

NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

RADIATION GUIDE 10.12

GUIDE FOR THE PREPARATION OF APPLICATIONS
FOR THE USE OF GAMMA IRRADIATORS
(ANSI Category I)

I. INTRODUCTION

A. Purpose of Guide

This guide describes the type of information needed by the New York State Department of Health staff to evaluate an application for a license to use sealed radioactive sources in self-contained dry source-storage gamma irradiators for the irradiation of materials.

This type of irradiator is described in the American National Standards Institute (ANSI) Standard N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)."*

As defined in ANSI Standard N433.1, a Category I irradiator is an irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration.

Depending on the particular design, the radiation source within the irradiator may be retained in a fixed position or the radiation source may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position which during normal use of the irradiator may cause a radiation hazard to any individual. Proper functioning of the interlocks assures that shielding is in place. Bypassing or failure of an interlock could cause individuals to be exposed to very high levels of radiation.

Category I gamma irradiators typically contain several hundred to several thousand curies of cesium-137 or cobalt-60 and range in weight from several hundred to several thousand pounds.

The New York State Department of Health will issue a single radioactive materials license to cover an institution's entire radioisotope program. Separate licenses are not normally issued to different departments, nor are they issued to individuals associated with the institution. The license will be issued in the institution's name in all cases.

*Copies may be obtained from the American National Standards Institute,
1430 Broadway, New York, NY 10018

The applicant should carefully study the regulations and this guide, and should submit all information requested. The Department will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

B. Applicable Regulations

All regulations pertaining to this type of license are found in Title 10, Chapter 1, Part 16 of the New York Code of Rules and Regulations (10 NYCRR 16). Chapter 1 is entitled the "State Sanitary Code" and Part 16 is entitled, "Ionizing Radiation." The statutory authority for the rules and regulations is found in the New York State Public Health Law, Section 225.

C. As Low As is Reasonably Achievable (ALARA)

Section 16.5 (a), Part 16, New York State State Sanitary Code, requires that persons who operate or permit the operation of radiation installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 16 as is reasonably achievable. License applicants should give consideration to the ALARA philosophy in the development of plans for work with radioactive materials.

II. FILING AN APPLICATION

A license application for a specific license to possess and use radioactive material for the gamma irradiation of materials should be filed on Form GEN 307B, "Application for Radioactive Materials License" and appropriate attachments. The applicant should complete all required items on the application form in sufficient detail for the application review staff to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form GEN 307B is limited, the applicant should append separate sheets of paper for items 5-26 listed in the form. Each separate sheet should contain the item number and application date in the lower right corner. When completely filled out, Form GEN 307B should be signed and dated as described in Item 26.

One copy of the application, with all attachments, should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original and one copy should be mailed to the New York State Department of Health, Bureau of Environmental Radiation Protection, 2 University Plaza, Albany, New York 12203.

III. CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form GEN 307B:

- Item 1a. Enter the name and mailing address of the corporation or other legal entity applying for the license, and the telephone number of administration. If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of radioactive material is not connected with your employment with a corporation or other legal entity.
- 1b. List the addresses and locations where radioactive material will be used or stored if other than that in item 1a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. The actual locations of use should be listed, whether or not they are the same as the mailing address in Item 1a.; i.e., a post office box number may be most suitable for Item 1a. in some cases, but this address does not adequately describe the location of use.
- Item 2 Enter the name and telephone number (including area code) of the individual to be contacted regarding the application. This person should be a member of your organization who knows your program and is able to answer questions about the application.
- Item 3 Indicate whether the application is for a new license, an amendment or a renewal.
- Item 4 State the name and title of the person designated by, and responsible to the institution's management for the coordination of the institution's radiation safety program. If the radiation safety officer is assisted by a consultant or part-time employee, state the consultant's name, and the amount of time to be devoted to the radiation safety program.
- Item 5 List the names of all persons who will use or supervise the use of the irradiator. It is sufficient to name one responsible individual who may also be the radiation safety officer, and provide information on the training of individuals who will use the irradiator under the supervision of that responsible individual, in Item 9b.
- Item 6a List the radionuclide to be used in each sealed source in the irradiator.
- Item 6b List the chemical and physical form of the isotope, number of curies per source, name of manufacturer and model number of each source, total number of sources that will be contained in the irradiator, and the maximum activity to be possessed in the irradiator at any one time.
- Item 7 Specify the name of the manufacturer and model number of the gamma irradiator and the purpose for which each unit will be used.

