approximate distance)
- C Engineering drawings of irradiator
- C Consideration of the following:
 - DOT's hazardous material routing requirements
 - Transport during time of low road usage
 - Use of good roads and avoidance of residential areas to maximum extent possible
 - Accompaniment of shipment by escort knowledgeable in the use of radiation survey instruments
 - Provision of escort with appropriate survey instruments and supplies to permit the establishment of a radiation exclusion area
 - Written procedures to be followed by the escort in an emergency situation.

- Use of exclusive-use vehicle and shoring to limit movement of package during transport
- Notification of State radiological health officials and local fire department of time and route of shipment.

C Planned date of shipment

Before applying to the NRC for its approval, the licensee should contact the radiological health organization within each State (as indicated below) through which the shipment will be made to confirm the points of contact and to discuss the proposed controls for the shipment. In several previous cases, short distance shipment of irradiators have been successfully made with the cooperation of State officials.

NRC Headquarters staff must review these requests, which are typically requests to amend materials (10 CFR Part 30) licenses. Licensees should address their requests, accompanied by the amendment fee specified in 10 CFR 170.31, to the appropriate Regional Office. The Regional Office will refer the request to NRC Headquarters staff for review by the Package Certification Section, SFPO. If the exemption is approved, SFPO staff will provide the language for the license condition.

In addition to an NRC exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

Response from Applicant:

Demonstrate that the request is authorized by law and will not endanger life or property or the common defense and security.

AND

The following:

- C Establish that the irradiator was built before 1966
- C Explain why an approved package cannot be used, the alternatives considered, and why each is not viable
- C Specify from what requirement(s) an exemption is requested and the period for which the exemption is requested
- C Describe procedures, controls, and other actions to be taken to ensure that the shipment will not endanger life or property or the common defense and security.

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Reference: The names, addresses, and telephone numbers for officials in Agreement and non-Agreement States are available by choosing “Directories” on the NRC’s OSP Home Page at <http://www.hsr.d.o.rnl.gov/nrc/home.htm>. As an alternative, contact NRC’s regional offices; see Figure 2.1.

Appendix R

Sample Self-Shielded Irradiator License

Sample Self-shielded Irradiator License

A sample self-shielded Irradiator license appears on the following pages.

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.

<p style="text-align: center;">Licensee</p> <p>1. Irradiation Studies, Inc.</p> <p>2. 1234 A Street, NW Washington, D.C. 20001</p>	<p>3. License number 08-00000-00</p> <hr/> <p>4. Expiration date [Insert a date, last day of month, 10 years after issuance date]</p> <hr/> <p>5. Docket No. 030-00000 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cesium-137</p> <p>B. Cesium-137</p> <p>C. Cobalt-60</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed sources (ABC Company Model CS-123)</p> <p>B. Sealed sources (J. L. Shepherd and Associates Model 6810)</p> <p>C. Sealed sources (ABC Company Model CO-456)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. No single source to exceed the maximum activity specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission or an Agreement State</p> <p>B. No single source to exceed the maximum activity specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission or an Agreement State</p> <p>C. No single source to exceed the maximum activity specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission or an Agreement State</p>
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- | | | |
|---|--|---|
| 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 |
| D. Strontium-90 | D. Sealed sources (ABC Company Model SR-789) | D. No single source to exceed the maximum activity specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission or an Agreement State |

NOTE: IF OTHER RADIONUCLIDES ARE REQUESTED, USE THE ABOVE FORMAT FOR EACH AUTHORIZED RADIONUCLIDE.

