

From: Stephen McGuire
To: WND1.WNP9(SNS)
Date: 10/24/96 1:24pm
Subject: Compatibility CO Regs - Licensing and Radiation Safety Requirements for Irradiators -Reply

Responses to your e-mail follow your questions:

>>> Stephen Salomon 10/22/96 02:10pm >>>
Stephen,

I am reviewing the subject for compatibility in Colorado. In conversations with Chuck Mattson in Colorado, he asked that we explain the following:

10 CFR 36.2 Definitions:

For seismic area, why is "in 250 years" used? Is there a Reg Guide for Part 36 that could be helpful?

Response: There is a little more discussion of seismic areas on the bottom of page 17 and the top of page 18 of Reg Guide DG-0003. 250 years is one of the time periods for which the USGS gives probabilities of acceleration. The selection of 250 years was a judgement. Since the lifetime of an irradiator is considerably less than 250 years, the value is unlikely to be exceeded during the life of the irradiator and even if exceeded it is unlikely to be exceeded by much.

10 CFR 36.39(j) Seismic. Colorado wants to eliminate "such as American Concrete Institute Standard ACI 318-89" because by Colorado statute the agency must supply a certified copy and have it readily available. He was unable to find such ACI 318-89. He wants to change the later part of the discussion to "...appropriate current sources such as national standards or local building codes." Do you have any problem with this approach?

Response: No problem with that. The reference was intended to be informational.

10 CFR 36.23(c) The last sentence in this provision. "The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam." He does not understand why? Is this covered in a Reg Guide or some other document that I could send him?

Response: If the monitor is in the direct beam, it will soon burn out and give a false indication that there is no radiation. There is no need for the monitor to be in the direct beam because there is plenty of scattered radiation in the maze that is easily detected.

Cheryl Trottier responded to this e-mail except the last point. It does not seem to be covered in the Reg Guide D003. Can you explain or point to another reference?

Thanks for your prompt response.

Steve Salomon, OSP



U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

DRAFT REGULATORY GUIDE

Steve Salmon

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Division 10
Task DG-0003

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DRAFT REGULATORY GUIDE DG-0003

GUIDE FOR THE PREPARATION OF APPLICATIONS
FOR LICENSES FOR NON-SELF-CONTAINED IRRADIATORS

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by October 1, 1994.

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.

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1. INTRODUCTION

PURPOSE OF THIS GUIDE

This draft regulatory guide is being developed to provide guidance to applicants and licensees on preparing applications for new licenses, license amendments, and license renewals to possess radioactive material in non-self-contained irradiators, specifically panoramic dry-source-storage irradiators (Category II), underwater irradiators (Category III), and panoramic wet-source-storage irradiators (Category IV). This type of license is provided for in the Nuclear Regulatory Commission's (NRC's) regulations in Title 10, Chapter I, Code of Federal Regulations, Part 36, "Licenses and Radiation Safety Requirements for Irradiators."

This guide does not cover self-contained dry-source-storage irradiators (Category I). Applications for this type of irradiator are discussed in Revision 1 to Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Irradiators," December 1988.

This guide identifies the information needed to complete NRC Form 313 for applications for a license for a non-self-contained irradiator. (NRC Form 313 is shown in Appendix A.) The guide is based on the new 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," which became effective on July 1, 1993, and the revised 10 CFR Part 20, "Standards for Protection Against Radiation," which must be implemented no later than January 1, 1994. Even though the information provided in this guide does not constitute regulatory requirements, applicants should address all the items on NRC Form 313 and should either follow the specific guidance in this guide or provide responses to the items adequate to assure safe operation of the irradiator and compliance with applicable regulations.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of this regulatory guide. It has not received complete staff review and does not represent an official NRC staff position. Regulatory guides are issued to describe and make available to the public methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated problems, or to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with them is not required.

After a license is issued, the licensee must conduct its program in accordance with: (1) the statements, representations, and procedures contained in the application and correspondence with NRC, (2) the terms and conditions of the license, and (3) the NRC's regulations. Section 30.9 of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," requires that the information provided in the application be complete and accurate in all material respects. Information is considered to be material if it is likely to change or affect an agency decision on issuing the license.

The information collections discussed in this draft regulatory guide are covered by NRC Form 313, "Application for Material License," which was approved by the Office of Management and Budget, approval number 3150-0120.

APPLICABLE REGULATIONS

NRC regulations applicable to irradiator operations are 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and 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."

2. FILING AN APPLICATION

WHERE TO FILE

To possess or use licensed material on Federal property or in any State subject to NRC jurisdiction, an applicant is to file an application with the NRC Regional Office for the State in which the material will be possessed or used. The five Regional Offices and their respective areas for licensing purposes are given in Figure 1.

NRC REGIONAL OFFICES



- Regional Office
- Technical Training Center
- ▲ Uranium Recovery Field Office
- ★ Headquarters

Note: Alaska and Hawaii are included in Region V.

Region	Address	Telephone
I	475 Allendale Road, King of Prussia, PA 19406-1415	215-337-5000
II	101 Marietta St., Suite 2900, Atlanta, GA 30323	404-331-4503
III	799 Roosevelt Road, Glen Ellyn, IL 60137	708-790-5500
IV	611 Ryan Plaza Drive, Suite 400, Arlington, TX 76011-8064	817-860-8100
V	1450 Maria Lane, Walnut Creek, CA 94596	510-975-0200

Figure 1. NRC Regional Offices

Twenty-nine states, called Agreement States (see Figure 2), to date have entered into agreements with the NRC that give them the authority to license byproduct, source, or special nuclear materials used or possessed within their borders. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC's Regional Offices or from the Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A non-Federal organization that wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application; these applications should be filed with the State officials and not with the NRC.

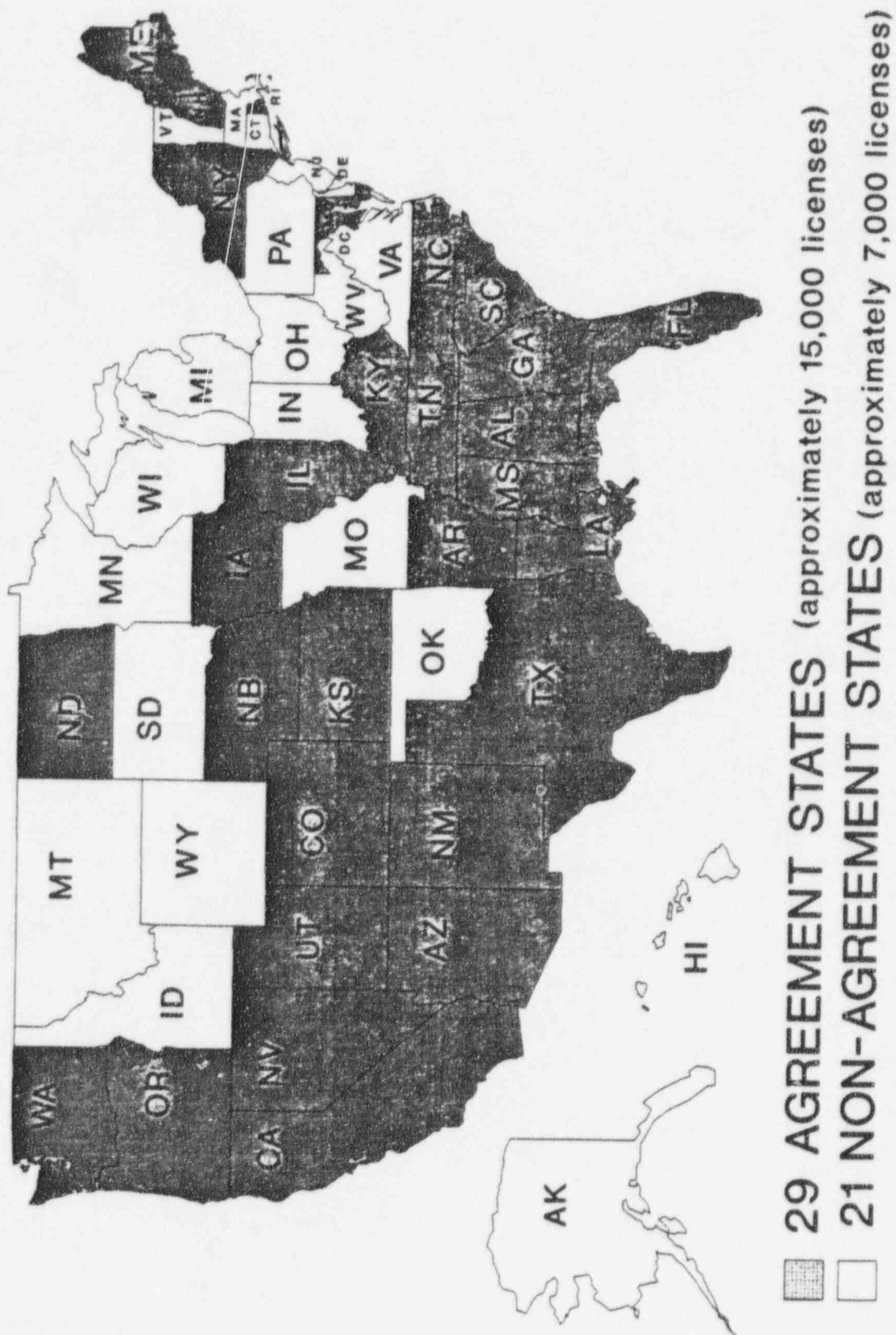
HOW TO FILE

To apply for an irradiator license, complete NRC Form 313, "Application for Material License" (shown in Appendix A to this guide). Complete Items 1 through 4 and 12 and 13 on the form itself. For Items 5 through 11, submit the information on supplementary pages. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers.

