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DRAFT REGULATORY GUIDE AND VALUE/IMPACT STATEMENT

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Contact: L. Hendricks (301) 443-5970

PROPOSED REVISION 1 TO REGULATORY GUIDE 10.9

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR THE USE OF GAMMA IRRADIATORS

1. INTRODUCTION

This guide describes the type of information that the NRC staff needs to evaluate an application for a license to use sealed radioactive sources for the gamma irradiation of materials (see Item 1.2 following). Section 4.a outlines items that should be contained in applications for self-contained, dry source-storage irradiators (an irradiator so constructed that the sealed source(s) and the material being irradiated are contained in a shielded volume, which in the designed configuration of the device is always physically inaccessible by any part of the human body). Section 4.b outlines the items that should be contained in applications for other types of irradiators.

1.1 Applicable Regulations

Regulations pertaining to this type of license are found in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings"; 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 71, "Packaging of Radioactive Materials for Transport and Transportation of Radioactive Material Under Certain Conditions"; 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement

This regulatory guide and the associated value/impact statement are being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. They have not received complete staff review and do not represent an official NRC staff position.

Public comments are being solicited on both drafts, the guide (including any implementation schedule) and the value/impact statement. Comments on the value/impact statement should be accompanied by supporting data. Comments on both drafts should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by JUN 25 1982

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, D.C. 20555, Attention: Director, Division of Technical Information and Document Control.

States Under Section 274." The applicant should study carefully the regulations and this guide and submit all information requested.

1.2 Items Requiring Separate Applications

Uses of byproduct materials other than for the gamma irradiation of materials are not within the scope of this guide. The term "Materials" does not include human beings (teletherapy license required); nor does it, generally, include explosive materials or food for human consumption (special authorization under the terms of a specific license required).

1.3 As Low As Is Reasonably Achievable (ALARA)

Paragraph 20.1(c) of 10 CFR Part 20 states that ". . .persons engaged in activities under licenses issued by the Nuclear Regulatory Commission (NRC) pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the NRC staff position on this important subject. License applicants should give consideration to the ALARA philosophy in the design of the irradiator facility and in the development of plans for work with licensed radioactive materials (see Regulatory Guide 8.10).

2. LICENSE FEES

An application fee is required for most types of licenses. The applicant should refer to § 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," of 10 CFR Part 170 to determine the amount of the fee that must accompany the application. Review of the application will not begin until the proper fee is received by the NRC.

3. FILING AND APPLICATION

3.1 Application Form NRC-313(I)

An application for a license to possess and use byproduct material for the gamma irradiation of materials should be filed on Form NRC-313(I), "Application for Byproduct Material License." All items on the application form should be completed in sufficient detail for the NRC to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on the application form is limited, the applicant should append additional sheets to provide complete information. Each separate sheet or document submitted with the application should be identified as to its purpose, e.g., response to an item of the application form, radiation safety instructions.

Three copies of the application should be completed. The original and one copy should be mailed to: Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. One copy should be retained by the applicant since the license will require that the institution adhere to the statements and representations made in the application and any supplement to it.

3.2 Proprietary Information

The applicant should not submit proprietary information unless it cannot be avoided in giving a complete description of the applicant's equipment, facilities, and radiation protection program. If the use of proprietary information cannot be avoided, the proprietary information should be separated from the rest of the application and an application for withholding from public inspection should be submitted in conformance with the requirements of § 2.790, "Public Inspections, Exemptions, Requests for Withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings."

3.3 Environmental Information

An environmental report is not specifically required for the type of activities included in the scope of this document.

3.4 Safeguards

No safeguard information is required in an application for licenses covered by this guide.

4. CONTENTS OF AN APPLICATION

4.a General Requirements: Self-Contained, Dry Source-Storage Irradiators

Many items of the NRC Form 313(I) are self-explanatory (see instructions with the form, Appendix A). The following comments apply to the items of the form as indicated.

Item 5. Location of Use of Byproduct Material

The street address, building number (if any), and room number where the irradiator will be used should be provided. If no street address is available, the applicant should provide a specific description that designates the location accurately.

Items 8A to D. Quantity and Form of Byproduct Material

The applicant should specify the isotope, number of curies per source, name of manufacturer and model number of each source, and total number of sources that will be contained in the irradiator. If the sources have been evaluated previously by the NRC or an Agreement State,* specification of the manufacturer

*An Agreement State is a State to which the Commission has relinquished authority for regulating the use of byproduct, source, and special nuclear material (in quantities less than critical mass) within the boundaries of the State.

and model number of the sources will be a sufficient description. If the sources have not been evaluated previously, the applicant should provide the information requested in "Guide--Information To Be Submitted for Evaluation of Sealed Sources Utilizing Radioactive Materials." This document is available from the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Item 8E. Purpose for Which Byproduct Material Will Be Used

The applicant should specify that the sources will be used in an irradiator (including name of manufacturer and model number) for the irradiation of materials (see Item 1.2).

Item 9. Storage of Sealed Sources

List as indicated on form and refer to detailed descriptions under Item 13, as appropriate.

Items 10 and 11. Radiation Detection Instruments

Describe the capability of the radiation survey instruments that are used in support of irradiator operations for accurately measuring normally expected radiation levels in the vicinity of the irradiator. Show that these instruments have sufficient range to detect unusual radiation levels that might be indicative of shielding failure, source disconnection, or major contamination. Describe how the radiation detection instruments will be tested by use of a check source of radiation before each use. Indicate the capability of the check source for exposing the detector to radiation levels of the same order of magnitude as those that are encountered during normal operations.

The applicant should specify that these instrument check tests will be supplemented by at least an annual calibration that meets the performance specifications identified in Section 4.b, Items 10 and 11 of this guide. Also specify that survey instruments will be calibrated before use following repair. Indicate that instruments will be used to measure radiation levels at various distances from the check source soon after their annual calibrations. Describe

what record of the instrument's readings will be kept for use and reference in subsequent instrument checks between calibrations.

