

**NEW YORK STATE
DEPARTMENT OF HEALTH
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION
INDUSTRIAL UNIT**



Radiation Guide 1.3 (a)

***GUIDE FOR THE PREPARATION OF APPLICATIONS FOR
THE USE OF SEALED SOURCES IN FIXED GAUGES***

07/07

1. INTRODUCTION

APPLICATIONS WHICH DO NOT FOLLOW THE FORMAT AND CONTENT OF THIS GUIDE CANNOT BE REVIEWED AND WILL BE RETURNED FOR REVISION.

1.1 PURPOSE OF GUIDE

The purpose of this regulatory guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals for the use of sealed sources in fixed gauges. These are devices used within an industrial facility for measuring thickness, fill-level and other properties.

This regulatory guide is intended to provide you, the applicant and licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to sealed sources in fixed gauges. The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program.

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations and procedures contained in your application; (2) the terms and conditions of the license; and (3) the Department of Health's regulations in 12 NYCRR 38. The information you provide in your application should be clear, specific and accurate.

1.2 APPLICABLE REGULATIONS

The New York State Department of Health issues licenses for the use of radioactive materials under the regulations of Titles 10 NYCRR Part 16 and 12 NYCRR Part 38. The statutory authority for the rules and regulations is found in the Public Health Law, Sections 201 and 225.

1.3 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

Part 38 requires that persons who operate or permit the operation of radioactive installations shall make every effort to maintain radiation exposures and releases of radioactive material as far below the limits of Part 38 as is reasonably achievable. License applicants should give consideration to the ALARA philosophy in the development of plans for work with radioactive materials.

2. FILING AN APPLICATION

You, as the applicant for a materials license, must complete DOSH Form 236 (7/06). You should complete Items 1 through 4 and 18 on the form itself. For Items 5 through 17, submit the information on supplementary pages. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8 ½ x 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8 ½ x 11 inches. You should complete all items in the application in sufficient detail for the Department to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and to minimize danger to life and property.

You must submit two copies of your application with attachments. Retain one copy for yourself, because the license will require that you possess and use licensed material in accordance with the statements and representations in your application and in any supplements to it.

Mail your completed application and the required fee to:

New York State Department of Health
Bureau of Environmental Radiation Protection
Industrial Unit
Flanigan Square, 547 River Street
Troy, New York 12180

Applications received without fees will not be processed and the fee is non-refundable.

3. CONTENTS OF AN APPLICATION

Indicate whether this is an application for a new license or a renewal of an existing license by checking the appropriate box at the top of the application form (DOSH 236). Also, please indicate the number of this application guide (Radiation Guide 1.3(a)).

Item 1. - APPLICANTS' NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license and the name of the company should be entered exactly as it appears on other legal documents.

The address specified here should be your mailing address to which correspondence should be sent. This may or may not be the same as the address at which the material will be used, as specified in Item 2.A.

Also enter your company's Federal Employers Identification Number (FEIN).

Item 2 - LOCATIONS OF USE AND STORAGE

List the address where radioactive material will be used or stored, if other than that in Item 1. A post office box number should not be stated as the address for place of use. This address will become part of the license conditions, if the license application is approved, and the address of locations at which radioactive materials are located or stored may not be changed without obtaining a license amendment. All locations of use must be zoned for commercial or industrial use.

Item 3 – NATURE OF BUSINESS AND PERSON TO BE CONTACTED ABOUT APPLICATION

Describe the type of business in which you are engaged.

Item 4 - LICENSE INFORMATION

Enter the license number of any previous or current licenses authorizing use of radioactive materials (including General Licenses) and the name of the issuing agency. If a license has ever been suspended or revoked, describe the circumstances on additional sheets.

Indicate whether this is an application for a new license or a renewal of an existing license.

Item 5 - DEPARTMENT OF USE

Indicate what department, unit or laboratory in your organization will use radioactive materials.

Item 6 - INDIVIDUAL USERS

List all individuals who will directly supervise the use of radioactive material.

Item 7. RADIATION SAFETY OFFICER

State the name and title of the person designated by and responsible to management for the coordination of the radiation safety program.

The individual responsible for your radiation safety program must be familiar with the Department's regulations (Part 38), your operating and emergency procedures and the conditions of your license. The individual must also have completed the device manufacturer's training program. If the RSO has completed the device manufacturer's program, you should submit a copy of the training certificate. If training will be completed after the application is submitted, a copy of the RSO's certificate must be submitted as soon as possible and before the license is issued.

The Radiation Safety Officer (RSO) should be responsible to management for the overall radiation program. 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 38. 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 are used only as authorized by the license.
- c. To ensure that the devices are properly secured against unauthorized removal at all times. This is particularly important for gauges used in process lines where they may be inadvertently mixed with salvaged materials when renovations are made or operations are discontinued.
- d. To serve as a point of contact and give assistance in case of emergency (device damage, fire, theft, etc.) and to ensure that the proper authorities (local police and State personnel) are notified promptly in case of accident, damage or loss of the devices.
- e. To ensure that the terms and conditions of the license, such as periodic leak tests and inventories, 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, and license conditions.