9. Authorized use:
- A. through D. For irradiation of materials in self-shielded irradiator devices in accordance with the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at [fill in the street address of the facility(s)].
11. Licensed material shall be used by, or under the supervision of individuals who have received the training described in [letter, application] dated [fill in date]. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
12. The Radiation Safety Officer (RSO) for this license is [insert name of RSO]. **(This condition is used on licenses where NRC reviews the qualifications of the RSO on a case-by-case basis. The licensee would be charged an amendment fee to change the RSO.)**

OR

12. A. The Radiation Safety Officer (RSO) for this license is [insert name of RSO].
- B. Before assuming the duties and responsibilities as RSO for this license, the individual shall have successfully completed one of the training courses described in Criteria in Section 8.7.1 of

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NUREG-1556, Volume 5, dated October 1998. **(This condition is used on licenses where the licensee has committed to train the RSO as described in NUREG-1556, Volume 5. No technical review would be needed for change of RSO, so the licensee would not be charged an amendment fee. The licensee must still notify NRC of the name of the new RSO.)**

13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State.
- 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 by an Agreement State, prior to the 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, a report shall be filed with the U. S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the appropriate U.S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source involved, the test results, and corrective action taken.
- E. Tests for leakage and/or contamination, limited to leak test sample collection shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is not authorized to perform the analysis. Analysis of leak test samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. **(This condition is used for licensees not authorized to perform leak test analysis.)**

OR

- E. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U. S. Nuclear Regulatory

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Commission or an Agreement State to perform such services. **(This condition is used for licensees authorized to collect *and* analyze leak test samples.)**

- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
16. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services. **(This condition is used for licensees *not* authorized to perform non-routine maintenance.)**
- OR**
16. Except for the repair or maintenance operations described in the [letter, application] dated [fill in the date], the licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services. **(This condition is used for licensees authorized to perform non-routine maintenance.)**
17. For each J. L. Shepherd Mark I or Model 81-22 cesium-137 irradiator installed and used, the licensee shall:
- A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
- B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
- C. Have room monitors installed that will:

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- (i) Operate at all times when the irradiator is in use; and
- (ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
- (iii) Detect any radiation leaking from the irradiator door; and
- (iv) Be visible to the irradiator user when the user is next to the irradiator; or
- D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
- (i) Determine the radiation level at the irradiator door when the door is closed; and
- (ii) Check for any increase in radiation levels each time the irradiator door is opened.
- E. If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit all reports required under 10 CFR Parts 20, 21 or 30.
- F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services. **(Use this condition only on licenses authorizing possession and use of J. L. Shepherd Mark I or Model 81-22 irradiators.)**
18. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U. S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
19. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change. **(Use this license condition only when a license authorizes a sealed source(s) in quantities that could exceed 30.35(d) limits during source exchanges. Possession of sealed sources >10,000 curies normally requires financial assurance.)**
20. In addition to the possession limits in Item 8, and except as permitted by Condition 19, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing financial assurance for decommissioning. **(Do not use this license condition if applicant provides evidence of financial assurance.)**
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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22. 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 U.S. 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 (insert date)



For the U.S. Nuclear Regulatory Commission

Date [insert license issue date]

By _____
[insert reviewer's name]
[insert reviewer's NRC address]

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Appendix S

Checklist for Self-Shielded Irradiator License Application

Checklist for Self-shielded Irradiator License Application

Item 1: Action Type

ACTION TYPE: <input type="checkbox"/> New <input type="checkbox"/> Amendment <input type="checkbox"/> Renewal	ADMINISTRATIVE REVIEW: <input type="checkbox"/> Current guidance used <input type="checkbox"/> References in application based on current regulations <input type="checkbox"/> All referenced attachments included <input type="checkbox"/> Signature on application
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Item 2: Legal Identity

NAME:	
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Items 2 & 3: Address

MAILING ADDRESS:	LOCATION OF USE/STORAGE ADDRESSES:

Item 4: Person to Be Contacted About This Application

CONTACT PERSON:	
TELEPHONE:	

Table S.1 Items 5 and 6: Material to Be Possessed and Uses

Yes	No	Radionuclide	Manufacturer and Model Number	Quantity	Use As Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Cesium-137	Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved SSD Registration Certificate: Sealed source manufacturer's (or distributor's) name and model number: _____ Device manufacturer's (or distributor's) name and model number: _____	Not to exceed either the maximum activity per source or the maximum activity per device as specified in SSD Registration Certificate.	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis supporting safe use)
		Cobalt-60	Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved SSD Registration Certificate: Sealed source manufacturer's (or distributor's) name and model number: _____ Device manufacturer's (or distributor's) name and model number: _____	Not to exceed either the maximum activity per source or the maximum activity per device as specified in SSD Registration Certificate.	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis supporting safe use)