Specify that those instruments used to detect radioactive contamination or the leakage of radioactive materials will have the same characteristics and be calibrated in the same way as described for the same kinds of instruments in Section 4.b, Items 10 and 11, in this guide.

Item 12. Personnel Dose Monitoring Devices

The applicant should (1) specify the type of personnel dose monitoring devices (film badge, thermoluminescence dosimeter (TLD), pocket chambers) to be used, (2) provide the name of the commercial supplier of the film badge or TLD and the dosimetry service, and (3) specify the frequency at which film badges or TLDs will be evaluated. For pocket chambers, the applicant should provide the name of the manufacturer, type, model number, and the range (mR) and frequency of reading and specify provisions for the maintenance and calibration.

Item 13. Facilities and Equipment

A number of self-contained, dry source-storage irradiators have been evaluated by the NRC or Agreement States. Since the manufacturers have submitted detailed descriptions of these irradiators to the NRC or Agreement States for generic evaluation, a detailed description of the engineering design of such an irradiator need not be repeated by each person making application for a license to use this equipment. The applicant need provide only the name of the manufacturer and model number of the irradiator if it has been so evaluated. Information on whether or not a particular irradiator has been so evaluated should be available from the manufacturer.

If the device has not been previously evaluated, the applicant should provide a complete description of the irradiator. This description should include the following:

a. Engineering drawings of the device. All drawings should have a drawing number, revision number, company number, title, date of revision, bill of materials or reference thereto, dimensional scale and dimensional tolerances. Additional sketches may be used if they provide necessary information concerning the main function or safety features of the device. Assembly views of engineering drawings and the use of photographs are helpful in providing a description of the irradiator. All engineering drawings and photographs should be of good quality and be legible. The description should specify the dimensions and materials of construction.

b. A complete description of all mechanical and electrical systems, including the shutter or source-positioning mechanism, interlocks, source-position indicators, warning lights, and alarm. Show how interlocks and warning lights are designed so that failure of the system or loss of electrical power will result in an adequately shielded, safe condition (i.e., access to the source or high radiation levels is prevented).

c. A copy of the radiation profile (in mR/hr) for a prototype model of the irradiator. Radiation levels should be measured with the irradiator containing the maximum quantity, in curies, of radioactive material to be contained and in the "store," "transit," "load and unload," and "operate" positions. The radiation survey of the prototype irradiator should provide a complete three-dimensional profile of the irradiator at 5 cm and 1 meter from the exterior surface. The applicant should specify the name of the manufacturer and the model number of the radiation survey instrument used and also the date it was calibrated and the method used. If the irradiator will be used in an area where the applicant will not restrict access for radiation protection purposes, specify that the radiation levels from the irradiator's source anywhere outside the irradiator will not exceed 2 mR/hr, and indicate how the irradiator will be secured against unauthorized use.

d. A description of the tests performed on the irradiator. These tests should establish the integrity of the irradiator shielding and the operability of the control system (such as source-positioning mechanism, shutters, on-off indicators) under ordinary conditions or in storage, use, and handling, and under accident conditions.

e. A facsimile of the labels to be attached to the device and a description of how and where the labels will be attached. The labels must, as a minimum, meet the requirements of paragraphs 20.203(f)(1) and (2) of 10 CFR Part 20.

The applicant should describe the space where the irradiator will be located, including an annotated sketch of the floor plan of the building in which the irradiator will be located. This sketch should note the location of the irradiator and should identify the types of activities that will be conducted in adjoining areas. If the irradiator has not passed prototype tests for a standard industrial fire, note that the room where the irradiator will be located will be equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) that is adequate to ensure the integrity of the irradiator and source in a fire.

Item 14. Waste Disposal

The applicant should describe plans for the disposal of the sealed sources and the contaminated smears (if any) from leak tests.

Item 15. Radiation Protection Program

a. Organization and Administrative Procedures

The applicant should provide an organizational chart that specifies the radiation safety officer, the operators, and their respective supervisors. The applicant should provide a copy of the written administrative procedures that govern the responsibility for the safe use of the irradiator. These procedures should clearly identify the functions, duties, and responsibilities of each operator and of the radiation safety officer.

The applicant should describe the methods of ensuring that only authorized persons will use the irradiator or have access to the space where it is located. These methods can include control of keys to the door of the room containing the irradiator control console, control of operating console keys, or other positive methods of excluding access.

b. Operating and Emergency Procedures

The applicant should provide a copy of the step-by-step procedures that will be followed by operators while using the irradiator. Procedures for ensuring safety and the security of the device during extended irradiations should be described in detail.

The applicant should provide a copy of concise, easily followed emergency procedures. These procedures should describe the conditions that will be indicative of an emergency situation and should state the emergency action to be taken. These procedures should include instructions for the immediate action to be taken to minimize radiation exposure to persons in the vicinity of the irradiator and should include the names and telephone numbers of persons who are to be contacted to direct remedial actions. Actions that are prohibited or to be avoided in the event of abnormal conditions should also be described.

The applicant should provide a copy of the procedures that will be used to determine possible leakage of radioactive material from the source capsule. Show that the test methods are sufficiently sensitive to detect 0.05 microcurie of activity. Describe the procedures that ensure the leak testing of the source every 6 months. Indicate that the test sample will be taken from appropriate accessible surfaces of the device in which the sources are permanently stored.

