

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



Radiation Guide 1.9

**GUIDE FOR APPLICATION TO
POSSESS RADIOACTIVE MATERIALS
INCIDENT TO EXEMPT DISTRIBUTION**

01/07

I. INTRODUCTION

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

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 possession of radioactive materials incident to exempt distribution. 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 the license activities proposed. 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.

APPLICABLE REGULATIONS

The New York State Department of Health issues licenses for the use of radioactive materials under the regulations of Title 12 NYCRR Part 38. The statutory authority for the rules and regulations is found in the General Business Law, Section 483; and Health Law, Section 27.

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.

II. 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.

III. CONTENTS OF AN APPLICATION

Item 1.

Enter the name and corporate address of the applicant and the telephone number of company management. The name of the firm must appear exactly as it appears on legal papers authorizing the conduct of business.

Item 2.

List all addresses and locations 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 a place of use. These addresses and locations will become part of the license conditions, if the license application is approved, and the addresses 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.

Enter the nature of the business the applicant is engaged in and the name and telephone number (including area code) of the individual to be contacted in connection with this application.

Item 4.

Enter any previous or current radioactive materials license numbers and identify the issuing agency. Also indicate whether you possess any radioactive material under a general license.

Describe the circumstances of any denial, revocation or suspension of a radioactive materials license previously held.

Indicate whether this is an application for a new license, or a renewal in one of the appropriate box above Item 1 on the application form. Also indicate the radiation guide number used with the application

Item 5.

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

Item 6.

Employees who will use material under the supervision of a responsible individual named in Item 7 do not need to be designated by name.

Item 7.

State the name and title of the person designated by, and responsible to, management for the coordination of the radiation safety program. This person will be the radiation safety officer. 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 (i.e., stored pending distribution).
- c. To ensure that the devices are properly secured against unauthorized removal at all times.
- d. 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, damage or loss of the devices.
- e. To ensure that the terms and conditions of the license are met and that the required records are maintained, such as receipt, return and shipping records.

Item 8.

- A. List the radionuclide and mass number of the particular radionuclides to be used.
- B. List the manufacturer and model number of the sources or source holders in the systems to be possessed.
- C. List the maximum activity of sources to be used in each system and total number of systems to be on-site at one time.

Item 9

Specify the name of the manufacturer of the system, and the purpose for which each unit will be used (i.e., storage pending exempt distribution under license issued by the USNRC).

Item 15.

Submit simple sketches of the storage and receiving areas.

Item 16.

The applicant does not need to establish a comprehensive radiation safety program. However, the applicant needs to provide information in the following areas:

- I Radiation Protection Program.
 - (a) Procedures for receipt of exempt devices, including any inspections that will be done to confirm device integrity upon receipt.
 - (b) Inventory management procedures to ensure that total on-site inventory does not exceed the possession limit to be specified in the license, and that all timepieces and parts are accounted for.
 - (c) Security procedures to be implemented to ensure that tritium containing timepieces or parts are protected from damage, theft or loss.
 - (d) Emergency Procedures. Describe the emergency instructions to be posted where the

devices are stored. These instructions should:

1. describe immediate action to be taken in the event of an accident or emergency,
2. state the names and telephone numbers of the responsible persons to be notified and
3. instruct personnel on other appropriate actions.

You should also explain how these procedures will be provided to non-employees who may respond to an accident or incident at the site.

A commitment that any timepieces or parts that are defective or otherwise not distributable will be accepted for return, and that no radioactive material will need to be disposed of due to operations at the site.

- II Other Procedures. If you will repair or service exempt devices (i.e. watches containing tritium) you **should** submit procedures for wipe tests along with an estimate of the total activity of tritium in watches to be repaired or serviced in a year. If this total activity is very high financial assurance may be required.

Item 17.

Waste Disposal. 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: Provide the signature of the chief executive officer of the corporation or legal entity applying for the license or of an individual authorized by management to sign official documents and to certify that all information in this application is accurate to the best of the signator's knowledge and belief.

IV. 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 in 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 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. 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, subd. 8 of the Disability Benefits Law (see enclosed forms). Such proof must be

current at the time of license application.

V. 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, procedures, and authorized users or radiation safety officer, or the 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.