Yes	No	Radionuclide	Manufacturer and Model Number	Quantity	Use As Listed on SSD Registration Certificate	Specify Other Uses Not Listed on SSD Registration Certificate
		Strontium-90	Each of the following requested sealed sources, devices, and source/device combinations is the subject of an approved SSD Registration Certificate: Sealed source manufacturer's (or distributor's) name and model number: _____ Device manufacturer's (or distributor's) name and model number: _____	Not to exceed either the maximum activity per source or the maximum activity per device as specified in SSD Registration Certificate.	Yes []	[] Not applicable _____ [] Uses are: _____ (Submit safety analysis supporting safe use)
		Other (specify)				
<i>Financial Assurance Required and Evidence of Financial Assurance Provided</i>						

Table S.2 Items 7 Through 11: Training and Experience, Facilities and Equipment, Radiation Safety Program, and Waste Management

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience	<p>Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Appendix G in NUREG - 1556, Vol. 5, dated October 1998.</p> <p style="text-align: center;">AND</p>				
<p>7.1 Radiation Safety Officer (RSO)</p> <p>Name: _____</p>	<p>Before being named as the RSO, future RSOs will have successfully completed the training described in Appendix G in NUREG - 1556, Vol. 5, dated October 1998. Within 30 days of naming a new RSO, we will submit the RSO's name to NRC for inclusion in our license.</p> <p>Optional Response</p> <p>Criteria for Acceptable Training for RSO and Self-shielded Irradiator Users</p> <p>Content:</p> <ul style="list-style-type: none"> C Radiation safety C Regulatory requirements C Practical explanation of theory and operation for each irradiator possessed by licensee <p>Instructor's Qualifications:</p> <p>Instructor is qualified as RSO or AU before providing training.</p> <p>Training Assessment:</p> <p>Management ensures that RSOs, AUs are qualified to work independently with each type of the licensee's irradiators.</p>				
7. Individual(s) Responsible for Radiation Safety Program and their Training and Experience	<p>Before using licensed material, authorized users will receive the training described in Appendix G in NUREG - 1556, Vol. 5, dated October 1998.</p> <p>Optional Response</p>				
7.2 Authorized User	<p>Review optional response against criteria listed under RSO.</p>				

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
8. Training for Individuals Working in or Frequenting Restricted Areas	The applicant's training program will be examined during inspection, but should <i>not</i> be submitted in the license application.	Need Not Be Submitted with Application			
9. Facilities and Equipment	<p>We will ensure that each area where a self-shielded irradiator is located corresponds to the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the applicable irradiator's SSD Registration Certificate; the floor beneath a self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; <i>and</i> each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires.</p> <p>Optional Response</p> <p>C Corresponds to Conditions/Considerations of Use on SSD Registration Certificate or justification for location and compensatory measures (e.g., increased surveillance, maintenance) to ensure that unit operates as designed and provides intended level of protection</p> <p>C Floor adequate to support weight</p> <p>C Secured to prevent unauthorized removal (e.g., locked room, bolted to floor)</p> <p>C Automatic fire detection and control or low radiation risk from fire (e.g., ground floor, fire-resistant building, little combustible material, trained fire fighters)</p>				
10. Radiation Safety Program		Need Not Be Submitted with Application			
10.1 Audit Program	The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, but should <i>not</i> be submitted in a license application.				