Procedures for the installation, relocation, removal, or maintenance of the irradiator should be described. If these tasks are to be performed by persons who are specifically licensed by the NRC or Agreement States for such work, the applicant should provide the names and license numbers of such persons.

c. Training Program

The applicant should provide a complete description of the training program for the operators. The description should specify the form of training (e.g., lectures, on-the-job training), an outline of the subject matter that is covered and the time devoted to each subject, and provisions for retraining. The names and qualifications of the instructors should be provided; and procedures for documenting training should be included. The application should also describe

the methods and criteria used both to determine the competency of each individual to operate the irradiator and to evaluate the effectiveness of the training program.

Items 16 and 17. Technical Qualifications of Personnel

The applicant should provide a resume of the training and experience in the use of radioisotopes and radiation for each person in the applicant's organization who will directly supervise the operations or who will have radiological safety responsibilities. The resume should include a description of training (both on-the-job training and formal course work), location where the training was received, and the duration of the training. Training information should also cover knowledge of (1) principles and practices of radiation protection, (2) radioactivity measurements, standardization and monitoring techniques, and instruments, (3) mathematics and calculations basic to use and measurement of radioactivity, and (4) biological effects of radiation. The description of actual use of radioactive materials should specify the isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. Additional information on specific training for operators of the facility should be submitted under Item 15 of the application as indicated above in this guide.

4.b General Requirements: Other Irradiators

Many items of the NRC Form 313(I) are self-explanatory (see instructions with the form, Appendix A). The following comments apply to the items of the form as indicated.

Item 5. Location of Use of Byproduct Material

See Section 4.a, Item 5.

Items 8A-D. Quantity and Form of Byproduct Material

See Section 4.a, Items 8A to D. Note additionally that radioactive sources for water-shielded irradiators must be doubly encapsulated.

Item 9. Storage of Sealed Sources

List as indicated on form and refer to detailed descriptions under Item 13, as appropriate.

Items 10 and 11. Radiation Detection Instruments

The applicant should provide for each type of instrument available the manufacturer's name and model numbers, how many of each type are available, the type of radiation detected (beta or gamma), the sensitivity range (milliroentgens per hour or counts per minute), and the window thickness in mg/cm^2. The type of use for each instrument should be specified. The type of use would normally be monitoring, surveying, assaying, or measuring.

The applicant should specify that among the detection instruments available there is at least one ionization-chamber type of radiation measuring instrument of a design that does not "blank-out," i.e., tend to read zero in a very intense radiation field, and that is capable of measuring accurately radiation levels from 2 mR/hr to at least 1 R/hr. If source leak tests are to be evaluated by the applicant, indicate that a radiation counting instrument will be used (such as a GM tube with a scaler) that is capable of measuring accurately 0.05 microcurie of activity on smear-test samples or, with the sample preparation technique employed, 5×10^{-5} μCi/ml of activity in a water sample.

Instrument calibration provisions should be described. State the frequency and describe the methods and procedures for calibration of survey and monitoring instruments as well as any other instruments and systems used in the radiation protection program such as measuring instruments used to assay sealed-source leak-test samples, contamination samples (e.g., air samples, surface smear-test samples), and bioassay samples.

(Note: An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.)

Show that daily or other frequent checks of survey instruments are supplemented at least every 6 months with a two-point calibration on each scale of each instrument with the two points separated by at least 50% of the scale. Also, show that survey instruments will be calibrated before use following repair. Indicate that survey instruments will be properly calibrated, i.e., instrument readings are within ±10% of the calculated or known values of each point checked or readings are within ±20% if a calibration chart or graph is prepared and attached to the instrument.

If the applicant proposes to calibrate its survey instruments, a detailed description of planned calibration procedures should be submitted. The description of calibration procedures should include the following as a minimum:

a. The manufacturer and model number of each radiation source to be used,

b. The nuclide and quantity of radioactive material contained in each source,

c. The accuracy of each source (the traceability of the source to a primary standard should be provided),

d. The step-by-step procedures, including associated radiation safety procedures, and

e. The name and pertinent experience of each person who will perform the calibrations.

If the applicant intends to contract out the calibration of survey instruments, the name, address, and license number of the calibration firm should be specified together with the frequency of calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Commission. If information concerning calibration procedures has not been filed, it should be obtained and submitted.

The applicant should indicate that, when appropriate, quantitative measuring instruments used to monitor the adequacy of containment and contamination control (such as those used for measuring leak-test, air effluent, bioassay, work area, and equipment contamination samples) will be calibrated prior to each use. The procedures and frequency for calibration of such instruments should be submitted and should include the following:

a. The name, manufacturer, and model number of each of the standard sources to be used,

b. The nuclide and quantity of radioactive material contained in each of the standard sources,

c. A statement of the accuracy of each of the standard sources, i.e., accuracy, as a minimum, ±5% of the stated value and traceable to a primary standard such as that maintained by the National Bureau of Standards,

d. Step-by-step calibration procedures and, if appropriate, associated radiation safety procedures, and

e. The name and pertinent experience of each person who will perform the instrument calibrations.

Item 12. Personnel Dose Monitoring Devices

See Section 4.a, Item 12.

Item 13. Facilities and Equipment

The applicant should provide a complete description of the irradiator construction and function, including annotated plans and elevation drawings showing dimensions and materials of construction. The application should:

a. Identify the location of the building(s) and other structures of the irradiator facility on a map or drawing (to scale) showing their location in the local community or local area. The boundary that encompasses the area owned or leased by the applicant should be shown. The restricted area(s), as defined in 10 CFR Part 20, § 20.3, should be shown or described.

b. Show the layout of the building(s) and structures using engineering drawings. Plans and elevations should be provided in sufficient detail to identify all features to be discussed, including operational and control areas. Spatial and equipment identification data should be included directly on layouts or (with suitable designations) in tabular listings. The applicant should discuss the components and systems in the area under consideration, including dimensions and materials of construction.