- Item 8
- (a) Individuals responsible for radiation safety. Section 16.4 (b), Part 16, New York State Sanitary Code (10 NYCRR 16) requires that you provide a Radiation Safety Officer and radiation protection program acceptable to the Department of Health. Submit the name of your Radiation Safety Officer.
 - (b) The Radiation Safety Officer (RSO) should be responsible to management for the overall radiation program within the institution. A statement should be submitted describing this individual's responsibilities and authority for carrying out the radiation safety program. The RSO is expected to coordinate the safe use of the devices and ensure compliance with the requirements of Part 16, New York State Sanitary Code. Typical duties of the RSO should include the following:
 - (1) To ensure that radioactive material, sealed sources, and devices in use and/or in the possession of the applicant are limited to those specified in the license.
 - (2) To ensure that the devices are used only by those individuals authorized by the license.
 - (3) To ensure that all users wear personnel monitoring equipment, such as film badges or thermoluminescent dosimeters (TLD) when required.
 - (4) To ensure that the devices are properly secured against unauthorized removal at all times when they are not in use.
 - (5) To serve as a point of contact and give assistance in case of emergency (device damage, fire, theft, etc) and to ensure that proper authorities (local police and state personnel) are notified promptly in case of accident or damage to the devices.
 - (6) To ensure that the terms and conditions of the license, such as periodic leak tests, are met and that the required records, such as personnel exposure records, leak test records, etc., are periodically reviewed for compliance with New York State Department of Health regulations, requirements and license conditions.

The Radiation Safety Officer will generally be an authorized user on this type of license. If this is not the case, you should submit information on the qualifications of this individual in response to item 9a.

- Item 9a Training and Experience of Authorized Users or Responsible Individuals - 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 use or supervise the use of the irradiator, or who will have radiological safety responsibilities. Give the title or position and describe the training and experience of each individual on separate sheets. The information submitted should be sufficient to show that each individual will be familiar with:

- (1) The basic design, operation and preventive maintenance of the irradiator;
- (2) The principles and practices of radiation protection;
- (3) Biological effects of radiation;
- (4) The written procedures for routine and emergency irradiator operations; and
- (5) New York State regulations.

You should also describe how specific instruction on the particular model irradiator to be used, or a similar model, was or will be obtained for each individual named in Item 5. The description of specific instruction should show that, under the supervision of a knowledgeable person, the named individual has used the irradiator or a similar irradiator to perform several irradiations of samples. This knowledgeable person might be the irradiator manufacturer's representative or another experienced operator.

Item 9b Personnel Training Program - According to Section 16.13 of Part 16, New York State Sanitary Code (10 NYCRR 16), all individuals who work in or frequent controlled areas must be instructed in the health protection problems associated with exposure to radioactive material. In addition, persons who actually work with radioactive material should receive training in the safe use of radioactive material.

You should submit a general description of the training you will provide to all individuals working in or frequenting your restricted areas and provide more specific information about training of irradiator operators.

Individuals who will operate the irradiator under the supervision of a responsible individual (described in Item 5) do not need to be designated by name, however the following should be submitted:

- (1) An outline of the training for these individuals, including the topics that will be covered. The following are examples of topics expected to be included in the training program: (a) the principles and fundamentals of radiation safety and good safety practices related to the use of radioactive materials; (b) the use of radiation detection instruments; and (c) the design and operation of the irradiator. This training usually is several hours in length and may be covered in part by instructions provided to workers to meet the requirements of Section 16.13, "Notices, Instructions, and Reports to Workers; Inspections."
- (2) The training program should include a means of evaluating the understanding of the individuals who have completed the training program. One acceptable technique is to use a written examination of about 25 questions so that all aspects of the training are covered. You should describe in your application how you will determine the trainee's understanding of the subject.