Complete all items in the application in sufficient detail for the NRC to determine that equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

All license applications will be available for review by the general public in NRC Public Document Rooms. Do not submit proprietary information unless it is absolutely necessary. If it is necessary to submit proprietary information, follow the procedure in Section 2.790 of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders." Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing the application.

Personal information about employees should not be submitted unless it is necessary. For example, the training and experience of employees should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses, home telephone numbers, dates of birth, social security numbers, and radiation dose information should not be submitted unless specifically requested by NRC.



All applications should be filed in duplicate. An additional copy should be retained for future reference.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on NRC Form 313. Some of the information requested may not be appropriate for all types of irradiators. For example, information on irradiator pools is not relevant to dry-source-storage irradiators, and some information on access control is not relevant to underwater irradiators. If the information requested is not relevant, write "not applicable" for that item. Any applicable sections of the regulations are noted in brackets by the appropriate item.

Item 1 - LICENSE INFORMATION

For a new license, check box A. For an amendment to an existing license, check box B. For a renewal of an existing license, check box C. If box B or C is checked, enter the license number.

Item 2 - NAME AND MAILING ADDRESS OF APPLICANT

The legal name of the corporation or other legal entity applying for the license should be provided. The address specified here should be the complete mailing address for correspondence and may contain a Post Office box number, a department name, a mailing code, or other information that will assist in getting mail to the applicant. This may or may not be the same as the address at which licensed material will be used, as specified in Item 3. In general, an "attention" line should be included in the address, but that line should specify a title rather than a particular person's name.

Item 3 - ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

State the location of use, specifying the street address (including building name and other locating information, if appropriate), city, and State or other descriptive address (such as 5 miles east on Highway 10, Any Town, State) to allow the NRC to easily locate the irradiator. A Post Office box

address is not acceptable. If more than one irradiator will be authorized on one license, the application should specify the location of each irradiator.

Item 4 - NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Provide the name of the individual who can answer questions about the application. The NRC will contact this individual if it has questions about the application. Include his or her telephone number. If the contact person changes, notify the NRC. Notification of a contact change is for information only and is not an application for a license amendment.

The individual named in Item 4 may or may not be the individual who signs the application in Item 13 on behalf of the applicant and who has the authority to make and back up commitments made to the NRC. Any commitments made by the applicant should be signed by the individual named in Item 13 since only that individual is considered by NRC to have the authority to make commitments on behalf of the applicant.

Item 5 - RADIOACTIVE MATERIAL

For each type of radioactive material to be used, specify:

1. The radionuclide to be possessed (e.g., cobalt-60).
2. The manufacturer's name and specific model number of each sealed source in the irradiator.
3. The maximum amount of radioactive material in any one sealed source, which may be expressed in becquerels or curies. (The use of either becquerels or curies is permitted, but for consistency, only one type should be used throughout the application.)
4. The maximum amount of radioactive material to be possessed at any one time, which may be expressed in becquerels or curies, as noted above. The maximum amount should include a margin to allow for source reloading and exchange.
5. The number of the certificate of registration issued under 10 CFR 32.210 by NRC or an Agreement State for each model of sealed source. If a model does not have a certificate of registration, the applicant or the source manufacturer must submit information on the source as required by 10 CFR 30.32(g) and 32.210.

Discussion

In general, the use of cesium-137 chloride is not acceptable in pool irradiators or dry-source-storage irradiators that load or unload sources under water at the irradiator because it does not meet the requirements of 10 CFR 36.21(a)(3). Cesium-137 chloride is generally acceptable for exclusively dry-use irradiators.

Item 6 - PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Specify the purpose for which the irradiator will be used. An example of an adequate response for a panoramic irradiator is, "Irradiation of products or food. There will be no irradiation of explosives and no irradiation of more than small quantities of flammable materials with a flash point below 60°C (140°F) without specific written authorization from NRC."

Discussion

Applicants should note that, in addition to NRC approval to operate an irradiator, they must follow the regulations of other Federal agencies that regulate the irradiation of medical products and food.

Prior written authorization from NRC is required by 10 CFR 36.69(b) before irradiation of more than small quantities of flammable materials with a flash point below 60°C (140°F). As defined in the National Fire Code NFPA 30, "Flammable and Combustible Liquids Code," published by the National Fire Protection Association,¹ the flash point is "the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid...." According to the NFPA 30 classification system, Class I and Class II liquids have flash points below 60°C (140°F). The flash points of many substances are tabulated in National Fire Code NFPA 325M, "Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids."¹ Flash points are also specified on the Material Safety Data Sheets for industrial chemicals, when applicable. Examples of common flammable liquids with a flash point below 60°C (140°F) are acetone, benzene,

¹Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9146, Quincy, MA 02269-9959 (telephone 1-800-344-3555).

most alcohols, number two fuel oil, gasoline, kerosene, toluene, and turpentine.

If the flash point of a flammable liquid is exceeded, the concentration of the vapor in air can exceed the flammable limit and the potential for an explosion can exist. The NRC's concern with irradiating flammable liquids is the possibility of explosion more than the possibility of fire.

The NRC considers that compliance with the requirements in 10 CFR 36.21, 36.27, 36.35, 36.39(h), 36.41(h), and 36.53(b)(7) will provide adequate protection against radiological impacts arising from a fire. NRC's regulations in 10 CFR 36.27 require heat and smoke detectors in the radiation room that, if a fire is detected, will automatically cause the source to become fully shielded and will activate an alarm. Also, 10 CFR 36.27(b) requires a fire extinguishing system; 10 CFR 36.39(h) requires an evaluation of the design of the fire protection and extinguishing systems; 10 CFR 36.41(h) requires tests of the installed detection and extinguishing systems; 10 CFR 36.21 requires that the sources be built to withstand a temperature of 600°C (1112°F) for 1 hour followed by the thermal shock of being cooled to 20°C within 15 seconds; 10 CFR 36.35 requires a barrier to protect the source rack; and 10 CFR 36.53(b)(7) requires an emergency procedure for fires and explosions. With these requirements, the NRC considers that a fire is likely to be controlled without presenting a threat to the integrity of the sources.

With an energetic explosion, however, it is necessary to consider the possibility of direct damage to the source encapsulation or to the source rack such that the rack could not be lowered to the shielded position.

Concerns for preventing an energetic explosion thus can be used to establish a definition for the term "small quantity" of flammable material as used in 10 CFR 36.69(b). A "small quantity" of flammable material can be defined as a quantity of flammable material that, when dispersed evenly throughout the radiation room with no loss to ventilation, would have a concentration below the lower flammable limit concentration. Although local concentrations could exceed the average room concentration, the movement of air into and out of the radiation room provides a margin of safety that is not given credit in the definition of "small quantity." In addition, no credit is taken for the time required to vaporize all the material, which also adds to the margin of safety. Further, small pockets of flammable vapor will contain quantities of energy too small to provide a driving force sufficient to significantly damage the irradiator. Because of these factors, the definition of

small quantity is considered to be sufficiently conservative to ensure safe operation of an irradiator.

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

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

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

In order to obtain NRC approval to irradiate more than small quantities of flammable material, the applicant must demonstrate that it is unlikely that the concentration of flammable vapor in air in a significant volume of the room would exceed the lower flammable limit. There are two methods to do this. The first method is to demonstrate that no single failure would be likely to cause the product to become immobilized in the radiation room and prevent the sources from being returned to the shielded position. Such a

situation theoretically might arise if the product carriers became jammed and pushed into the source rack preventing its return to the shielded position. The second method is to demonstrate that even if the product became immobilized and the source rack could not be returned to the shielded position, the ventilation system would be adequate to prevent the concentration of flammable vapor in a significant volume of the room air from reaching the lower flammable limit.