Item 8 –RADIOACTIVE MATERIAL TO BE POSSESSED

- 8.A. Identify each radioisotope that will be used in a gauging device (if you will analyze leak tests, see Appendix A and include instrument calibration sources here).
- 8.B. Identify the manufacturer and model number of each sealed source that will be used in a gauging device.

- 8.C. Specify the amount of radioactive material that will be in each sealed source.
- 8.D. Identify the manufacturer and model number of each gauging device in which the sealed sources will be used.

Item 9. PURPOSE FOR WHICH RADIOACTIVE MATERIALS WILL BE USED

Specify the purpose for which the gauging device you want to possess will be used.

Item 10 & 11 - TRAINING AND EXPERIENCE OF INDIVIDUAL USERS

Because of the limited natures of a fixed gauge license, extensive training and experience is not necessary. Generally the device manufacturer will provide any necessary training in taking wipes, testing the on-off mechanism, and other routine activities. Evidence of such training should be submitted for each person who will supervise the use of gauges; or you may state that these persons will receive training before gauges are put into use. This documentation will be reviewed at the time of inspection.

If you wish to engage in non-routine activities, such as moving gauges or performing maintenance on them, you should contact this office regarding the need for additional staff training.

Items 12 & 13. INSTRUMENTATION AND CALIBRATION

For routine use of these devices, radiation survey instruments are not normally required.

Item 14 - PERSONNEL MONITORING

For routine use of these devices, the use of personnel monitoring devices (film badges or thermoluminescent dosimeters) are not normally required. Applicants who want to perform non-routine activities should contact this office.

Item 15- FACILITIES AND EQUIPMENT

The applicant should provide a description of the intended location of each gauge. Submit simple sketches of the use and storage areas. If the license is to cover a large number of gauges, you may submit only a list of gauges and their locations, such as an inventory list, and maintain more detailed information on file.

Item 16 - RADIATION PROTECTION PROGRAM

Because of the limited nature of fixed gauge 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 at six month intervals. 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 analysis of leak tests, the information requested in Appendix A to this guide should be submitted.

- b. A commitment that gauges and source holders will be installed and serviced by the manufacturer or another company specifically licensed by the USNRC or an Agreement State to perform these functions should be submitted. If the applicant will perform any in-house servicing, the manufacturer's recommended procedures should be followed and a copy of the procedures should be submitted with the application, along with an outline of the training the manufacturer provides for those who will perform these functions.
- c. A commitment that inventories of all fixed gauges will be performed at intervals not to exceed six months should be submitted. Inventory records must include gauge identifying information, the location of each gauge, the date and the name of the person performing the inventory.
- d. Emergency Procedures. Describe the emergency instructions to be posted where the sources are used. These instructions should (a) describe immediate action to be taken in the event of an accident or emergency, (b) state the names and telephone numbers of the responsible persons to be notified and (c) instruct personnel on other appropriate actions.
- e. Procedures for ensuring that all gauges will be locked in the "off" (shielded) position before any person is permitted to perform any functions that might result in radiation exposure from the primary beam of the radioactive source (e.g., inserting any part of the body between the source and the detector portion of the gauge). This may be contained in your lockout/tagout procedures for the equipment which each gauge monitors, or on which it is mounted. Submit your procedures for compliance with this requirement.

Item 17 - WASTE MANAGEMENT

The applicant must plan for proper disposal of the sealed sources when their use has been discontinued. Due to the anticipated loss of access to commercial radioactive waste sites you should plan to return all sources to the supplier or manufacturer. You should submit confirmation that the supplier or manufacturer agrees to accept the sources back, and state that all sources to be possessed under the license will be obtained from suppliers which agree to accept them back.

Item 18 - CERTIFICATION

The application must be dated and signed by the Chief Executive Officer of the corporation or legal entity applying for the license, or by a person who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of your knowledge and belief. Unsigned applications will be returned for proper signature.

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 source must be within $\pm 5\%$ of the stated activity value and traceable to primary standards maintained by the National Institute of Standards and Technology.
- (e) The method, including a sample calculation, used to convert instrument readings to units of activity, e.g., microcuries.

4. ADDITIONAL DOCUMENTS TO BE SUBMITTED

In addition to the foregoing, you must also submit:

1. A copy of a letter sent to the Police Department in each permanent use location listed in item 2 of the application, which informs them that radioactive materials will be on the premises and instructs them on any precautions to be taken and notifications to be made in the event of a fire or emergency.
2. A copy of a letter sent to the Fire Department in each permanent use location listed in item 2 of the application, which informs them that radioactive materials will be on the premises and includes a completed Hazardous Materials Form (F100965-001), and instructs them in any precautions to be taken and notifications to be made in the event of a fire or emergency.
3. All applicants must provide proof that you have obtained the required Workers' Compensation and Disability Benefits coverage, or that you are not required to provide coverage under Section 57 of the Workers' Compensation Law and Section 220, subdivision 8 of the Disability Benefits Law. Such proof must be current at the time of license application.

5. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application; (2) the terms and conditions of the license; and (3) the Department's regulations.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; Department regulations do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application form or in letter form and should be submitted in duplicate to the address specified in Section 2 of this guide. Your application should identify your 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. For example, if you wish to change the RSO, your application for a license amendment should specify the new individual's name, training and experience. The qualifications of the new RSO should be equivalent to those specified in Item 6 of this guide.