

NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

RADIATION GUIDE 10.6

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR THE USE OF
SEALED SOURCES IN GAS CHROMATOGRAPHY DEVICES AND
X-RAY FLUORESCENCE ANALYZERS

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 for the use of sealed sources in gas chromatography devices and x-ray fluorescence analyzers. These are well designed units that represent very little hazard to the public. As a result, the information required for authorization to use one of these devices is not extensive.

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.

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)

Item (a) of 10 NYCRR 16.5 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 specific licenses to possess and use radioactive material in gas chromatography devices and x-ray fluorescence analyzers should be submitted on Form GEN 307B, "Application for Radioactive Materials License."

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 5-25 listed in the form. Each separate sheet should contain the item number and the application date in the lower right corner. When completely filled out, Form GEN 307B should be signed and dated by a representative of the institution's management.

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 12237.

III. CONTENTS OF AN APPLICATION

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

- Item 1 a. Enter the name and corporate address of the applicant and the telephone number of administration.
- b. List all addresses and locations where radioactive material will be used or stored, if other than that in Item 1(a). A post office box number should not be stated as the address for a place of use. These addresses and locations will become part of the license conditions, if the license application is approved, and the addresses or locations at which radioactive materials or radioactive wastes are located or stored may not be changed without obtaining a license amendment.
- Item 2 Enter the name and telephone number (including area code) of the individual to be contacted.
- Item 3 Indicate whether the application is for a new license, an amendment or a renewal.
- Item 4 & 5 List all individuals who will use or directly supervise the use of radioactive material. Give the title or position and describe the training and experience of each individual on Form GEN 307C.

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 6 a. List the radionuclide and mass number of the particular radionuclides to be used.
- b. List the physical form, such as foil, plated or other sealed source for each radionuclide listed in 6a. Include the manufacturer and model number of the detector cells or source holders in which the sealed sources will be contained. Include the maximum activity of sources contained in each detector cell or source holder.

Item 7 Specify the name of the manufacturer of the gas chromatography device or x-ray fluorescence analyzer and the purpose for which each unit will be used.

Item 8 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 of the New York State Sanitary Code. Typical duties of the RSO should include the following:

- a. 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.
- b. To ensure that the devices, particularly in the field, are used only by those individuals authorized by the license.
- c. To ensure that all users wear personnel monitoring equipment, such as film badges or thermoluminescence dosimeters (TLD), when required.
- d. To ensure that the devices are properly secured against unauthorized removal at all times when they are not in use.
- e. 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.
- f. 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.

Item 9 Because of the limited nature of a gas chromatography or x-ray fluorescence analyzer license, only minimal training and experience of the users is necessary. Training may be obtained at the time of the installation of the gas chromatograph or purchase of x-ray fluorescence or from other individuals who have used similar devices. No description of the training is specifically required in the application.

Item 9 Personnel Training Program. Radiation workers (e.g., technicians) must receive instruction as specified in Section 16.13 of 10 NYCRR 16. Note that many of these items pertain to circumstances at a particular institution; therefore, it may not be assumed that this instruction has been adequately covered by prior occupational training.

Ancillary personnel (e.g., clerical, housekeeping, security personnel, etc.) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions.

Describe the training that will be provided to all personnel who work with, or in the vicinity of, radioactive materials.

Verify that personnel will be properly instructed:

- a. Before assuming duties with, or in the vicinity of, radioactive materials.
- b. During annual refresher training.
- c. Whenever there is a significant change in duties, regulations or the terms of the license.

Instruction as required by 10 NYCRR 16.13 should include:

- a. All terms of the license pertinent to radiation safety.
- b. Areas where radioactive material is used or stored.
- c. Potential hazards associated with radioactive material.
- d. Radiological safety procedures appropriate to their respective duties.
- e. Pertinent New York State Department of Health regulations.
- f. Rules and regulations of the licensee.
- g. Obligation to report unsafe conditions to the radiation safety officer.
- h. Appropriate response to emergencies or unsafe conditions.
- i. Right to be informed of their radiation exposure.
- j. Locations where the licensee has posted or made available notices, copies of pertinent regulations and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 NYCRR 16.13.

Item 10 Instruments. For routine use of these devices, radiation and measuring instruments are not normally required.