If an applicant is applying for authorization to irradiate more than a small quantity of flammable material, the application should include the name of the flammable material that has a flash point below 60°C (140°F), its flash point, its flammable limit as percent by volume in air, its specific gravity as a liquid, its vapor density relative to that of air, the maximum quantity to be in the direct radiation beam in the radiation room at any one time, and a description of the packaging for the product.

In addition, the application should either (1) describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position or (2) describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position. If this second approach is taken, the applicant should also provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should also identify the means to detect ventilation system failure.

Item 7 - INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

7.1 Radiation Safety Officer (RSO) [10 CFR 30.33(a)(3) and 36.13(d)]

Specify the name, training, and experience of the individual who will be responsible for the radiation safety program (the RSO).

An individual may be designated as an alternate RSO. If an alternate RSO is designated, specify the name, training, and experience of that person. If an alternate RSO is designated, describe how any confusion will be avoided about which of these individuals has ultimate responsibility for the radiation protection program. Even if there is an alternate RSO, the designated RSO

remains ultimately responsible for the day-to-day operation of the radiation program.

If an RSO is to be replaced, the name, training, and experience of the new RSO should be submitted to NRC in a license amendment before the new individual assumes the position. If the replacement is sudden, the NRC Regional Office should be contacted with the information as soon as it is known that the RSO will be changed. While the amendment request is being reviewed by NRC, the proposed RSO may assume the responsibilities of the RSO position.

Describe the provisions for contacting the RSO in case a problem needing the attention of the RSO arises while he or she is not at the facility or is not in the area.

Discussion

If the RSO has had neither previous formal training in health physics nor certification by the American Board of Health Physics, the RSO should complete a radiation safety course. Training consisting of approximately 40 hours has typically been considered acceptable by the NRC staff when the training covers the following topics: (1) radioactivity and radioactive decay, (2) interactions of radiation with matter, (3) biological effects of radiation, (4) radiation detection using radiation detection instruments and personnel dosimeters, (5) basic radiation protection principles and good safety practices (including time, distance, and shielding), and (6) radiation protection regulations. The course should include a written test or evaluation of the individual's comprehension of these topics.

In addition to the above general course, if the RSO has not had prior experience working at an irradiator, he or she should have spent the equivalent of at least 40 hours in self-study or directed study on information directly applicable to radiation safety at irradiators, including applicable regulations (10 CFR Parts 20 and 36) and reports or studies describing safety problems at irradiators. Information on irradiator accidents, unusual events, and violations of NRC regulations can be found in the NRC report NUREG-1345, "Review of Events at Large Pool-type Irradiators," E. A. Trager, Jr., March

1989.² There should be an evaluation of the individual's comprehension of this information. The license application should list the documents studied or to be studied in the description of the training of the proposed RSO and should describe how the applicant will evaluate the individual's comprehension of the information studied.

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

7.2 Organizational Structure and Authorities and Responsibilities of Management [10 CFR 30.33(a)(3) and 36.13(d)]

Describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the RSO and those other management personnel who have important radiation safety responsibilities and authorities. In particular, the application should describe who has the authority to stop unsafe operations. Appendix B provides a list of the RSO's responsibilities that is acceptable to the NRC staff; applicants may incorporate this list in their applications.

Discussion

The RSO should have independent authority to stop operations that he or she considers unsafe and to conduct tests or measurements considered to be necessary. The RSO should be relatively independent of production responsibilities, to the extent practical, considering the size of the staff at the irradiator. The RSO should report directly to the irradiator manager. The RSO should have sufficient time and commitment from management to fulfill the responsibilities listed in Appendix B.

²Copies of NUREG-1345 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082 (telephone (202)512-2249). Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Item 8 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

8.1 Initial Training for Irradiator Operators [10 CFR 19.12, 36.13(b), and 36.51]

Describe the training provided to individuals to qualify them to be irradiator operators, including:

- (1) Classroom training;
- (2) On-the-job or simulator training;
- (3) Means employed by the applicant to test each individual's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures, and
- (4) Minimum training and experience of personnel who may provide training.

Discussion

The training required to qualify an individual to be an irradiator operator is described in 10 CFR 36.51. The training described in 10 CFR 36.51(a) should be approximately 40 hours in length for panoramic irradiators and approximately 20 to 30 hours for underwater irradiators. Up to 50% of that time may be self-study or reading time instead of classroom lecture time. The written test described in 10 CFR 36.51(b) should cover the range of topics addressed in the training. The on-the-job training described in 10 CFR 36.51(c) should be under the supervision of an experienced operator and should last at least 1 month full-time (170 hours). If an approved operator does not operate the irradiator for more than a year, his or her performance during operation should (1) be audited for at least a day before he or she is permitted to operate the irradiator independently and (2) receive a safety review as described in 10 CFR 36.51(d).

The requirements in 10 CFR 36.51(a), (b), and (c) are those required for an individual to become qualified initially as an irradiator operator. They do not apply to individuals qualified to be operators before July 1, 1993, the effective date of 10 CFR Part 36. The safety review and evaluation requirements of 10 CFR 36.51(d) and (e), however, apply to all operators. Current licensees should conduct a safety review to discuss the new Part 36

regulations and any changes in procedures that have occurred as a result, and conduct a safety review annually thereafter.

The subjects, required by 10 CFR 36.51, that individuals must be trained in to become an irradiator operator are:

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

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

(3) The operation of the irradiator. The objective is to help the person understand the operating and emergency procedures, not to make the individual an engineer.

(4) Licensee operating and emergency procedures that the individual will perform. This is the most important part of the training because the safe operation of the irradiator depends on these procedures being followed correctly. The objective is that the operator is able to correctly perform the procedures that he or she will be expected to perform. The training does not have to include procedures that the individual will not perform. For example, if the individual will not perform leak tests, the individual need not be trained in the procedure.

(5) Case histories of accidents and problems involving irradiators. The individual should be taught about situations that could lead to trouble. Instruction material on accidents is often difficult to obtain. However, NUREG-1345, "Review of Events at Large Pool-Type Irradiators," should provide some relevant information. Also, descriptions of events from NRC information notices on irradiators, which are reproduced in Appendix C to this guide, can be used as a source of information. Other sources of information should also be sought.

8.2 Safety Reviews for Operators [10 CFR 36.51(d)]

Describe the safety reviews that will be provided to operators to meet the requirements of 10 CFR 36.51(d). Describe who will conduct these reviews and their training and experience. Describe how drills will be conducted.

Discussion

The safety reviews described in 10 CFR 36.51(d) should be about 4 hours per year for panoramic wet-source-storage irradiators and 2 hours per year for dry-source-storage and underwater irradiators. Safety reviews may be conducted once per year or throughout the year on an as-necessary (or an as-appropriate basis), as long as the time spent totals 4 hours or more per year. The regulation requires that each operator have a brief written test on the information presented. The word "inspections" in 10 CFR 36.51(d)(4) means the "evaluations" performed under 10 CFR 36.51(e).

The "drill" in 10 CFR 36.51(d)(6) means actually going through a procedure using the actual equipment in as realistic a manner as practical, but not necessarily with total realism if that would be difficult. For example, for a drill on the response to a fire alarm it is not necessary that the alarm actually sound if sounding the alarm would be difficult or disruptive. The operator could be told that the alarm had sounded and asked to do what he would do in that situation. In a drill it is also acceptable to correct errors as they occur rather than waiting until the drill is over. Not all operators must be put through the drill. It is acceptable to have one operator go through the drill and have other operators either watch the drill or be asked to critique or comment on the actions as they occur.

If a senior operator (who might also serve as the RSO, for example) conducts the safety reviews for other operators and prepares the written test for other operators, the preparation of the test and its answers may be considered demonstration that the testing requirement in 10 CFR 36.51(d) has been met by the senior operator.

8.3 Training for Other Individuals Who Must Respond to Alarms [10 CFR 19.12 and 36.51(g)]

Describe the training and testing to be given to employees other than irradiator operators who must be prepared to respond to alarms as described in

10 CFR 36.51(g). Describe the annual refresher training. Identify who (by category of worker) will be given the training.

If the individuals who will respond to alarms are not facility employees (for example, a local fire department), describe any training or orientation that will be offered. (Testing of nonemployees is not expected.)

Discussion

The training and testing should be sufficient to determine that the person knows what to do in case of an alarm. The preferred type of testing is a drill in which the person being tested responds to an alarm while being observed by an evaluator. Drills should be repeated until the evaluator is satisfied with the response. After initial training, there should be annual refresher training and testing.

8.4 Training for Other Individuals Permitted Unescorted Access to Restricted Areas [10 CFR 19.12]

According to 10 CFR 19.12, all individuals who work in or frequent restricted areas must receive appropriate instruction on radiation safety. Describe the training to be provided to meet this requirement.