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Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program					
10.2 Radiation Monitoring Instruments	<p>We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG - 1556, Vol. 5, dated October 1998. Additionally, each survey meter will have been calibrated by the manufacturer or other person authorized by the NRC or an Agreement State to perform survey meter calibrations no more than 12 months before the date the meter is used.</p> <p style="text-align: center;">OR</p> <p>We will use instruments that meet the radiation monitoring instrument specifications published in Appendix K to NUREG - 1556, Vol. 5, dated October 1998. Additionally, we will implement the model survey meter calibration program published in Appendix K to NUREG - 1556, Vol. 5, dated October 1998, and we will ensure that each survey meter will have been calibrated no more than 12 months before the date the meter is used.</p> <p><i>Note:</i> Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiator will contain a condition requiring calibrated survey meter or room monitor.</p>				

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
<p>10. Radiation Safety Program</p> <p>10.2 Radiation Monitoring Instruments (<i>Cont'd</i>)</p>	<p>Optional Response</p> <p>A description of alternative equipment and/or procedures for:</p> <p>C ensuring that interlocks function, as required, to return moving self-shielded irradiator sources to the shielded position and/or</p> <p>C determining source shielding integrity after an incident involving the self-shielded irradiator</p> <p>Request to perform instrument calibration contains information described in Appendix K:</p> <p>C Personnel w/ adequate training and experience:</p> <ul style="list-style-type: none"> - principles and practices of radiation protection - radiation measurements and instruments - math, calculations basic to use and measurement - biological effects of radiation - observation and supervised hands-on participation in instrument calibration <p>Facilities, equipment, and procedures ensure regulatory compliance and doses ALARA</p> <p>C isolated area</p> <p>C assigned dosimetry worn</p> <p>C use of calibrated, operable survey meter to detect unexpected changes in exposure rates</p>				

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Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program	<p>Optional Response (Cont'd)</p> <p>Model Procedure:</p> <p>C source of radiation is used which:</p> <ul style="list-style-type: none"> - is a point source accurate to $\pm 5\%$, traceable to NIST - uses same photon energy as the source in irradiator - is strong enough to give 30 mR/hr at 100 cm <p>C inverse square law is used and decay corrections are made</p> <p>C each calibration recorded and records maintained for 3 years (10 CFR 20.2103(a))</p> <p>C meter readings within $\pm 20\%$ of actual values</p> <p>C number, location of calibrated points dependent on scales</p> <p>C scales for measurements greater than 1 R/hr — no calibration is required but check for operation and approximately correct response</p> <p>C calibration report</p> <p>C calibration tag or sticker placed on each meter indicates:</p> <ul style="list-style-type: none"> - type of radiation source used - proper deflection for battery check - an indication that a scale was checked for function only but not calibrated - calibration date - due date - rate from check source, if used 				
10.2 Radiation Monitoring Instruments (Cont'd)					
10. Radiation Safety Program	Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices, received and possessed under the license.				
10.3 Material Receipt and Accountability	<p>Optional Response</p> <p>A description of the frequency and procedures for ensuring that no irradiators have been lost, stolen, or misplaced.</p>				

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program 10.4 Occupational Dose	<p>Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the Criteria in the section entitled "Radiation Safety Program - Occupational Dose," in NUREG - 1556, Vol. 5, dated October 1998.</p> <p>Optional Response</p> <p>Processed dosimetry (e.g., film, TLD): C Processed, evaluated by NVLAP-approved processor C Exchange frequency as recommended by processor</p> <p>Pocket chambers: C Assigned to single individual; dose is read, recorded, and chamber recharged, as appropriate, before chamber reassigned C Range of 0-200 mrem C Checked for correct response to radiation at intervals not to exceed 1 year C Readings within $\pm 20\%$ C Program prescribes action to evaluate dose</p>				
10. Radiation Safety Program 10.5 Public Dose	<p>No response is required from the applicant in a license application, but documentation demonstrating compliance will be examined during inspection.</p>	Need Not Be Submitted with Application			

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Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program 10.6 Operating & Emergency Procedures	<p>If we change our operating and emergency procedures without amending our license, we will ensure that: the changes are reviewed and approved by licensee management and the RSO; affected licensee staff are trained in the procedures before they are implemented; the changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application; and the changes do not degrade the safety of the program.</p> <p style="text-align: center;">AND EITHER</p> <p>Operating and emergency procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled "Radiation Safety Program - Operating and Emergency Procedures" in NUREG - 1556, Vol. 5, dated October 1998.</p> <p style="text-align: center;">OR</p> <p>Alternative procedures.</p>				