Item 11 Facilities and equipment. The applicant should provide a description of the means of storage for the devices at the permanent or temporary use sites when the devices are not in actual use. Devices must be stored in a manner to ensure that the sources are secure and are not subject to unauthorized removal. Submit simple sketches of the use and storage areas.

Item 12 Not applicable.

Item 13 Not applicable.

Item 14 **General Rules for the Safe Use of Radioactive Material.** Because of the limited nature of gas chromatography and x-ray fluorescence analyzer licenses, the applicant does not need to establish a comprehensive radiation safety program. However, the applicant needs to provide information in the following areas:

- a. The procedures for leak testing the sealed sources. If the applicant will use a commercial leak-test kit, the name of the supplier and the model number of the kit should be specified. If the applicant will perform in-house leak tests, the information requested in Appendix A should be submitted.

Gas chromatograph detector cells containing Hydrogen 3 are not required to be leak tested.

- b. For gas chromatographs, the procedure for cleaning detector cells and/or removal and exchange of the foil or plated source. The applicant should specify how detector cells will be cleaned or sources serviced. The applicant may specify that detector cells will be returned to the supplier for cleaning or servicing. If the applicant will perform in-house cleaning or servicing, the manufacturer's recommended procedures should be followed and a copy of the procedures should be submitted with the application.
- c. For gas chromatographs, the procedure for venting detector cells containing Hydrogen 3. If detector cells containing Hydrogen 3 will be used, the applicant should provide for venting of the detector cells. The procedure for venting should be specified in the application.
- d. A copy of the written radiation safety procedures that personnel will follow if the devices will be transported to temporary locations. The applicant should refer to Appendix B of this guide for a description of the items that should be included in the radiation safety procedures.

Item 15 **Emergency Procedures.** Describe the emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas, (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (c) instruct personnel on appropriate methods for re-entering, decontaminating and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures is contained in Appendix C to this guide.

Item 16 Not applicable.

Item 17 **Waste Disposal.** The applicant should specify the procedure for disposal of the foils, plated or sealed sources when their use has been discontinued. Return of sources to the supplier is an acceptable method for disposal.

Item 18 Not applicable.

Item Personnel Monitoring Devices. For routine use of devices, the use of personnel monitoring devices (film badges or thermoluminescent dosimeters) is not normally required. Applicants who want to perform nonroutine activities that will require the use of personnel monitoring devices should provide the name of the supplier of the monitoring devices and the frequency of exchange. For guidance concerning personnel monitoring requirements, the applicant should refer to Section 16.11 of 10 NYCRR 16.

Item Certificate

Provide the signature of an individual authorized by management to represent the applicant institution. Include the date of signature.

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 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 10 NYCRR 16.

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, 547 River Street, Flanigan Square, Radioactive Materials Section, Room 530, Troy, New York 12180-2216.

VI. LICENSE TERMINATION REQUESTS

- a. 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.
- b. Submit survey 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 10 NYCRR 16. A decontamination guide is available from the New York State Department of Health, Bureau of Environmental Radiation Protection.
- c. 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.

LIST OF APPENDICES

Appendix

- A. Leak Testing of Sealed Sources
- B. Radiation Safety for Temporary Sites
- C. Emergency Procedures
- D. Forms
- E. Bibliography

APPENDIX A

LEAK TESTING OF SEALED SOURCES

Applicants who request authorization to perform leak tests of sealed sources, i.e., collect the wipe tests and analyze the results, should provide the following information:

- (a) The name and qualifications of each individual who will perform the leak tests.
- (b) Procedures and materials to be used in collecting test samples.
- (c) The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assaying the test samples.
- (d) Instrument calibration procedures, including the name of the manufacturer and model number of each standard source to be used, the step-by-step calibration procedures to be followed, and the name, experience, and training of each individual who will perform the calibrations. In providing information about the standard sources used in the calibrations, applicants should provide information concerning the accuracy of each source used. Each should be, as a minimum, $\pm 5\%$ of the stated value and traceable to primary standard, such as that maintained by the National Bureau of Standards.
- (e) The method, including a sample calculation, used to convert instruments readings to units of activity, e.g., microcuries.