Item 9 - FACILITIES AND EQUIPMENT

9.1 General Description of the Facility and Site [10 CFR 30.33(a)(2) and 36.13(e), and 36.39(j)]

Describe the irradiator (in general, not duplicating more detailed information provided in other sections). Include diagrams, sketches, and photographs, as appropriate, to show locations of safety-related equipment and features mentioned in Part 36. In addition, sketch and describe the uses of property adjacent to the facility. Provide a schedule for constructing the irradiator in case the NRC wants to schedule an inspection of the construction.

Special seismic requirements are contained in 10 CFR 36.39(j) for irradiators located in seismic areas. For a license application to operate a panoramic irradiator whose construction will start after July 1, 1993, discuss whether the facility is in a seismic area as defined in 10 CFR 36.2.

Discussion

Maps of the United States showing seismic areas are published by the U.S. Geological Survey (see S. T. Algermissen et al., "Probabilistic Estimates of Maximum Acceleration and Velocity in Rock in the Contiguous United States."³)

9.2 Access Control [10 CFR 36.13(e), 36.23, 36.31(a), 36.39(g), and 36.41(g)]

Describe the access control system and how it works with respect to the requirements of 10 CFR 36.23. Include drawings or sketches as appropriate. For panoramic irradiators, describe the alarm systems and who will be made aware of alarms. Describe the lock and key system for controlling source movement and discuss how it meets the requirements of 10 CFR 36.31(a).

It is important for the description to be in enough detail to allow the NRC license reviewer to determine that the design of the access control system is adequate to meet all the requirements of 10 CFR 36.23. An acceptable way to do this is to quote the section, sentence-by-sentence or paragraph-by-paragraph, and provide the relevant description underneath.

Discussion

The requirement in 10 CFR 36.23 for a door or other physical barrier applies to each entrance of the radiation room of a panoramic irradiator, whether intended for personnel access or intended solely for product entrance or exit. Panoramic irradiators with a conveyor system could meet the requirement by providing such small clearances around the product carriers that a person could not squeeze through or by using barriers that would require unusual exertion to bypass. A photoelectric system cannot be considered a physical barrier. The requirement is that the door or barrier must prevent inadvertent entry by a person, not that it need prevent a deliberate or determined effort to bypass the barrier. The purpose of this requirement is to

³United States Department of the Interior, Geological Survey, Open-File Report 82-1033, 1982. This report may be purchased for \$24.50 from: U.S. Geological Survey, Books and Report Sales, Box 25425, Denver, Colorado 80226. Prepayment is required. Minor updates of this report are possible as new information becomes available.

prevent someone from carelessly, inattentively, or accidentally entering the radiation room while the source is exposed.

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

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

9.3 Shielding [10 CFR 36.25, 36.39(a), 36.39(j), and 36.41(a)]

For panoramic irradiators, describe the shielding to be used and its composition. A diagram should show the configuration of shielding walls and indicate the thickness of each. Penetrations in the shield wall should be indicated. If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 millisievert (2 millirems) per hour, identify the areas and tell how access to those areas will be controlled. Explain how compliance with the 100 mrem/year dose limit for the public in 10 CFR 20.1301(a)(1) will be achieved. For panoramic irradiators whose construction will start after July 1, 1993, identify building code requirements to which shielding walls will be built and inspections of the construction that will be performed by local authorities. For requests to possess more than 2×10^{17} becquerels (5,000,000 curies) in a panoramic irradiator, describe how cooling of the shielding walls will be accomplished (see 10 CFR 36.39(a)). If the

irradiator is an underwater irradiator, state "Not applicable" for this section.

Discussion

The intent of Part 36 is that shield walls retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources. For irradiators whose construction starts after July 1, 1993, and that are not located in seismic areas, defined in 10 CFR 36.2), it is acceptable that shielding meet generally accepted building code requirements for reinforced concrete, for example, American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete."⁴

In seismic areas, local building codes are likely to specify requirements for such things as spacing of reinforcing bars, how to tie reinforcing bars together, preferred arrangements for reinforcing bars, and requirements for joining reinforcing bars to floor slabs. If local building codes do not contain seismic requirements, "other appropriate sources" could include Chapter 21, "Special Provisions for Seismic Design," of the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete."

9.4 Fire Protection [10 CFR 36.27, 36.39(h), and 36.41(h)]

For panoramic irradiators, describe the type and location of the heat and smoke detectors to be used to detect a fire in the radiation room. Use diagrams and sketches, as appropriate. (The heat and smoke detectors should be able to promptly detect a fire, but they do not necessarily have to be located within the radiation room.) Describe the alarms to alert personnel capable of summoning assistance. Describe how the sources will automatically become fully shielded if fire is detected. Describe how the heat and smoke detectors will be tested.

If the irradiator is an underwater irradiator, write "Not applicable" because 10 CFR 36.27 contains no fire protection requirements for underwater

⁴This standard is available for purchase from the American Concrete Institute, Box 19150, Redford Station, Detroit, Michigan 48219.

irradiators, since the sources are always underwater and not subject to damage by fire.

For panoramic irradiators, describe the fire extinguishing system that is capable of extinguishing the fire without personnel entering the room. Describe how flooding into unrestricted areas will be avoided. Identify the location of shut-off valves. If the fire detection or extinguishing systems are built to meet fire protection codes, those codes should be identified. Describe the acceptance testing of the systems.

Irradiator applicants who wish to apply for an exemption from the requirement for a fire suppression system should provide the following information: (1) the maximum quantity of combustible materials that may be in the room, (2) the procedures used to ensure that the maximum quantity of combustible materials will not be exceeded, (3) the reasons a fire will not prevent the sources from returning to the shielded position, and (4) evidence of approval by local fire officials. This exemption is likely to be more appropriate for research facilities, rather than large commercial irradiation facilities that may have large volumes of cardboard boxes as well as other combustible materials.

9.5 Radiation Monitors [10 CFR 36.23(c), 36.29, 36.39(e), 36.41(e), and 36.59(b)]

Describe the location and type of monitors used to meet the requirements of 10 CFR 36.23(c), 36.29, and 36.59(b). Describe the location and types of alarms and who will be alerted by the alarms. Use diagrams and sketches, as appropriate. Discuss the alarm set-points or the methods for establishing the alarm set-points. In general, G-M detectors are considered to have adequate sensitivity. For irradiators whose construction begins after July 1, 1993, describe the evaluation performed to meet 10 CFR 36.39(e) on detector location and sensitivity and the acceptance testing that will be performed to meet 10 CFR 36.41(e).

9.6 Irradiator Pools [10 CFR 36.33, 36.39(c), and 36.41(c)]

Describe the pool lining. For irradiators without a stainless steel liner that were initially licensed after July 1, 1993, explain why the pool has a low likelihood of substantial leakage and how decontamination could be

accomplished if necessary. For irradiators first licensed prior to July 1, 1993, write "Not applicable."

Describe the high and low water-level indicators and their locations. Describe the purification system for the pool; explain why the purification system is considered capable of maintaining pool water conductivity less than 20 microsiemens per centimeter. Describe the means to replenish pool water. Describe the barrier used during normal operation to prevent personnel from falling into the pool. Describe how high radiation doses from radiation streaming will be avoided when using long-handled tools or poles. Use sketches if appropriate.

For irradiators first licensed after July 1, 1993, if the pool has outlets more than 0.5 meters below the surface that could allow water to drain out of the pool, describe the means of preventing inadvertent excessive loss of pool water. (Outlets in this context do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools.)

For irradiators whose construction started after July 1, 1993, describe how the pool design ensures its integrity as required by 10 CFR 36.39(c), how the design of the water purification system is adequate, and how the inspections and tests to be done meet the requirements of 10 CFR 36.41(c) and (d).

9.7 Source Rack Protection [10 CFR 36.35]

If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from hitting or touching the source rack or mechanism that moves the rack. Provide diagrams or sketches if appropriate.

9.8 Power Failures [10 CFR 36.37, 36.39(i), and 36.41(i)]

For panoramic irradiators, describe how the source rack will be lowered if offsite power is lost for longer than 10 seconds. Describe how loss of power will affect the lock on the doors in the radiation room for a panoramic irradiator. For irradiators whose construction begins after July 1, 1993, to meet 10 CFR 36.39(i), describe the automatic return of the source rack to the fully shielded position in the event of a power failure, and describe the testing of that function to meet 10 CFR 36.41(i).

Item 10 - RADIATION SAFETY PROGRAM

10.1 Operating and Emergency Procedures [10 CFR 36.13(c) and 36.53]

An applicant may submit an outline or summary of its written operating and emergency procedures. This outline should allow licensees the flexibility to change procedures in ways that do not affect safety without the need for a license amendment.

The outlines or summaries of the written operating and emergency procedures should have enough detail to allow the NRC license reviewer to determine that following the steps outlined will ensure compliance with NRC regulations.