c. Describe pertinent physical features of the irradiator, its systems, and the surrounding areas, including rooms, walls, roofs, and floor radiation shielding characteristics. The locations of the source(s) in the stored and in the exposed positions should be indicated. These descriptions should include details of fire-resistant characteristics of the source room and building and of the automatically operated fire detection and control system (such as sprinklers) to be used. Show that the system is adequate to prevent a fire that could damage the sources. Describe the procedures that will ensure a check of the operability of each unit of the fire protection system every 6 months. The shielding description should include notation of all voids such as those used for ventilation ducts, control cables, electrical conduits, and viewing windows.

d. Describe mechanical and electrical systems used in the operation of the irradiator, including the source holders and the source-handling mechanisms.

e. Describe all of the design features that protect the source from damage during operation of the facility from, for example, conveyor malfunctions, falling objects or packages, and faulty source movement mechanisms.

f. Describe the shutter or source-positioning mechanisms that are used for exposing the source.

g. Describe the systems, procedures, and physical barriers that will serve to prevent exposure of personnel to the irradiation source(s). Provide a complete description of physical barriers, interlocks, source position indicators, warning lights, alarms, and warning signs, including the manner in which compliance with pertinent requirements of 10 CFR Part 20, paragraphs 20.203(c)(6) and (7) will be achieved. Show how these safety provisions and systems ensure compliance with paragraph 20.203(c) and § 20.101 of 10 CFR Part 20.

h. If the facility includes a water storage pool, describe the pool construction and the water circulation, treatment, monitoring, and makeup systems. State the ranges of pH and conductivity that will be maintained for the pool water (within the manufacturer's recommended specifications). Describe the frequency of checks and the steps that will be taken to ensure that the pH and conductivity of the water in the storage pool are within stated tolerances. If the water is found to be out of the stated ranges, indicate the timing for returning the water to proper conditions. If the storage pools are not built in impervious soils, show that the leak rate of the secondary water-containment envelope is low enough to ensure that, in the event of a gross pool leak, makeup water could be supplied to the pool at a rate sufficient to keep the sources adequately covered. Describe the features incorporated in the design of the pool for ultimate decommissioning of the facility, including the considerations for disposing of potentially contaminated soil or other fill materials exterior to the pool walls.

i. If the facility includes in-air irradiation, describe the ventilation system (equipment, operating specifications, ventilation rate, location of intake and exhaust) and include an analysis of ozone production and the measures taken to protect personnel and safety-related equipment against exposure to ozone.

j. Provide an analysis and calculations of radiation levels in all areas surrounding the source room with the source in both the shielded and the exposed positions. Include an estimate of the degree and type of occupancy for each area.

k. Describe the system that provides a readily visible indication of the source position (stored, intermediate, exposed).

l. For a large irradiation facility that is not self-contained, that falls within the purview of paragraph 20.203(c)(6) or (7), and that is in a seismic area, provide an analysis that demonstrates the shielding (pool or cell and complementary structures) is constructed so that it will be able to withstand lateral or vertical displacements that might occur from ground movements. The applicant should submit an analysis of the previous earthquake activity in the tectonic province of the irradiator and in adjacent tectonic provinces if the site is near a tectonic border. An explanation should be submitted that substantiates that the facility is designed and constructed to withstand the movement.

For such irradiators in seismic areas, specify how the irradiator will be equipped with a seismic switch that will signal the radiation source to return to the safe storage position should the switch be actuated. Specify whether the switch will be an omnidirectional horizontal or a vertical uniaxial type and that it will be set to signal at 0.05g (gravitational acceleration) or less. For the purposes of applications for irradiator licenses, a "seismic area" may be considered to be any area where horizontal acceleration in rock of 0.3g (30% of the acceleration produced by gravity) or more may occur with a 90% probability of not being exceeded in 50 years (i.e., where there is only a 10% probability that a greater horizontal acceleration would occur in 50 years), as determined by the U.S. Geological Survey and as set out in U.S. Department of the Interior, Geological Survey Open File Report 76-416, 1976, "A Probabilistic Estimate of Maximum Acceleration in Rock in the Contiguous United States."

Item 14. Waste Disposal

The applicant should name the organization that will dispose of the sealed sources and the contaminated smears (if any) from leak tests.

Item 15. Radiation Protection Program

a. Ensuring that Occupational Radiation Exposures Are As Low As Is Reasonably Achievable (ALARA)

Describe the management policy and organizational structure related to ensuring that occupational radiation exposures are ALARA. Describe the applicable responsibilities and the related activities to be conducted by the individuals having responsibility for radiation protection. Indicate whether, and if so how, the guidance given in Regulatory Guide 8.10 will be followed; if it will not be followed, describe the specific alternative approaches to be used.

The application should contain a commitment by the applicant that all safety-related operations will be conducted in conformance with detailed written procedures. A detailed description of the procedures should be provided.

b. Organization

The applicant should provide a programmatic organizational chart that specifies all of those persons who will act in a management or supervisory capacity or who will have radiation safety responsibilities. The applicant should provide a copy of the written administrative procedures that govern the responsibility for the safe use of the irradiator. The procedures should clearly specify the functions, duties and responsibilities, and authority of each supervisor and of the radiation safety officer. Reference Items 16 and 17, as appropriate.

c. Administrative Procedures

The administrative procedures should contain the internal inspection system that will be used by the applicant to ensure that operations will be performed safely and in accordance with NRC requirements. The applicant should specify the minimum frequency of on-the-job audits and should provide the names and positions of the individual or individuals who will perform the audits. Reference Items 16 and 17, as appropriate.

The applicant should describe the methods of ensuring that only authorized persons will use the irradiator or have access to the space where it is located. These methods can include control of keys to the door of the room containing the irradiator control console, control of operating console keys, or other positive methods of excluding access.