APPENDIX B

RADIATION SAFETY FOR TEMPORARY SITES

The applicant must establish procedures to ensure compliance with the provisions of 10 NYCRR 16. The procedures should be in the form of written instructions to users and should cover the following items:

- (a) Safety measures to be used in transporting the devices in the applicants' vehicle (for example, fully securing the devices within the transportation vehicle). Transportation activities must be carried out in accordance with the requirements of Section 16.17 of 10 NYCRR 16 and Department of Transportation regulations.
- (b) Means of preventing unauthorized access, use or removal of the devices during use at temporary job sites. Instructions should state that individual users are never to leave the devices unattended.
- (c) Means of preventing unauthorized use or removal of the devices from the designated place(s) of storage at permanent locations and at temporary job sites.
- (d) Emergency procedures to be followed in case of accidents involving damage or loss of the devices, including name and telephone number of the individual(s) within the applicant's organization who should be notified and who would, in turn, notify the local police and State personnel.
- (e) Specific instructions to the users informing them that any maintenance on the devices involving dismantling, removal of source holders or detector cells, etc., must not be performed by the user and must only be performed by the manufacturer of the device, unless the applicant has specifically requested authority for performing maintenance in the application.

APPENDIX C

EMERGENCY PROCEDURES

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
4. CALL FOR HELP: Notify the Radiation Safety Officer immediately.
5. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____ *

OFFICE PHONE: _____

HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED
BY THE RADIATION SAFETY OFFICER:

*The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

APPENDIX E

BIBLIOGRAPHY

Part 16 - 10 NYCRR 16 New York State Sanitary Code

NRC Regulatory Guides

Regulatory Guide 8.4, "Direct-Reading and Indirect-Reading Pocket Dosimeters."

Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable."

Technical Reports

International Atomic Energy Agency (IAEA)¹ Technical Report Series No. 120, "Monitoring of Radioactive Contamination on Surfaces," 1970.

IAEA Technical Report Series No. 133, "Handbook on Calibration of Radiation Protection Monitoring Instruments," 1971.

International Commission on Radiological Protection (ICRP)² Report No. 12, "General Principles of Monitoring for Radiation Protection of Workers," Pergamon Press, 1969.

International Commission on Radiation Units and Measurements (ICRU)³ Report No. 12, "Certification of Standardized Radioactive Sources," September 12, 1968.

National Council on Radiation Protection and Measurements (NCRP)⁴ Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," 1978.

NCRP Report No. 58, "A Handbook of Radioactivity Measurement Procedures," 1978.

Standards

ANSI⁵ N13.2-1969, "Administrative Practices in Radiation Monitoring (A Guide for Management)."

ANSI N13.4-1971, "Specification of Portable X- or Gamma Radiation Survey Instruments."

ANSI N13.5-1972, "Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation."

ANSI N13.6-1966 (R1972), "Practice for Occupational Radiation Exposure Records Systems."

¹IAEA (International Atomic Energy Agency) reports may be obtained from UNIPUB, Inc., P.O. Box 433, New York, NY 10016.

²ICRP (International Commission on Radiological Protection) reports may be obtained from Pergamon Press, Maxwell House, Fairview Park, Elmsford, NY 10523.

³ICRU (International Commission on Radiation Units and Measurements) reports may be obtained from ICRU Publications, P.O. Box 30165, Washington, D.C., 20014.

⁴NCRP (National Council on Radiation Protection and Measurements) reports may be obtained from NCRP Publications, P.O. Box 4867, Washington, D.C. 20014.

⁵ANSI (American National Standards Institute) standards may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, NY 10018.

ANSI N14.5-1977, "Leakage Tests on Packages for Shipment of Radioactive Materials."

ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides."

Other Resources

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Cember, Herman, "Introduction to Health Physics," Pergamon Press, New York, 1969, pp 334-9

Steere, Norman V, Editor, Handbook of Laboratory Safety, Chapter on "Determining Industrial Hygiene Requirements in Installations Using Radioactive Materials," pp 482-502; also "Basic Units of Radiation Measurements," pp 391-426, CRC Press, Inc., 2000 N.W. 24th Street, Boca Raton, Florida 33431, 1970.

Wang, Yen, Editor, Handbook of Radioactive Nuclides, Part VIII, "Radiation Protection and Regulation," pp 573-831, CRC Press, Inc., 2000 N.W. 24th Street, Boca Raton, Florida 33431, 1969.