10.1.1 Operating Procedures

As described in 10 CFR 36.53, operating procedures are required for the following topics:

1. Operation of the irradiator, including entering and leaving the radiation room. The description should be in enough detail to show how compliance with 10 CFR 36.67, "Entering and Leaving the Radiation Room," will be achieved and should include a description of the initial entry and survey after an irradiation. Describe how access to keys by individuals who have not been qualified to be operators will be prevented, as required by 10 CFR 36.31(a). At a panoramic irradiator when product movement is occurring, 10 CFR 36.65 requires the presence of an irradiator operator and another person who is trained on how to respond and prepared to render or summon assistance if the access alarm sounds. For static irradiations, a person who is trained to respond to alarms must be onsite. In 10 CFR 36.65, the term "onsite" is intended to give flexibility to licensees. For example, for a research irradiator at a university, the onsite person could be a guard located on campus but not in the building containing the irradiator provided the guard would hear the alarm and was trained as required by 10 CFR 36.51(g). The guard would not have to be trained as an irradiator operator.

2. Use of personnel dosimeters. The description should include the categories of personnel who must wear dosimeters; the locations in the facility they must be worn; and how the requirements of 10 CFR 36.55, "Personnel Monitoring," will be met. The use of personnel dosimeters should begin before opening shipping casks containing sources.

3. Surveying the shielding of panoramic irradiators. The description should include how the surveys required by 10 CFR 36.57(a) will be done, including the types of instruments to be used. The initial survey should be considerably more thorough than subsequent surveys and should be performed by a well-qualified individual, such as the radiation safety officer or a health physics consultant. The initial survey should emphasize accessible areas, especially frequently occupied areas, areas around penetrations, and entrances to the radiation room, but should also include some locations not easily accessible. If the measured radiation dose rates are not distinguishable from normal background, the survey may indicate "background," rather than a numerical value. (Because of statistical fluctuations in the dose rate, the survey meter readings will fluctuate. Establish a range of dose rates to represent the natural background radiation dose rate. Readings within the range may be entered as background on survey records.) Describe the actions to be taken if radiation levels exceed the limits specified in 10 CFR 36.25.

4. Monitoring pool water for contamination before the pool water is released to unrestricted areas. The description should include the types of instruments to be used, their estimated sensitivities, methods and frequency of calibration, and how the requirements of 10 CFR 36.59(b) will be met. In addition, this procedure or another procedure should describe the surveys of other potentially contaminated liquids, sediments from pool vacuuming, and resins whose monitoring is required by 10 CFR 36.57(d) or (e). In general, the sensitivity required can be obtained with a thin-window G-M probe; sodium iodide detectors are generally not necessary. If water from the irradiator pool or resins is monitored in a low background area (less than 0.5 microsievert or 0.05 millirem per hour) and no radiation above background is measured, the material may be considered nonradioactive and released without restriction. For this item, write "Not applicable" for dry-source-storage irradiators.

5. Leak testing of sources. If the applicant will perform its own leak testing for dry-source-storage irradiators, describe the leak testing procedure, including (1) the instruments to be used and their calibration method and frequency, (2) the methods of performing the analyses, and (3) the pertinent training of the individual who analyzes the samples. Describe how the sample will be collected and analyzed. The wipe should be taken on the accessible surface closest to the source, not wiping the source itself. The value

of 200 becquerels (0.005 microcurie) applies to each source individually and is an action level that means that the contamination should be investigated, not that there necessarily is a leaking source. In general, the sensitivity required can be obtained with a thin-window G-M probe; sodium iodide detectors are generally not necessary.

If the licensee will not perform the leak testing, identify who will perform the leak test and either provide their license number or provide the procedures they will use.

This procedure applies to dry-source-storage irradiators only; for pool irradiators write "Not applicable."

6. Inspection and maintenance checks required by 10 CFR 36.61. Do not describe the inspection and maintenance procedures here. Instead, describe these procedures under Item 10.2 below.

7. Loading, unloading, and repositioning sources (if the operations will be performed by the licensee). All radiation safety aspects should be described, including contamination surveys of the shipping cask, radiation monitoring during operations, and recording the location of each individual source placed in the source rack. If the loading, unloading, or repositioning will not be performed by the licensee, identify who will perform these services.

8. Inspection of movable shielding required by 10 CFR 36.23(h), if applicable.

10.1.2 Emergency or Abnormal Event Procedures

The emergency and abnormal event procedures listed below should include who will be notified of the event, whether NRC will be notified, the role of the RSO, and what records of the event will be kept. The procedures should include the initial actions to be taken immediately after discovering the emergency or abnormal event. The procedures generally should not include postemergency corrective actions and repairs, since there will be time to carefully consider such actions on a case-by-case basis after the situation is under control. Describe procedures for each of the following.

1. Sources stuck in the unshielded position.

2. Personnel overexposures.
3. A radiation alarm from the product exit portal monitor or pool monitor.
4. Detection of leaking sources, pool contamination, or an alarm caused by contamination of pool water. The description should include who will be notified and how the requirements of 10 CFR 36.59(c) will be met.
5. A low or high water-level indication, an abnormal water loss, or leakage from the source storage pool. (The procedure should address all three of these conditions, but should generally include only the initial emergency response, not subsequent actions or postemergency repairs.)
6. A prolonged loss of electrical power (more than 10 seconds). Be sure to include entry procedures.
7. A fire alarm or explosion in the radiation room.
8. An alarm indicating unauthorized entry into the radiation room, area around the pool, or another alarmed area.
9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility.
10. Jamming of the automatic conveyor systems.

10.2 Inspection and Maintenance [10 CFR 36.13(h), 36.53(a)(6), and 36.61]

Describe the inspection and maintenance checks required by 10 CFR 36.61, including the frequency of the checks. The required checks are:

1. Operability of each aspect of the access control system required by 10 CFR 36.23.

2. Functioning of the source position indicator as required by 10 CFR 36.31(b).
3. Operability of the radiation monitor for radioactive contamination in pool water required by 10 CFR 36.59(b), using a radiation check source, if applicable.
4. Operability of the over-pool radiation monitor at underwater irradiators as required by 10 CFR 36.29(b).
5. Operability of the product exit monitor required by 10 CFR 36.29(a).
6. Operability of the emergency source return control required by 10 CFR 36.31(c).
7. Leak-tightness of systems through which pool water circulates (visual inspection).
8. Operability of the heat and smoke detectors and extinguisher system required by 10 CFR 36.27 (but without turning extinguishers on).
9. Operability of the means of pool water replenishment required by 10 CFR 36.33(c).
10. Operability of the indicators of high and low pool-water levels required by 10 CFR 36.33(d).
11. Operability of the intrusion alarm required by 10 CFR 36.23(i), if applicable.
12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 10 CFR 36.35.
14. Amount of water added to the pool to determine whether the pool is leaking.
15. Electrical wiring on required safety systems for radiation damage.
16. Pool water conductivity measurements as required by 10 CFR 36.63.

10.3 Radiation Detection Instrument Calibrations [10 CFR 36.55(b), and 36.57(c)]

Specify how survey instruments and pocket dosimeters (if used) will be calibrated or provide the name, address, and the NRC or Agreement State license number of the organization that will provide the service (and that is licensed to perform this activity.)

Discussion

It may be that a calibration service company does not have a license, perhaps because it is located in a non-Agreement State and uses radium, a radioactive material not regulated by the NRC. It is also possible that a service company has a license, but the license does not specifically authorize it to provide instrument calibration services to other licensees. In these cases, submit a description of the radioactive sources and the procedures used by the company for calibrating survey instruments.

Applicants who plan to calibrate their own radiation survey instruments should describe the radiation source to be used (radionuclide, activity, manufacturer, and model number) and the written procedures for calibrating the survey instruments. The training and experience of the individual who will calibrate the instruments should also be described. As a minimum, the written procedures should specify that:

1. Calibration will be performed at least annually with radionuclide sources at distances sufficient to approximate point sources.
2. Survey instruments will be calibrated at two points on each scale or range that the instrument offers or one point per decade for digital instruments, up to 0.01 sievert (1 rem) per hour. (Calibration is likely to require at least the following activities of typical radionuclide sources: 3000 gigabecquerels (80 millicuries) of cesium-137, 700 gigabecquerels (20 millicuries) of cobalt-60, or 1000 gigabecquerels (30 millicuries) of radium-226.)
3. Survey instruments will be adjusted to provide readings on all calibrated scales or ranges within 20% of true value.

If pocket dosimeters are to be used, describe the response checks to be performed and the range of the dosimeters. An annual response check with a response within $\pm 30\%$ of the true dose is acceptable. High-range pocket dosimeters are not required since the purpose of these dosimeters is essentially to demonstrate that little or no dose was received.