A description should be provided of the process for review, change, and approval of all administrative, operating, maintenance, testing, and other procedures. The identity should be provided of the persons (by position) who have the responsibility for writing procedures and of the persons who must approve them before they are implemented. Reference Items 16 and 17, as appropriate.

The following categories should be considered but need not necessarily form the basis for classifying administrative procedures:

1. Standing orders to licensed users and to shift supervisors and shift crews, including authorities and responsibilities.
2. Special orders of a transient or self-canceling character.
3. Irradiator and equipment control procedures.
4. Control of maintenance and modifications.
5. Master surveillance testing schedule(s).
6. Procedures for logbook use and control.
7. Temporary procedures (authority to issue and approve).
8. Procedural system (writing, review, approval, implementation).
9. Internal inspection (audit) system.

d. Operating and Emergency Procedures

The applicant should provide a copy of the step-by-step procedures that will be kept at the irradiator control console and that will be followed by operators while using the irradiator. These "cookbook" procedures should include instructions concerning interlocks to be checked, surveys to be taken, frequency of reading of pocket dosimeters, and instructions for dealing with equipment malfunctions (such as the loss of electrical power, the loss of air pressure to control equipment, or the failure of the radiation monitoring, interlock, or safety systems).

The applicant should provide a copy of concise, easily followed emergency procedures. These procedures should describe the conditions that will be indicative of a malfunction or of an emergency situation and should state the emergency action to be taken. Instructions should specify the immediate action to be taken to place the irradiator in a safe condition and to minimize radiation exposure to persons in the vicinity of the irradiator and should include the names and telephone numbers of persons who are to be contacted to direct remedial actions. Immediate action procedures that the applicant will require "operators" to memorize should be identified.

The applicant should describe the procedures for operations that are performed primarily by licensed users (irradiator operators) in the control area(s) of the facility and the procedures for those operations that are performed by shift crews in operating the irradiator facility.

The applicant should provide a detailed description of the source-loading and irradiator-installation procedures. This description should include all tools and equipment to be used. The step-by-step procedures for all steps of the operation should be provided.

The applicant should provide a copy of the procedures that are to be used to determine possible leakage of radioactive material from the source capsule. Show that the test methods are sufficiently sensitive to detect 0.05 microcurie of activity. Describe the procedures that ensure the leak testing of the source at least every 6 months. A description should be provided of the frequency for and procedures used in inspecting and testing the source capsules to ensure mechanical integrity, including inspecting and testing for physical deformation such as bending or bowing and for evidence of corrosion of source encapsulation. The applicant should also specify the actions that are to be taken if such in situ visual or simple mechanical inspection and testing reveals any significant change in the sources.

The applicant should provide a copy of the procedures that will be followed during inspection and preventive maintenance of the irradiator. The identities and qualifications of the persons or contractors performing this work should

be specified. The frequency of this inspection should be specified. Examples of components that should be included are interlocks, radiation monitoring instruments, water level indicators, and water treatment systems. Indicate that components directly related to radiation safety (such as interlocks, radiation level monitors, or warning lights) will be checked prior to operation each day that the irradiator is in use in accordance with paragraph 20.203(c)(6)(vii). In addition, indicate that other components that are related to radiation safety (such as water level indicator and water treatment sytems) will be checked at least weekly and that still other components (such as source-hoist mechanisms and product-positioning systems) will be checked at least semiannually. A schedule of more complete checks of the entry control and warning systems should be submitted in accordance with paragraph 20.203(c)(6)(vii).

If the irradiator is of the type that uses product carrier boxes or totes that will be used repeatedly to transport the items to be irradiated around the source, special attention should be given to the likelihood of these product carrier boxes interfering with the movement of the source rack.* Procedures for the inspection of product carriers or totes for damage should be described. The procedures should provide for disposal of product carriers or totes when signs of deterioration appear or after a specified number of passes through the system. Radiation-induced deterioration of carrier boxes has been observed with as little as four passes through some irradiators.

The applicant should provide the criteria for selection of portable and laboratory technical equipment and instrumentation for performing radiation and contamination surveys and for other radioactivity monitoring and sampling, for area radiation monitoring, and for personnel monitoring. The applicant should describe the type of detectors and monitors and the quantity, sensitivity, range, and frequency and methods of calibration for all of the technical equipment and instrumentation mentioned.

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*Turned-down corners of cardboard product carrier boxes at irradiator facilities have resulted in the source rack jamming in the position exposing the source. The contents of the cardboard carrier boxes close to the source ignited over the time that the source was exposed, which activated the sprinkler system. (It is estimated that 9 hours of continuous exposure to a 1-million-curie cobalt-60 source can cause stationary combustible products to smolder or ignite.)

The applicant should describe the instrument storage, calibration, and maintenance facilities. Describe and identify the location of the radiation protection facilities (including locker rooms, shower rooms, and access control stations), laboratory facilities for radioactivity analyses, protective clothing, decontamination control equipment, or other control areas or equipment that will be available. Reference Items 10 and 11, as appropriate.

The applicant should describe the methods, frequencies, and procedures for conducting radiation surveys. Describe the procedures and methods of operation that have been developed for ensuring that occupational radiation exposures will be ALARA. Also describe the procedures that are to be used in (a) the receipt, handling, and loading of radiation sources into the irradiator; (b) the storage, exchange, packaging, and shipment of sources; (c) the inservice inspections of irradiator equipment and sources; and (d) the normal operations and routine maintenance of equipment and facilities.

The applicant should describe the physical and administrative measures for controlling access, egress, and stay time for radiation areas and contamination zones, and should describe the methods and procedures for personnel monitoring, including methods of recording, reporting, and analyzing results. Reference Item 12, as appropriate. Include the criteria for selecting personnel who will be required to wear personnel-monitoring devices and the criteria for selection of the routine monitoring period, i.e., badge or TLD exchange frequency.