- (3) A discussion of the on-the-job training that will be given to individuals. The training should consist of a minimum of several complete sample irradiation procedures for the trainee under close supervision by a responsible individual specified in Item 5.
- (4) The name of the training instructor. If this person is not a responsible individual specified in Item 5, submit this person's qualifications. The minimum qualifications for an instructor should be the same as those of an individual specified in Item 5.
- (5) A commitment that records documenting the training of each individual will be maintained.

Item 10

- (a) Radiation Detection Instruments - Section 16.10 (a) of Part 16, New York State Sanitary Code (10 NYCRR 16) requires the performance of surveys to evaluate the extent of radiation hazards that may be present and to comply with regulatory requirements. In order to perform appropriate surveys, you need to have operable, calibrated instrumentation.

State that you will have available for use a calibrated, operable survey meter that can measure up to several hundred milliroentgens per hour. You do not need to name the manufacturer or the model number of the survey meter. The reason for the survey meter is the need to detect radiation levels that may indicate safety interlock and shielding failure, sealed source displacement, or sealed source failure with a resultant spread of contamination.

- (b) In order to perform adequate surveys, instruments must be operable and calibrated with an appropriate radiation source. State that the instrument will: be calibrated so that the readings are within $\pm 20\%$ of the actual values over the range of the instrument; and be calibrated at least annually and after servicing (other than a simple battery exchange). Also, state that calibration records will be kept for a minimum of 3 years after each calibration, and identify your selected means of calibration. There are three options for calibration:
 - (1) If the instrument will be returned to the manufacturer for calibration, so state.
 - (2) If a contractor will perform the calibration, state the name and address or the firm and its NRC or Agreement State license number.
 - (3) If the instrument will be calibrated in-house, provide the experience and training in instrument calibration of each named individual who will perform the calibrations, and the methodology to be used.

Item 11 Facilities and Equipment - Section 16.103 of Part 16, New York State Sanitary Code (10 NYCRR 16) states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and safety and to minimize danger to life or property. In this item you should present information about the space where the irradiator will be located.

You should briefly describe the space where the irradiator will be located and comment on: control of access by unauthorized individuals; and fire protection considerations.

Regarding control of access, if the irradiator will be located in a room that can be locked to prevent access by unauthorized persons, state that this is the case and that the room will be locked when not under the supervision of an authorized individual. Submit an annotated sketch showing the location of the irradiator within the building and room, and identifying the uses of adjoining areas.

Regarding fire protection considerations, if the irradiator has not passed prototype tests for a standard industrial fire, state 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. Alternatively, you should describe the conditions (e.g., ground floor location in fire resistant building with little combustible material) and other controls (e.g., coordination with and training of fire fighting personnel) which assure a very low level of radiation risk attributable to fires.

Item 12 Procedures for ordering and receiving radioactive material - Indicate whether the manufacturer or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State will perform the installation services and initially test the device for proper operation of the source exposure mechanism, safety warning components, labels, and for removable contamination.

Item 13 Procedure for package opening - Not Applicable

Items 14 and 15 General Rules For the Safe Use of Radioactive Material and Emergency Procedures

You should provide your personnel with written operating and emergency procedures and you should state in your application that the written procedures will be provided to each person who uses the irradiator. The operating procedures should be maintained at the control station and the emergency procedures conspicuously posted in the area. It is not necessary to submit the detailed operating and emergency procedures with your application. However, you should list the topics covered in your procedures, and you should state that these procedures include instructions in the following topics:

- (a) Step-by-step procedures for operation of the irradiator. Information may be extracted from the irradiator manufacturer's manual.

- (b) Determination and recording of radiation doses to individuals operating the irradiator.
- (c) The method(s) of assuring that only authorized individuals will use the irradiator or have access to the area.
- (d) Inspections and test procedures for ensuring that all safety interlocks, devices and components associated with the irradiator are functioning properly.
- (e) Emergency situations, e.g. if a survey reveals abnormal radiation levels around the irradiator, personnel should leave the irradiator room, lock the door, and contact the individual responsible for the irradiator program. In addition, your procedures should require that a survey be made with a radiation survey meter outside the irradiator room to determine whether the limits of Section 16.7 of Part 16, New York State Sanitary Code (10 NYCRR 16), will be met or whether further restriction of the area is necessary.