10.4 Pool Water Purity [10 CFR 36.33(e), 36.39(d), 36.41(d), and 36.63]

Describe the equipment to maintain pool water purity and clarity, the frequency of measurements of purity, and the criterion to be used for acceptable purity (e.g., 20 microsiemens per centimeter or equivalent). If

conductivity meters are to be used, describe the method and frequency of calibration.

Describe what actions will be taken to lower pool water conductivity if the conductivity rises above 20 microsiemens per centimeter.

For dry-source-storage irradiators, write "Not applicable."

Discussion

The purpose of keeping the water clean is not only to keep the water clear, but also to reduce corrosion of the sources. Clear water is desirable so that the sources and source rack can be visually inspected to check their condition and to retrieve any items that may drop into the pool. The probability of corrosion can be reduced by controlling impurity levels. The requirements in 10 CFR 36.63 are written in terms of conductivity (20 microsiemens per centimeter) because conductivity, an indicator of impurity levels, is most easily measured and most commonly used as a measure of water purity. Chlorides are one of the most aggressive impurities in promoting corrosion of stainless steel, and chloride concentrations should be controlled to 3 parts per million or less. Water with a conductivity of less than 20 microsiemens per centimeter will normally have a chloride concentration of less than 3 parts per million. However, in some situations high water conductivities may be caused by impurities other than chlorides. In such situations, if it can be shown that those impurities at the concentrations present do not promote corrosion, it may be more appropriate to base purity control on measurements of chloride concentrations rather than conductivity so that a conductivity much higher than 20 microsiemens per centimeter could be permitted. If the applicant elects to control impurities on the basis of chloride concentrations, the applicant should apply for an exemption to 10 CFR 36.63. Requests for exemptions that commit to maintaining chloride concentrations to less than 3 parts per million are likely to be granted.

10.5 Loading and Unloading Sources [10 CFR 36.13(g)]

If the applicant's own personnel will load and unload sources, describe the qualifications and training of the personnel and the procedures to be used. If the applicant will contract for source loading and unloading, identify the organizations that will be used.

10.6 Annual Review of the Radiation Protection Program [10 CFR 20.1101(c)]

Describe the annual review of the content and implementation of the radiation protection program that is described in this Item 10. Describe how the review will be conducted and who (by position) will conduct the reviews. Describe who will review the results of the review and any recommendations made in the review.

Discussion

The annual review should include (1) a review of the adequacy of the operating and emergency procedures listed in 10 CFR 36.53, (2) a review of the results of the inspection and maintenance checks listed in 10 CFR 36.61, (3) a review of personnel monitoring results, (4) a review of radiation survey and monitoring results, and (5) a review of the adequacy of the training of workers. Ideally, the person who conducts the review should be knowledgeable in radiation protection but independent of the day-to-day operation of the radiation protection program.

10.7 Financial Assurance and Recordkeeping for Decommissioning [10 CFR 30.35]

Irradiator applicants are required by 10 CFR 30.35(b) to submit either (1) a certification that financial assurance for decommissioning has been provided in the amount of \$75,000 or (2) a decommissioning funding plan that contains a cost estimate for decommissioning (generally to justify a cost of less than \$75,000) plus a certification that financial assurance for decommissioning has been provided in an amount equal to the cost estimate. For information on financial assurance mechanisms, the applicant should consult Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72."

For license renewal applications in which the applicant has previously provided financial assurance of \$75,000, write "Certification for financial assurance was submitted previously." For license renewal applications in which the applicant previously submitted a decommissioning funding plan with a cost estimate less than \$75,000, the cost estimate should be updated and financial assurance should be provided for the new cost amount.

Applicants should list the records that will be maintained to comply with 10 CFR 30.35(g) and should specify the location where the records will be kept. No records are required by 10 CFR 30.35(g)(1) and (2) if no spills or contamination have occurred. Records are required for 10 CFR 30.35(g)(3) only if a decommissioning funding plan to justify an amount other than \$75,000 was submitted.

Item 11 - WASTE MANAGEMENT

The general requirements for disposal of licensed radioactive material are contained in 10 CFR 20.2001 through 20.2007. Because of the nature of the licensed material contained in irradiators, the only option for disposal is to transfer the material to an authorized recipient as specified in 10 CFR 20.2001(a)(1). This states, in part, that sealed sources will be shipped only to authorized recipients and transport must be in accordance with 10 CFR Part 71. The transfer should be done as soon as practical after there is no further use for the sources.

Authorized recipients are the original supplier of the irradiator sealed sources, a commercial firm licensed by the NRC or by an Agreement State to accept radioactive waste from other persons, and another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of licensed material.

Item 12 - LICENSE FEES

An application fee paid in full is required by 10 CFR 170.12(a) for most irradiator licenses, including applications for license amendments and renewals. (Note that construction of the irradiator may not begin before submitting the license application and fee to the NRC (10 CFR 36.15)). Refer to 10 CFR 170.31, "Schedule of Fees for Materials Licenses and other Regulatory Services, Including Inspections, and Import and Export Licenses," to determine the amount of the fee that must accompany the application. Review of the application will not begin until the full fee has been received. All application fees may be charged irrespective of the NRC's disposition of the application or the withdrawal of the application. (Note that in addition to the application fee, annual fees will be assessed as described in 10 CFR 171.16.)

Item 13 - CERTIFICATION

An application should be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that it contains information that is true and correct to the best of his or her knowledge and belief. Unsigned applications will be returned for proper signature.

Correspondence to the NRC from the applicant should be signed by the certifying official named in Item 13. The NRC will send correspondence to that official. Commitments made by the applicant must be signed by the official listed in Item 13.

4. AMENDMENTS TO A LICENSE

After a license is issued, the program must be conducted in accordance with (1) the statements and representations contained in the application and any other correspondence with the NRC, (2) the terms and conditions of the license, and (3) the NRC's regulations. Operating and emergency procedures may be modified in accordance with 10 CFR 36.53(c) without amending the license.

It is the obligation of licensees to keep their licenses current. It is important to anticipate the need for a license amendment insofar as possible. If any of the information provided in the application is to be modified or changed, except for changes made in procedures in accordance with 10 CFR 36.53(c), submit an application for a license amendment. The terms and conditions of the license must be complied with until the license is actually amended; changes may not be implemented based on a submission requesting an amendment to the license.

An application for a license amendment may be submitted either on the application form (NRC Form 313) or in letter form. It should be submitted in duplicate to the Regional Office at the address specified in Section 2 of this guide, "Filing an Application." The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. Amendments may be in the form of page changes to the original application. Include the appropriate fee for a license amendment with the application. The NRC will not accept an

application or an application for a license amendment for filing or processing before the proper fee is paid in accordance with 10 CFR 170.12.

5. RENEWAL OF A LICENSE

Licenses are generally issued for a period of 5 years. An application for renewal must be sent to the Regional Office at the address specified in Section 2 of this guide, "Filing an Application." An entirely new application for renewal may be submitted as if it were an application for a new license without referring to previously submitted information. (This approach is preferable for the first renewal after July 1, 1993, the effective date of Part 36.)

As an alternative, applicants may:

1. Review the current license to determine whether the information concerning the sealed sources and the irradiator accurately represents the current and anticipated program. Identify any additions, deletions, or other changes and then prepare information appropriate for the required additions or changes.
2. Review the documents submitted in the past to determine whether the information in them is up to date and accurately represents the facilities, equipment, personnel, radiation safety procedures, locations of use, and so on. The documents that represent the current program should be identified by date. Any out-of-date or superseded documents should also be identified. Identify any changes that should be made in the documents to reflect the current program.
3. Review NRC regulations to ensure that any changes in the regulations are appropriately covered in the program description.
4. After this review is completed, submit a letter to the NRC in duplicate, with the proper fee, requesting renewal of the license and providing the information specified in Items 1, 2, and 3, as necessary.
5. Include the name and telephone number of the person to be contacted about the renewal application and include the current mailing address if it is not indicated correctly on the license.

Discussion

If an application for license renewal is filed at least 30 days before the expiration date of the license and the appropriate fee for license renewal is included, 10 CFR 30.37(b) provides for the license to remain in effect until the NRC takes final action on the application. However, if an application is filed less than 30 days before the expiration date and the NRC cannot process it before that date, the license will expire.

It is important that the appropriate fee accompany the application for license renewal and that the application is dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and certify that it contains information that is true and correct to the best of his or her knowledge or belief. In accordance with 10 CFR 170.12, the NRC will not accept an application for filing or processing before the proper fee is paid. Unsigned applications will be returned for proper signature.

6. TERMINATION OF A LICENSE

To terminate a license, 10 CFR 30.36(b) requires that a licensee notify the NRC promptly and request termination of the license. This notification must include: (1) a completed form NRC-314, "Certificate of Disposition of Materials," certifying that all sources have been disposed of properly and (2) the results of a final radiation survey of the premises where the licensed activities were carried out. This termination report must be sent to the NRC before the expiration date of the license. If there is loose contamination at the irradiator, it will also be necessary to submit a decommissioning plan as described in 10 CFR 30.36(c)(2).