Each operating and emergency action procedure should be identified by title and included in a described classification system. The following categories should be considered but need not necessarily form the basis for classifying these procedures:

1. Irradiator and system operating procedures.
2. General facility procedures.
3. Off-normal operating procedures.
4. Emergency action (to correct malfunction) procedures.
5. Alarm response procedures.
6. Temporary procedures.

e. Other Procedures

The applicant should provide an explanation of how other operating and maintenance procedures are classified, what group or groups within the operating organization have the responsibility for following each class of procedures, and the general objectives and character of each class or subclass of procedures. Reference Items 16 and 17, as appropriate.

The applicant should describe the procedures for emergency preparedness in dealing with various types of accidents that affect or threaten the health and safety of the public, employees of the licensee, or other persons assigned temporarily or permanently to work at the facility. The description of procedures should include the identity of and arrangements with facilities or persons having a capability to furnish necessary advice or assistance in dealing with facility emergencies (such as medical facilities or medical treatment for individuals affected by radiological emergencies).

The categories of procedures listed below should also be considered. If their general objectives and character are described elsewhere in the application, they may be described by specific reference to the section where they are covered.

1. Facility radiation protection procedures.
2. Emergency preparedness procedures.
3. Instrument calibration and test procedures.
4. Water quality control procedures.
5. Radioactive waste management procedures.
6. Maintenance and modification procedures.

f. Instructions to Workers

The applicant should provide a complete description of the training program to be conducted pursuant to § 19.12, "Instructions to Workers," of 10 CFR Part 19. The description should specify the form of training (lectures or on-the-job), an outline of the subject matter that is covered, the time devoted to each subject, the equipment used, and the methods and criteria used to determine the competency

of each individual to work about or operate the irradiator. Provisions for initial training and for retraining should be specified.

The description of the on-the-job training should specify the minimum time period that an individual will work under the direct supervision of a qualified instructor prior to being certified as an operator. Classifications of personnel who will receive different levels of instruction should be identified. The applicant should identify the personnel in the organization who are responsible for the training programs, including the maintenance of records on the status of trained personnel, the training of new employees, and the refresher or upgrade training of people. Reference Items 16 and 17, as appropriate.

Items 16 and 17. Technical Qualifications of Personnel

a. Personnel Positions

Describe the organization, functions, and responsibilities of the positions that are established to operate and maintain the irradiator facility; provide an organization chart showing the title of each position, the number of operating shift crews, and the positions for which licensed users are required. The functions, responsibilities, and authorities of positions corresponding to the following should be described: overall irradiator facility management, operations supervision, shift crew supervision, "irradiator operators," technical supervision, radiation protection supervision, instrumentation and controls engineering supervision, instrumentation and controls maintenance supervision, and internal inspection and audit supervision.

Describe the line of succession of authority and responsibility for overall facility operation both for normal operations and for emergencies. Specify the delegation of authority to operating shift crew supervisors, including the authority to issue standing or special orders or procedures.

b. Qualifications

Describe the requirements established for education, training, and experience for each management, operating, technical, and maintenance position category

in the operating organization. The application should contain a commitment that the qualification requirements will be met by all incumbents of the identified positions.

The qualifications of the initial incumbents of organizational positions should be presented as resumes for key facility managerial and supervisory personnel through the supervisory level of shift crews (i.e., each person who will directly supervise the operations or who will have radiological safety responsibilities). The resumes should describe the training and experience in the use of radioisotopes and radiation. The descriptions of the training should include both on-the-job training and formal course work, location where the training was received, and the duration of the training. The descriptions should also cover the incumbent's knowledge of (1) principles and practices of radiation protection, (2) radiometric measurements and techniques and instruments for standardization and monitoring, (3) mathematics and calculations basic to use and measurement of radiation and radioactivity, (4) biological effects of radiation, (5) design and construction of the irradiator and its associated safety systems, (6) the applicant's radiation safety program, (7) the applicant's operating and emergency procedures, and (8) pertinent requirements of the NRC and other cognizant regulatory agencies. The description of experience and actual use of radioactive materials should specify the isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type(s) of use(s).

c. Training Program

The application should include a complete description of the training program for irradiator operators. The description should include the proposed subject matter of each course, including a syllabus or equivalent description of the course, the duration of the course (approximate number of hours or days in full-time attendance), the type of training (lectures, on-the-job), and the identity of the organization or person(s) teaching the course or supervising the instruction. The description of the on-the-job training should specify the minimum time period that an individual will work under the direct supervision of a qualified instructor or operator prior to being certified as an irradiator

operator. The application should also describe the methods and criteria used both to determine the competency of each individual to operate the irradiator and to evaluate the effectiveness of the training program.

The application should contain commitments to train replacement personnel and to provide refresher or requalification training for persons who are certified as irradiator operators. A description of the type and frequency of refresher or requalification training should be provided. Reference Item 15, as appropriate.

5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supportive documents. The license must therefore be amended if the licensee plans to make any changes or modifications in facilities, equipment (including monitoring and survey instruments), procedures, personnel, or byproduct material to be used.

Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number, should clearly describe the exact nature of the changes, modifications, additions, or deletions, and should include all additional supporting information, including the identities and qualifications of the persons or contractors who will perform the work. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. If a section of a manual or instruction is to be amended, dated substitute pages should be provided, and the changed sections should be noted in the margin.

6. RENEWAL OF A LICENSE

Byproduct material licenses are normally issued for a period not in excess of 5 years.

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This filing will ensure that the license does

not expire until final action on the application has been taken by the NRC staff as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313(I), appropriately supplemented, and should contain complete and up-to-date information about the applicant's current program.

In order to facilitate the review process, the application for renewal should be submitted without using references to previously submitted documents and information. If such references cannot be avoided, they should be clear and specific and should identify the pertinent information by date, page, and paragraph.