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program 10.6 Operating & Emergency Procedures (<i>Cont'd</i>)	<p>Optional Response</p> <p>Develop, maintain, and implement model-specific operating and emergency procedures which contain:</p> <ul style="list-style-type: none"> C Analysis of each material to be irradiated to ensure compatibility and determine if special procedures are needed C Procedure on how to operate and perform routine maintenance according to manufacturer's (or distributor's) written instructions and recommendations C Security, access control (e.g., control key to irradiator room) C Steps to take to keep radiation doses received ALARA C Accountability (e.g., log book, leak tests, inventory) C Access control to damaged or malfunctioning irradiators C Steps to take and whom to contact when irradiator malfunctions or is damaged <p style="text-align: center;">AND</p> <p>Provide copies of operating and emergency procedures to all users, and maintain current copy at irradiator control panel (or post notice describing where to find copy)</p>				

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Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
<p>10. Radiation Safety Program</p> <p>10.6 Operating & Emergency Procedures (<i>Cont'd</i>)</p>	<p>Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiator will contain the following conditions:</p> <p>C Must have calibrated and operable survey meter <i>or</i> room monitor</p> <ul style="list-style-type: none"> - Room monitor: <ul style="list-style-type: none"> < operable when irradiator is in use < activates audible/visible alarm at 2 mrem/hr < located to detect radiation from irradiator door < visible to irradiator user - Survey meter: <ul style="list-style-type: none"> < used to determine radiation levels when door is closed < check for increased levels whenever door is opened; surveyor positioned to minimize radiation exposure <p>C Before irradiator is used, check visual indicator to ensure source is in safe stored position</p> <p>C If abnormal radiation levels are detected or irradiator malfunctions</p> <ul style="list-style-type: none"> - stop irradiator use - restrict access to irradiator - notify RSO - determine if NRC must be notified <p>C Repairs only by those specifically authorized by NRC</p>				

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program 10.7 Leak Tests	<p>Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for 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 self-shielded irradiator manufacturer's (or distributor's) and kit supplier's instructions.</p> <p style="text-align: center;">OR</p> <p>Leak tests will be performed at intervals approved by the NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services for 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 self-shielded irradiator manufacturer's (or distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix P of NUREG-1556, Vol. 5, dated October 1998.</p>				

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Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program 10.7 Leak Tests (<i>Cont'd</i>)	<p>Optional Response</p> <p>Evaluate alternative equipment/procedures for determining if there is leakage from sealed sources.</p> <ul style="list-style-type: none"> C Identify who will make the analysis and qualifications to make quantitative measurements C Leak test frequency as specified in the appropriate SSD Registration Certificate C How and where test samples will be taken C Materials to be used C Methods of handling samples to prevent or minimize exposure to personnel C Type of instrument(s) used, counting efficiency, and minimum levels of detection for each radionuclide <p><i>Note:</i> An instrument capable of making quantitative measurements should be used; hand-held survey meters will not normally be considered adequate for measurements</p> <ul style="list-style-type: none"> C Standard calibration sources, including the following information for each source: the radionuclide, quantity, accuracy, and traceability to primary radiation standards. <i>Note:</i> Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST. C Sample calculations to convert measurement data to Bq (or microcuries) C Instructions on actions to take and notifications to make regarding leaking sources. 				
10. Radiation Safety Program 10.8 Maintenance	<p>ROUTINE CLEANING AND LUBRICATION</p> <p>We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer's (or distributor's) written recommendations and instructions.</p> <p>Optional Response - Routine Cleaning & Lubrication</p> <ul style="list-style-type: none"> C Considers ALARA C Ensures irradiator functions as designed C Ensures source integrity not compromised 				

Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
<p>10. Radiation Safety Program</p> <p>10.8 Maintenance (<i>Cont'd</i>)</p>	<p>NON-ROUTINE MAINTENANCE</p> <p>We will have the self-shielded irradiator manufacturer (or distributor) or other person authorized by NRC or an Agreement State perform non-routine maintenance.</p> <p>Optional Response - Non-routine Maintenance</p> <p>Provide the information listed in Appendix I supporting a request to perform non-routine maintenance in-house.</p> <p>C Types of work to be performed</p> <p>C Who will perform maintenance, training, experience, why competent (e.g., previous experience and radiation safety training; vendor maintenance certification; pre-planned procedures with direct health physics supervision)</p> <p>C Handling procedures: doses to public, personnel ALARA and regulatory limits; security; posting; manufacturer's (or distributor's) written instructions and recommendations; evaluation of non-manufacturer- (or non-distributor-) supplied components, materials to ensure no degradation of safety; before return to routine use, test irradiator to verify it functions as designed, source integrity not compromised</p> <p>C Use of whole body and extremity monitoring</p> <p>C Possess survey instrument (detects gamma; range to several hundred mR/hr; checked before use; calibrated annually, after repair; readings within $\pm 20\%$; calibrated by manufacturer or NRC or Agreement State licensee — moving-source irradiator specifications in Appendix K)</p> <p>C 10 CFR 20.1301 surveys (when and where instrument survey performed, records for 3 years)</p>				
<p>10. Radiation Safety Program</p> <p>10.9 Transportation</p>	<p>No response is needed from applicants during the licensing phase. However, before offering a Type B package for shipment, 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.</p>	Need Not Be Submitted with Application			

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Item Number and Title	Suggested Response	Applicant's Response			
		Yes	No	Other	
				Yes	No
10. Radiation Safety Program 10.10 Minimization of Contamination	The applicant is not required to submit a response to the minimization of contamination section if the applicant's responses meet the criteria for the following sections: "Radioactive Material - Sealed Sources and Devices," "Facilities and Equipment," "Radiation Safety Program - Operating and Emergency Procedures," "Radiation Safety Program - Leak Tests," and "Waste Management - Self-Shielded Irradiator Transfer and Disposal."	Need Not Be Submitted with Application			
11. Waste Disposal 11.1 Self-Shielded Irradiator Disposal & Transfer	The applicant does not need to provide a response to this item during the licensing phase. However, the licensee should develop, implement, and maintain self-shielded irradiator transfer and waste disposal procedures in its radiation safety program.	Need Not Be Submitted with Application			

Appendix T

**Addendum: Summary of Comments
Received on Draft NUREG - 1556, Vol. 5,
and Other Changes**

Addendum: Summary of Comments Received on Draft NUREG - 1556, Vol. 5, and Other Changes

On December 23, 1997, NRC announced in the *Federal Register* (62 FR 67100) that draft NUREG-1556, Vol. 5 was available for comment. NRC requested that comments be submitted by March 23, 1998. NRC also mailed copies of the document to its self-shielded irradiator licensees.

NRC received two comments, both from licensees. The comments, a letter and an e-mail message, are available for inspection in NRC's Public Document Room.

Letter

Issue 1: The writer is with a medical institution that holds an NRC license issued pursuant to 10 CFR Parts 30 and 35. The institution requested an amendment to its license to add a self-shielded irradiator to irradiate blood in accordance with procedures specified by the American Association of Blood Banks and FDA regarding blood transfusions. The writer believes that, given the proposed use of the irradiator, the institution's license should have retained its assigned Fee Category 7.C. and should not have been assigned an additional separate fee category. [The writer has raised this issue in previous correspondence with OCFO and regional staff, who have responded to him.]

Response to Issue 1: Although fee-related issues are outside the scope of NUREG-1556, Vol. 5, the NRC staff wishes to provide the following information in addition to the separate correspondence. 10 CFR 170.3 defines human use as "the internal or external administration of byproduct, source, or special nuclear material, or the radiation therefrom, to human beings." 10 CFR 170.31 states, in pertinent part, that Fee Category 7.C. is for "[o]ther licenses issued pursuant to Parts 30, 35... for human use of byproduct... material, except licenses for byproduct material... in sealed sources contained in teletherapy devices."