If all the licensed radioactive material cannot be disposed of properly before the expiration date, a request for license renewal for storage only of the radioactive material must be provided to the NRC. The renewal is necessary to avoid violating NRC's regulations that do not allow possession of licensable material without a valid license.

7. IMPLEMENTATION

The purpose of this section is to provide information to applicants regarding the NRC staff's plans for using this regulatory guide.

This draft guide has been distributed for comment to encourage public participation in its development. Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method to be described in the active guide reflecting public comments will be used in the evaluation of applications for new licenses or license renewals for non-self-contained irradiators.

NRC FORM 313 (5-93) 10 CFR 30.32, 33 34, 35, 36, 38 and 40	U. S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES 6-30-98 ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 8 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (NRCB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.												
APPLICATION FOR MATERIAL LICENSE														
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.														
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO: LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415 ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION II 101 MARIETTA STREET, NW, SUITE 2800 ATLANTA, GA 30323-0189														
IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION III 798 ROOSEVELT ROAD GLEN ELLYN, IL 60137-5627 ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 811 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-8064 ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO: RADIOACTIVE MATERIALS SAFETY BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION V 1480 MARIA LANE WALNUT CREEK, CA 94595-5305														
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.														
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APPENDIX B

RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the daily operation of the irradiator.

The RSO's duties and responsibilities include:

- Investigating overexposures and implementing corrective actions as necessary;
- Establishing, collecting in one binder or file, and implementing written policy and procedures for:
 - Assuring that an irradiator whose construction begins after July 1, 1993, is designed in accordance with NRC requirements, its construction is monitored, and the features and systems specified in 10 CFR 36.41 are tested and found to be acceptable before loading sources;
 - Authorizing the purchase of byproduct material (e.g., new irradiator sources);
 - Receiving and opening packages of byproduct material (e.g., casks containing irradiator sources);
 - Storing byproduct material;
 - Keeping an inventory of byproduct material (e.g., location of each irradiator source (identified by its serial number) within the source rack);
 - Using byproduct material safely (e.g., detailed operating procedures);
 - Taking emergency action (e.g., detailed emergency procedures);
 - Making those changes to operating and emergency procedures that do not need Commission approval (in accordance with the requirements of 10 CFR 35.53(b));
 - Performing inspection and maintenance checks;
 - Performing periodic surveys;
 - Performing checks and calibrations of radiation detection instruments and water quality devices (e.g., conductivity meters);
 - Disposing of byproduct material (e.g., by transfer to authorized recipient);

- Training personnel, including irradiator operators, those permitted unescorted access to the radiation room or the area around the pool of an underwater irradiator, and those who must be prepared to respond to alarms;
 - Keeping copies of all records required by NRC regulations, the license and all amendments, and the written policy and procedures required by the regulations and the conditions of the license.
-
- Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the RSO of the cause of the exposure and consideration of actions that might be taken to reduce the probability of recurrence;
 - At least annually, review the radiation protection program content and implementation, and then brief management on the results of the review and any needed improvements.

APPENDIX C

INCIDENTS AT LARGE IRRADIATORS

The incidents described here are examples of dangerous or potentially dangerous incidents that have occurred at irradiators. They are described here so that irradiator licensees can learn to avoid the problems that others have had. The descriptions are taken from NRC Information Notice No. 91-14, "Recent Safety-Related Incidents at Large Irradiators," March 5, 1991.

1. Fatality Caused by Source Rack Jam, Bypassed Interlocks, and Faulty Survey Meter

At a 340,000-Curie Co-60 irradiator in Israel, a product jam occurred, causing the product transport mechanism to stop, the "source-down" signal to come on, and the gamma alarm to sound. The sounding of the gamma alarm was considered unusual. Acting against operating and safety instructions, the operator did not notify his supervisor and instead handled the situation on his own. He turned the alarm system off by disconnecting the console cables, defeated the door interlock by cycling the power switch, unlocked the door, and entered the radiation room. He did not check the survey meter he carried before entering the radiation room, and consequently he was unaware that the meter was not operational.

Seeing torn cartons, but unable to see that the source rack remained up because it was resting on the edge of a carton, the operator got a cart and began removing the damaged cartons. After about a minute, he began to feel a burning sensation in his eyes and left the room. The operator was not wearing his film badge, but the whole body dose for the 1 1/2 to 2 minutes he was in the radiation room was estimated to be about 1,000 to 1,500 rads. The source rack was later released and lowered to the pool under the direction of the supplier, and no further overexposures were reported. The operator died from acute radiation syndrome effects 36 days after the accident.

2. Fatality and Injuries After Sources Fall out of Rack and Interlocks Bypassed

At an 18,000-Curie Co-60 irradiator in El Salvador, the sounding of the source transit alarm alerted the night shift operator (Worker A) that the source was neither fully up nor fully down as a result of a fault condition, which should have caused the source rack to be automatically lowered to the pool. He followed the reset procedure at the control panel, but he had no success in stopping the alarm and releasing the door. He tried to free the source rack by detaching the normal regulated air supply and applying higher pressure to force the source rack into the fully raised position (a procedure not recommended by the supplier). This attempt also failed. The worker was eventually able to stop the alarm, but the general failure light and the "source-up" light remained on. He then manipulated the microswitch system to produce a "source-down" light.

Worker A disabled the door interlock system by rapidly cycling the buttons on the radiation monitor panel, while turning the key in the door switch (another procedure not recommended by the supplier), thus simulating

the detection of normal background radiation in the radiation room by the fixed monitor and succeeded in opening the door. He then shut off the power supply to the facility and entered the radiation room believing that, as with unpowered x-ray equipment, there would be no continuing radiation. Without first checking the radiation levels with a portable radiation instrument, he began to remove the deformed product boxes that had jammed. At this point he noticed that the descent of the source rack was prevented by the slack cable of the hoist mechanism. Unable to free the rack by himself, he left the radiation room and turned the power back on, noticing that the failure light was "on" and the "source-down" light was intermittent, but that no alarm was sounding.

Worker A then enlisted Workers B and C to help free the source rack. They had no experience or knowledge of the irradiation facility. After assuring Workers B and C that there was no risk as the machine was turned off, the three men entered the radiation room and began removing the jammed product boxes, while standing directly in front of the source rack. As the product boxes were removed and the source rack was lowered to the surface of the water, the workers noticed the blue glow in the pool from Cerenkov radiation. Worker A was surprised at this and after fully lowering the source rack, he told the others to exit quickly. When leaving the radiation room, Worker A was questioned by Worker B as to the use of the portable radiation monitor that was located some distance from the irradiator. He explained that the instrument was for radiation detection and measurement, but that it had not been necessary to use it.

Worker A became ill minutes after leaving the radiation room and was taken to the hospital. Workers B and C later became ill and also went to the hospital. The company was unaware of the accident for several days because the workers were incorrectly diagnosed as having food poisoning. It was later discovered that some of the source pencils had fallen from the source rack into the pool and that one of the pencils had fallen into the radiation room. At least four more persons were overexposed before the circumstances of the accident were fully realized.

Worker A was hospitalized for extensive radiation burns to his legs and feet and gastrointestinal and hematopoietic radiation syndrome. His right leg was amputated and, 197 days after the accident, Worker A died as a result of his radiation exposure. Worker B was treated for symptoms of acute radiation exposure and severe burns. After the amputation of both legs, he was transferred to a rehabilitation facility 221 days after the accident. Worker C suffered less severe symptoms of radiation exposure and remained on sick leave from work for 199 days after the accident. Long-term effects to these workers may include eye damage from radiation exposure. A more detailed description of the incident can be found in the IAEA publication STI/PUB/847.*

3. Faulty Cable Brake Causes Exposed Source, but Good Survey Prevents Overexposure

An irradiator operator noticed that the product had received an unacceptably low dose. He shut down cell operations and, with the source position

*STI/PUB/847, "The Radiological Accident in San Salvador," IAEA, Vienna, 1990. Copies can be obtained for reference and training tools from UNIPUB, 4611-F Assembly Drive, Lanham, MD 20706-4391.

monitor indicating that the sources were down and the in-cell radiation monitor showing radiation levels at zero, he entered the cell with a portable radiation survey instrument. He noticed elevated radiation levels between 1-2 mR/hr on the survey instrument and aborted his attempt to enter the cell. The operator restricted the area and notified supervisory personnel. Investigation into the cause of the elevated radiation readings revealed that one of the source racks was not fully down and that the top of the rack was about 1-1/2 feet from the top of the pool. An inspection of the winch mechanism indicated that the cable brake had failed to stop the winch, allowing the cable to completely unwind. As a result, the source rack was raised instead of lowered with the continuing rotation of the winch mechanism. The source rack was then manually lowered into the pool. It was determined that radiation exposure caused deterioration of the wiring in the Geiger-Muller tube of the cell monitor, which caused this system to fail to warn of the elevated radiation levels in the radiation room. The necessary repairs were made to the control panel and the cell monitor, and procedures were instituted to upgrade the safety systems of the facility. The operator followed safety and operating procedures during the incident and avoided overexposure by correctly using the portable survey instrument.