APPENDIX A

NRC Form 313 (I)
(12-81)
10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

Form Approved by OMB
3150-0042

INSTRUCTIONS FOR PREPARATION OF APPLICATION FOR BYPRODUCT MATERIAL LICENSE

NRC FORM 313 (I)

GENERAL INFORMATION

An applicant for a "Byproduct Material (Radioisotopes) License," should complete NRC Form 313 (I) in detail and submit in duplicate to the U.S. Nuclear Regulatory Commission. The applicant should endeavor to cover his entire radioistope program with one application, if possible. However, separate applications should be submitted for gamma irradiators. Applications for medical uses should be submitted on NRC Form 313 (M) and applications for use of sealed sources in radiography should be submitted on NRC Form 313R. Supplemental sheets may be appened when necessary to provide complete information. *Item 18 must be completed on all applications. Submission of an incomplete application will often result in a delay in issuance of the license because of the correspondence necessary to obtain information requested on the application.*

NOTE. –When the application includes one of the special uses listed below, the applicant should request the appropriate pamphlet which provides additional instructions:

1 Industrial Radiography–"Licensing Requirements for Industrial Radiography" (use application NRC Form 313R for Radiography);

2 Laboratory and Industrial Uses of Small Quantities-"Guide for Preparation of Applications for Laboratory and Industrial Uses of Small Quantities of Byproduct Material."

3. Broad License (research and development)–"Licensing Guide for Type-A Licenses of Broad Scope for Research and Development;"

4. Licensing Guides for the performance of well logging operations.

5. Licensing guide for the use of sealed sources in portable and semi-portable gauging devices.

The Commission charges fees for filing of applications for licenses as specified in Section 170.12, Title 10, Code of Federal Regulations, Part 170. The applicant should refer to Section 170.31, *Schedule of fees for materials licenses*, to determine what fee should accompany the application. No action can be taken on applications until fees are paid. Checks or money orders should be made payable to the U.S. Nuclear Regulatory Commission.

Two copies of the completed NRC Form 313 (I) and two copies of each attachment thereto, should be sent to the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. One copy should be retained for the applicant's file. Applications may also be filed in person at the Commission's office at 1717 H Street, N.W., Washington, D.C. or at 7915 Eastern Avenue, Silver Spring, Maryland.

EXPLANATION OF FORM NRC-313 (I)

NRC Form 313 (I) is designed for use in supplying information on programs of varying complexity. The applicant should provide complete information on his proposed program for the possession and use of licensed material. For those items that do not apply, indicate as N.A. (not applicable).

Item No.

1. Self-explanatory

2. The "applicant" is the organization or persons legally responsible for possession and use of the licensed materials specified in the application.

3. Self-explanatory

4. Self-explanatory

5. The actual sites of use should be listed as indicated. Permanent facilities such as field offices for portable gauges or devices should be identified in Item 5 by Street, Address, City and State. Temporary field locations of use should be specified as "temporary job sites of the applicant" and list the States throughout which the temporary job sites will be located. Attach additional properly keyed sheet if more space is needed.

6. Self-explanatory

7. The "Radiation Protection Officer" is the named individual who is expected to coordinate the safe use of the licensed material specified in the application and who will ensure compliance with the applicable parts of Title 10, Code of Federal Regulations.

8. List by name each radioisotope to be possessed and used under the license. Example:

A	B	C	D
(1) Iodine-131	(1) Iodide	(1) Not Applicable	(1) 10 millicuries
(2) Iodine-131	(2) Iodinated Human Serum Albumin	(2) N. A.	(2) 1 millicurie
(3) Krypton-85	(3) Gas	(3) N. A.	(3) 1 millicurie
(4) Cesium-137	(4) Sealed Source	(4) Iso. Corp Model Z-78	(4) 2 source of 150 millicuries each

Attach additional properly keyed sheets if more space is needed.

8.E State the use of each licensed material listed in 8.A. B. C. and D.

9. Description of containers and/or devices in which sealed sources listed in Item 8 will be stored or used. Example:

A	B	C
(1) #4 – Source housing	Iso. Corp	Model Z-278

10-18 Self-explanatory. (For those items that do not apply, indicate as N.A. (not applicable).

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Forms 313M, 313I, or 313R. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. AUTHORITY Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. PRINCIPAL PURPOSE(S) The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a byproduct material license or amendment thereof.

3. ROUTINE USES The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident of exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N. W., Washington, D.C.

4. WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION Disclosure of the requested information is voluntary. If the request information is not furnished, however, the application for byproduct material license, or amendment thereof, will not be processed.

5. SYSTEM MANAGER(S) AND ADDRESS Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

NRC Form 313 I (12-81) 10 CFR 30 — U.S. NUCLEAR REGULATORY COMMISSION	1. APPLICATION FOR: *(Check and/or complete as appropriate)*
APPLICATION FOR BYPRODUCT MATERIAL LICENSE INDUSTRIAL	☐ a. NEW LICENSE
See attached instructions for details. *Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.*	☐ b. AMENDMENT TO: LICENSE NUMBER ☐ c. RENEWAL OF: LICENSE NUMBER

2. APPLICANT'S NAME *(Institution, firm, person, etc.)*	3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION
TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION	TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
4. APPLICANT'S MAILING ADDRESS *(Include Zip Code)* *(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)*	5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED *(Include Zip Code)*

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
(See Items 16 and 17 for required training and experience of each individual named below)

	FULL NAME	TITLE
a.		
b.		
c.		