- Item 16 Confirm that you will perform a radiation survey prior to first use of the irradiator and after any change is made in the installation or its use that could result in a change in radiation levels (e.g., a major repair or source change). This survey will include the irradiator room and all adjacent areas, and a copy of the initial survey report will be sent to the New York State Department of Health within 30 days.
- Item 17 Waste Disposal - You should state that disposal of used sources or other radioactive waste will only be by transfer to a licensee specifically authorized to accept such materials.
- Item 18 Not Applicable
- Item 19 Not Applicable
- Item 20 Not Applicable
- Item 21 Not Applicable
- Item 22 Other procedures and precautions - Tests to determine if there is any leakage from the sealed sources in the irradiator are necessary and must be performed at intervals not to exceed six months. The measurement of the leak test sample should be a quantitative measurement and must be sufficiently sensitive to detect 0.005 microcurie of activity.

The options for leak testing are:

- (a) Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.

- (b) Use a commercial leak test kit. You take the sample and send the sample to the kit supplier, which reports the results to you.
- (c) You perform the entire leak test sequence, including taking the sample and measurement.

For option (a), specify the name, address and license number of the consultant or commercial organization.

For option (b), specify the kit model number and the name, address and license number of the kit supplier. State if the test samples will be taken by the individual specified in Item 5 who is responsible for the irradiator program. If another irradiator operator will take the test sample, instructions for taking the sample should be included in your operating and emergency procedures. Include in the instructions a requirement that any indication of possible source leakage should be reported to the individual responsible for the irradiator program for appropriate action.

For option (c), specify how and by whom the test sample will be taken and the qualifications of the individual(s) who will collect and measure the sample for activity. You should commit to use of an instrument capable of quantitatively measuring 0.005 microcurie or more of activity.

- Item 23 Personnel monitoring program - (1) Specify the type of personnel monitoring devices to be used (film badge, TLD, pocket chambers); (2) Provide the name of the commercial supplier of the film badge or TLD, dosimetry service; and (3) Specify the frequency at which film badges or TLDs will be evaluated. For pocket chambers, 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 24 Not Applicable
- Item 25 ALARA (As Low As is Reasonably Achievable) Program - See Section C of the Introduction to this Guide.
- Item 26 Certificate - The application must be dated and signed by the representative of the applicant named in Item 1a who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of his/her knowledge and belief.

IV. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users or radiation safety officer, or radioactive material to be used.

Applications for license amendments may be filed either on the application form (GEN 307B) or in letter form. 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.

V. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the New York State Department of Health, as provided for in Section 16.105 of Part 16, New York State Sanitary Code.

Renewal applications should be filed on Form GEN 307B appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, should meet all licensing and regulatory requirements in effect at the time of renewal, and should be signed and dated by a representative of the licensee's administrative management.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

- (a) The reference is made in response to a particular item of required information;
- (b) The reference is clear and specific (e.g., title of document, date of submission, page and paragraph); and
- (c) The referenced document contains all information required for a particular item at the time of renewal.

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to the New York State Department of Health, Bureau of Environmental Radiation Protection, 2 University Place, Albany, New York 12203.

VI. LICENSE TERMINATION REQUESTS

Submit a signed Form GEN 322 indicating the disposition of the radioactive material. Form GEN 322 is available from the New York State Department of Health, Bureau of Environmental Radiation Protection.

Submit survey results showing that all previously occupied areas are free of contamination and all sources of radioactive material have been removed in accordance with Section 16.10 of Part 16, New York State Sanitary Code. A decontamination guide is available from the New York State Department of Health, Bureau of Environmental Radiation Protection.

Such submissions must be made at least 30 days prior to relinquishing possession or control of premises where radioactive material is or has been stored or used.