Self-shielded irradiators contain byproduct material and are not included in Fee Category 7.C. because their use is not within the definition of "human use." Rather, blood that has been irradiated in the self-shielded irradiator is administered to patients; that blood does not contain NRC-licensed material and the patient is not administered any radiation from the sources in the self-shielded irradiator. Fee Categories 3.F. and 3.G. cover self-shielded irradiators.

Issue 2: NUREG-1556, Vol. 5 does not address using self-shielded irradiators for "human use as a blood irradiator."

Response to Issue 2: Use of a self-shielded irradiator to irradiate blood is not within the 10 CFR Part 170 definition of "human use" or the 10 CFR Part 35 definition of "medical use." However, as indicated in the Discussion on page 8.8 of this document, the NRC staff recognizes that irradiation of blood is normally an "allowed use" of a self-shielded irradiator. The list of "typical

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uses” on page 1-1 has been revised; the new text is shown in bold italics: “*irradiating blood and blood products.*”

Issue 3: The writer refers to the statement on page 1-2 of draft NUREG-1556, Vol. 5: “NRC will now authorize self-shielded irradiators on the same license as the licensee’s other licensed material.” The writer asks if “there could still be separate categories under one license, or could it be covered under one category as I have requested?”

Response to Issue 3: Under the current regulations in 10 CFR Part 170, self-shielded irradiators are a separate fee category. The radioactive materials and authorized uses listed on an NRC license can include more than one fee category.

E-Mail Message

Issue 1: The writer points out that, in the second to last bullet on page H-1, the word “individual” is vague and could mean radiation worker or member of the public.

Response to Issue 1: Page H-1 contains a bulleted list of typical duties and responsibilities of an RSO. The item in question has been revised to read as follows (with bold italics showing new wording): “Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual *member of the public* likely to receive the highest dose from the licensed operation does not exceed the annual limit *in 10 CFR 20.1301.*”

Issue 2: Addressing Appendix K, the writer disagrees with checking a survey meter or room monitor “at the beginning of each day with a check source.” The writer’s room monitor is checked semiannually by the irradiator manufacturer. The writer believes semiannual checks are sufficient and points out the following problems: many licensees would need to obtain a check source (with possible need to amend their licenses); his irradiator is not used every day so that daily checks of the room monitor with a radioactive source would not be in desirable from an ALARA standpoint since a worker performing these checks would “double his usual dose of radiation.” The writer believes that there must be a “better way to address the safety issue” described in Appendix E.

Response to Issue 2: The writer is referring to the portion of Appendix K that provides specifications for radiation monitoring instruments for moving-source irradiators. These specifications are based on the requirements of the July 3, 1984, Order shown in Appendix E. Neither the Order nor Appendix K specifies *daily* (emphasis added) checks of the room monitor, the writer’s principal concern. Rather, the Order and Appendix K specify checks “at the beginning of *each day of use* (emphasis added).”

As further described in Appendix E, the Order was issued because a lock mechanism on a moving-source irradiator failed and could have caused a substantial exposure to a worker. The

use of a calibrated and operable survey instrument or room monitor warns workers if similar malfunctions occur. In comparison, 10 CFR 35.51 and 10 CFR 35.615(d)(3) also require, respectively, checks of survey instruments on each day of use and checks of teletherapy room monitors each day before patient treatment.

Workers should not receive significant additional dose if they check the room monitor on each day of use with a low-activity check source (e.g., exempt quantity) and follow appropriate radiation safety procedures.

Summary of Other Changes

The NRC staff made other changes to the text in addition to those discussed above. These changes encompass the following:

- C Inclusion of information on implementation
- C Addition of Appendix N, a list of incidents that must be reported to NRC
- C Inclusion of a mechanism for making certain changes in operating and emergency procedures without amending the license
- C Editorial changes based on reviews of other volumes in the NUREG-1556 series
- C More comprehensive listing of abbreviations
- C Improved consistency in the use of abbreviations and URL addresses