7. RADIATION PROTECTION OFFICER	*Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.*

8. LICENSED MATERIAL

LINE NO.	ELEMENT AND MASS NUMBER A	CHEMICAL AND/OR PHYSICAL FORM B	NAME OF MANUFACTURER AND MODEL NUMBER *(If Sealed Source)* C	MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D
(1)				
(2)				
(3)				
(4)				

	DESCRIBE USE OF LICENSED MATERIAL E
(1)	
(2)	
(3)	
(4)	

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9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)			
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED *(alpha, beta, gamma, neutron)* E	SENSITIVITY RANGE *(milliroentgens/hour or counts/minute)* F
(1)						
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. **CALIBRATED BY SERVICE COMPANY**

NAME, ADDRESS, AND FREQUENCY

☐ b. **CALIBRATED BY APPLICANT**

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

12. PERSONNEL MONITORING DEVICES

TYPE *(Check and/or complete as appropriate.)* A	SUPPLIER *(Service Company)* B	EXCHANGE FREQUENCY C
☐ (1) FILM BADGE		☐ MONTHLY
☐ (2) THERMOLUMINESCENCE DOSIMETER *(TLD)*		☐ QUARTERLY
☐ (3) OTHER *(Specify)*: _____		☐ OTHER *(Specify)*:
_____		_____
_____		_____

13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

☐ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS *(Include filtration, if any)*, ETC.
☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING *(fixed and/or temporary)*, ETC.
☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

NRC FORM 313 I (12-81)

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

WARNING.–18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*	b. CERTIFYING OFFICIAL *(Signature)*
	c. NAME *(Type or print)*
(1) LICENSE FEE CATEGORY:	d. TITLE
(2) LICENSE FEE ENCLOSED: $	e. DATE

NRC FORM 313 I (12-81) GPO 886-426

DRAFT VALUE/IMPACT STATEMENT

1. PROPOSED ACTION

1.1 Description

A revision to Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators," is proposed to incorporate lessons learned following an incident at a Type IV (panoramic, wet storage) gamma irradiator facility at Broken Bow, Nebraska. The incident occurred when turned-down corners of product carrier boxes intruded into the path of the source, preventing the source's return to the unexposed position. Nine hours later, the contents of the product carrier boxes, which were exposed to the source all this time, ignited. The sprinkler system was activated and put out the fires as they arose. The proposed revision of Regulatory Guide 10.9 includes procedures for inspection of product carrier boxes and guidance on fire protection features to prevent fires that could affect the integrity of the sources.

In addition, a statement on maintaining the pH and conductivity of storage pool water within acceptable ranges to avoid accelerated corrosion of source capsules at conditions of low pH and high conductivity is being added.

1.2 Need for the Proposed Action

Damaged product carrier boxes should never be allowed to enter the irradiation cell because of the possibility of jamming the source in the exposed position for an extended period of time. In the situation described above, if the machine safety interlocks had not functioned properly, a radiation hazard to personnel would have existed. In addition, the resultant fires, caused by prolonged exposure of product carrier boxes while an attempt was made to unjam the source, could have damaged the sources and hence posed a radiation hazard to personnel during cleanup and decontamination operations. Therefore, the

operability of the fire protection features to prevent fires capable of damaging the sources should be ascertained every 6 months.

Water quality should be maintained within manufacturer's specifications for pH and conductivity to avoid accelerated corrosion of source capsules that ultimately could cause sources to leak.

1.3 Value/Impact

1.3.1 NRC Operations

The proposed revision of Regulatory Guide 10.9 would provide more uniform standards for evaluating applications for licenses to use gamma irradiators.

1.3.2 Other Government Agencies

The revision of this guide is expected to have no effect on other government agencies.

1.3.3 Industry

The cost to industry of visually inspecting or routinely disposing of damaged product carrier boxes would be insignificant in comparison to the cost of shutdown while trying to unjam the source. Adequate fire protection is required before the licensee can insure the facility. Costs incurred during shutdown for examination of the fire protection system may be counterbalanced by the saving of several days of shutdown that would be required for cleanup and maintenance after a fire.

Likewise, the cost of assaying and correcting water pH and conductivity is insignificant in comparison to the cost of decontaminating the facility and replacing leaky sources.

1.3.4 Workers

The proposed revision would enhance worker protection by preventing radiation exposures in the event of interlock failures or cleanup operations in the event a jammed source caused products to catch fire and damage the sources or

if corrosion caused by low pH and high conductivity caused source capsules to leak.

1.3.5 Public

The public would be affected by the proposed revision of Regulatory Guide 10.9 only in the event of a fire of sufficient magnitude to require fire fighting help from the local fire department or in the unlikely event a facility is left untended with a jammed source and nonfunctional safety interlock systems.

1.3.6 Decision on the Proposed Action

The NRC should revise Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators," to include guidance on descriptions of fire protection features of the irradiator facility, on procedures for inspection of product carrier boxes, and for assaying and correcting water pH and conductivity.

2. TECHNICAL APPROACH

No alternative technical approaches have been identified.

3. PROCEDURAL APPROACH

The only procedural approach considered is the revision of Regulatory Guide 10.9.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

NRC authority for issuance of this guide derives from the Atomic Energy Act of 1954, as amended, through those portions of the Commission's regulations in Title 10 of the Code of Federal Regulations cited in the introduction to the guide.

4.2 Need for NEPA Statement

The proposed action is not a major Federal action significantly affecting the quality of the human environment, and does not require an environmental impact statement.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflict with any existing regulation or other government policy is known to exist.

6. SUMMARY AND CONCLUSIONS

A proposed revision to Regulatory Guide 10.9 should be developed to reflect lessons learned from the event at Broken Bow, Nebraska, and should be issued for public comment. The proposed revision should call for descriptions of pertinent fire protection features of the irradiator facility and procedures for inspection of product carrier boxes. The proposed revision should also call for procedures for assaying and correcting water pH and conductivity.

119406002001 1 QPSASO
US NRC REGION I
R J BORES
631 PARK AVENUE
REGION I
KING OF PRUSSIA PA 19406