4. Violations Result in NRC Fines

During an inspection and subsequent investigation at an irradiator, NRC identified the following violations: (1) failing to promptly and effectively repair the lock on the personnel-access door to the irradiator cell, (2) modifying a procedure without first obtaining NRC approval (i.e., replacing a safety component in the irradiator start-up system) as required in the license, and (3) deliberately bypassing administrative procedures and safety interlocks and physical barriers to gain entry to the irradiator cell by climbing over the irradiator cell access door. An NRC investigation also determined that senior licensee management knew of the violations and made incomplete and inaccurate statements to the NRC during an enforcement conference and the subsequent investigations into the circumstances of these violations. The potential for extremely high radiation exposures and the licensee's lack of candor with NRC raised questions about the ability and willingness of the licensee to comply with NRC requirements. NRC considered these violations of the safety requirements to be serious and proposed a civil penalty against the licensee. Senior management involved in this incident are no longer associated with the facility. The licensee has instituted a quality assurance program and additional training requirements.

5. Fines for Deliberate Interlock Bypass

A licensee deliberately bypassed the radiation monitor interlock systems and substituted an administrative procedure for the engineered safeguard provided by the radiation monitor interlock. The substituted cell entry procedure was implemented without NRC review, approval, and incorporation in the license. The alternative procedures did not constitute an entry control device that functioned automatically to prevent inadvertent entry and did not comply with NRC access control requirements. In addition, the licensee installed jumper cables to bypass ventilation system interlocks, which were designed to automatically protect individuals from noxious gases produced as a result of irradiation.

Because of the extremely high radiation exposures that could result if interlocks are not operational, the NRC concluded that this incident was a very serious violation of safety requirements. The licensee was not allowed to operate the irradiator until all safety systems were fully operational. This violation of NRC requirements, along with other safety-related violations, resulted in NRC proposing a substantial civil penalty.

6. Cesium-137 Source Leaks

A leaking cesium-137 source capsule contaminated the pool water at Radiation Sterilizers, Inc.'s plant in Decatur, Georgia, and it remained undetected for an extended period of time because the licensee did not use the pool water monitoring system associated with the demineralizer. The contamination problem was finally discovered when the licensee took discrete samples and performed radiation surveys of the pool water after activation of the radiation-level monitoring system, which had automatically locked the sources in the safe-storage position because of the excessive radiation levels while the sources were in the stored position.

Failure to continuously use the demineralizer and pool water monitoring system was contrary to the licensing agency's understanding of the operations. Had the demineralizer been operated continuously, pool water contamination possibly could have been detected earlier, enabling the licensee to begin mitigating the contamination.

7. Crane Brake Fails While Lowering Shipping Cask

A contractor who provided lifting-crane services at a licensed facility was moving a shipping cask from the source storage pool to a mezzanine area, when the cask made an uncontrolled descent of approximately 19 feet. The cask stopped its descent approximately 5 feet below the surface, only after an operator activated a manual brake. No personnel were injured and there was no damage to, or contamination of, the licensee's facility or equipment as a result of this event. However, had the cask not been secured quickly, it could have damaged the radioactive sources in the pool or the pool itself.

This incident was a result of improper brake adjustment of the crane hoist. The crane brake was subsequently repaired and recertified for normal operations in accordance with current Occupational Safety and Health Administration regulations. Braking system inspection and adjustment, as well as functional load testing, are now established daily procedures before crane operation.

8. Faulty Welds Cause Pool Leakage

A licensee experienced a loss of pool water for several weeks that was approximately three times higher than expected from evaporative losses. The licensee performed tests to determine the nature and quantity of the water loss and began daily assays of the pool water to determine compliance with release limits for unrestricted areas. Suspecting a leak in the irradiator pool, the licensee inspected the stainless steel liner and found localized caustic stress corrosion in many welds.

Apparently, welds made during construction of the facility in 1968 were not in accordance with industry standards. Thus, these faulty welds were subject to caustic stress corrosion, which resulted in the recent pool water losses.

9. Hose Rupture Releases Contaminated Water

While the licensee was attempting to decontaminate pool water that had been contaminated by a leaking source, a hose on a filtration system ruptured. Contaminated pool water was then pumped onto the facility floor and leaked outside into the surrounding soil. The licensee failed to report the incident to NRC and made deliberate efforts to prevent NRC's discovery of this incident.

Subsequently, the licensee was indicted by a Federal Court. A conviction resulted in a fine for the company and 2 years probation for a management employee. Licensee failure to make required reports prevents the NRC from performing its radiological health and safety function and from making a timely assessment of the nature and severity of an incident.

10. Licensee Bypassed Access Control Interlocks and Lied to NRC

A licensee deliberately bypassed the safety interlock systems. The NRC subsequently learned that licensee personnel had willfully violated requirements, and that senior licensee management knew, or should have known, of these violations. When NRC attempted to inspect and investigate these suspected violations, senior licensee management knowingly provided false information to the NRC. Subsequent enforcement action included suspension of the license.

11. Line Rupture Causes Loss of Pool Water

A water line fractured in the pool circulation system, which resulted in the loss of 5 feet of pool water. The line break led to a loss of shielding water because the intake and outlet pipes were misaligned during maintenance. The pipe break appears to have occurred because the pipe was made of polyvinyl chloride, designed for cold water, rather than for the heated water temperatures typical for the irradiator. The piping was replaced with polypropylene pipe.

12. Frozen Valve Causes Source Rack To Jam in Up Position

A night shift operator noticed that the travel time for the source to reach the fully unshielded position was excessive. After completing the next phase of irradiation, the source would not retract to the fully shielded position, even using emergency equipment. The operator discovered that the solenoid valve, which was supposed to retract the source to a shielded position, was frozen by weather conditions. The frozen valve was in a room above the irradiator facility. The operator went there and turned on a room heater to thaw out the valve so that it would operate. The operator violated license requirements to (1) notify the Radiation Safety Officer (RSO) that the source

had not returned to its shielded position because of the frozen valve and (2) obtain RSO permission to enter and heat the room housing the valve.

13. Frayed Cable Causes Source Rack Jam

A licensee had identified a frayed lift cable a few days previously, but instead of immediately replacing the cable, the licensee decided to wait for scheduled maintenance. The cable jammed and froze the source rack in a less than fully shielded position. Employees cut the cables and let the source rack free-fall into the pool. The incident could have been prevented by replacing the frayed cable immediately and selecting cable material with fray-resistant qualities.

14. Bent Shroud Prevents Source Rack from Being Lowered

A source rack became stuck in the exposed position. Conveyors stopped, the source-down light came on, but cell radiation levels remained high. Cable-slack data indicated that the rack was stuck about 5-1/2 feet down from its full-up position. The RSO attempted some raising and lowering maneuvers, but the rack then stuck in a full-up position. The RSO, able to run the product containers out of the cell, saw some were misaligned on the carrier. The RSO notified a State inspector, who arrived in the afternoon. It was determined that the rack cable was off its pulley. The bottom of a splice in the cable was resting on the lip of the tube leading to the cell. After the cable was set on its pulley, the cable was guided through the tube and the rack was lowered, but it caught again.

A borrowed radiation-resistant camera arrived the next morning. An adequate view of the rack was obtained by midnight. Apparently the stationary aluminum shroud between product containers and rack had been deflected and caught on the rack frame. The rack was carefully raised and dropped to break the jam. On the second try, the rack broke free and dropped into the pool. Analysis revealed that a product container had probably tipped onto the shroud, causing interference with the rack.

This incident was apparently caused by inadequate design of the shroud. This led to the shroud deforming, which interfered with rack motion. Inadequate maintenance contributed to the problem. The cable should have been replaced instead of spliced. A few months later, the entire source hoist mechanism failed and had to be replaced. This failure occurred when the source rack was submerged.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this draft regulatory guide. The regulatory analysis prepared for the proposed 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," is entitled "Regulatory Analysis and Environmental Assessment of NRC Regulations on Licenses and Radiation Safety Requirements for Large Irradiators," and is dated February 1989. This regulatory analysis for the rule provides the regulatory basis for this regulatory guide, and it examines the costs and benefits of the rule as implemented by the guide. A copy of the regulatory analysis is available for inspection or copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC.



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