

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



Radiation Guide 1.4

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR TYPE A BROAD SCOPE LICENSE

ATTACHMENTS: **LLRW Minimization and Management Guide**
 Licensing Guide(s) _____
 NRC Guides 8.20 and 8.23

07/07

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This guide describes the additional information you need to provide when applying for a Type A license of broad scope (hereinafter called a broad license) for radioactive material. This information addresses administrative issues not covered in our guide for limited licenses.

1.2 CONCEPT AND CONDITIONS OF BROAD LICENSES

Broad licenses differ from all other types of materials licenses in that they are primarily* based on the administrative procedures and organizational qualifications of the licensee to operate safely under the license rather than on a detailed review by the department of the qualifications, equipment, and procedures for each use and user. The applicant, through its radiation safety officer and radiation safety committee and based on past experience and performance under specific licenses, performs these detailed reviews in lieu of such reviews by the department. Persons licensed under broad licenses may not (1) conduct tracer studies in the environment involving direct release of radioactive material (field uses), (2) use 10,000 curies or more of radioactive material for irradiation of materials, (3) use radioactive material in humans, (4) add or cause the addition of radioactive material to any food or other product designed for ingestion by or application to a human being, or (5) provide commercial services such as instrument calibration, leak-testing or radioactive waste disposal.

Broad licenses will be issued only to organizations that have:

1. Considerable experience in the use of radioactive materials under specific licenses of limited scope. Although not specified in the regulations, it is recommended that an applicant have had a limited specific license for at least a 5-year period.
2. A good performance record, including satisfactory understanding of and compliance with regulatory requirements and license conditions, based on department licensing and inspection of prior activities.
3. A radioactive materials utilization program of such scope that the organization needs a variety of radionuclides and operational flexibility to cover numerous use and users.
4. An administrative organization and procedures appropriate and adequate to ensure safe operations and to review and approve proposed uses, users, facilities, and procedures under the license.

* However, the Department will still review the licensee's radiation protection program and generic procedures. Appropriate guides are enclosed for these portions of your radioactive materials program. You should submit responses to all items on the application form which apply to your program.

Items 2, 3 and 4 will also determine whether licenses will be renewed as broad scope by the department, or converted to specific licenses upon renewal. The department may also act to convert a broad license to a specific license at other times when it becomes apparent that a program does not require or cannot adequately administer this type of license.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA)

Code Rule 38 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 the code as is reasonably achievable. License applicants should give consideration to the ALARA philosophy in the development of plans for work with radioactive materials and the ALARA concept should be incorporated into the radiation protection program.

1.4 RADIOLOGICAL CONTINGENCY PLANNING

Section 38.6(d) of Code Rule 38 includes a schedule of possession limits above which contingency planning for emergency preparedness is required. A number of transuranic radionuclides have limits of a few curies.

You should submit a radiological contingency plan if (1) you request possession of radionuclides in forms other than as sealed sources; and (2) the sum of the quotients of the requested quantities for individual radionuclides divided by the quantities of these radionuclides specified in the schedule of possession limits is greater than one; and it is otherwise indicated by Code Rule 38.

You should consult section 38.6(d) of Code Rule 38 for information on evaluating whether a plan is needed and what must be submitted to the Department.

1.5 PRELICENSING CONFERENCE

After an application has been reviewed by the department and found to be completed and responsive, a prelicensing conference may be scheduled by the department at your facility. The department licensing staff and perhaps a member of the inspection staff would participate in this visit. You should be represented by your radiation safety officer (RSO), the chairman and preferably other members of your radiation safety committee (RSC), and one or more representatives of institutional management. The management representatives may or may not be members of the RSC and may be present for the entire conference or only for the summary, as is frequently the case during licensee inspections.

Discussions during the conference provide the department staff with a better understanding of your program and qualifications that can be obtained from the review of the written application. The conference includes observation and discussion of your facilities and equipment as they exist and as they will be provided for new or expanded uses.

A prelicensing conference provides the department staff an opportunity to evaluate whether your program needs a broad license. It also provides the staff an opportunity to impress on your management, RSO, and RSC the importance of their responsibilities under a broad license and to discuss and agree upon additional information or commitments that may be needed. If a broad license is not warranted, the department staff may suggest and agree upon continuation of your program with an appropriate specific license.

2. FILING AN APPLICATION

You should apply for a license by completing DOSH 236. You should complete items 1 through 4, and 18 on the form itself unless additional space is needed. For items 5 through 17, submit the required information on supplementary sheets. You should identify and key each sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and if possible, drawings should be on 8 1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8 1/2 x 11 inches.

You should complete all items in the application in enough detail for the department to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should not be submitted unless they are a part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if requested by the department.

You should file your application in duplicate. 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 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.

3. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of DOSH 236:

ITEM 1 - APPLICANT'S NAME AND MAILING ADDRESS

Applicants should be corporations or other legal entities. Because a broad licensee must have a radiation safety committee, it is not appropriate for a private individual to apply for a broad license.

The address specified here should be your office mailing address in New York State for correspondence. This may or may not be the same as the address at which the material will be used, as specified in Item 2.

ITEM 2 - LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, State) to allow us to easily locate your facilities. A Post Office Box address is not acceptable. If radioactive material is to be used at more than one location, you must give the specific address of each location. In Items 9 and 15 of the application, describe the intended use and the facilities and equipment at each location.

If you plan to use radioactive material at temporary job sites, specify so and describe your procedures; including your procedures for transportation, storage, control of material against access by unauthorized users, and control of contamination.

ITEM 3 - NATURE OF BUSINESS AND PERSON TO BE CONTACTED ABOUT APPLICATION

Describe the type of business in which you are engaged and name the individual who knows your proposed program and can answer questions about the application. Also, please note the telephone number at which the individual may be contacted. If the contact changes, notify the Department. Notification of a contact change is for information only and would not be considered an application for a license amendment.

ITEM 4 - LICENSE INFORMATION

Enter the license numbers 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, an amendment or a renewal.

ITEM 5 - DEPARTMENT OF USE

Indicate what department or organizational unit will use radioactive materials.

ITEM 6 - INDIVIDUAL USERS

The usual response should be "Radioactive materials are to be used by or under the supervision of individuals designated by the radiation safety committee."

ITEM 7 - RADIATION SAFETY OFFICER

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

ITEM 8 - MATERIAL TO BE POSSESSED

Describe the radioactive material you wish to possess by isotope, chemical or physical form, and quantity in millicuries or microcuries. You should state the maximum quantity of each radioactive material you wish to possess at any one time. The usual entry is "___ millicuries of each radionuclide with atomic numbers 1-83; total possession limit _____ millicuries or curies." The maximum quantities for individual nuclides and total possession should be commensurate with your needs, facilities, procedures, and personnel and should be consistent with your prior licensed activities. If a few nuclides will be needed in much larger quantities than others, they should be listed separately in Items 8a, 8b, and 8c, rather than increasing the quantity of all nuclides to include these larger quantities. If certain nuclides in the form of sealed sources will be needed in quantities larger than requested in Items 8a, 8b, and 8c in any form, these should be listed separately. Larger sealed sources should also be described by manufacturer and model number under Item 8b. Similarly, if certain relatively more hazardous nuclides (e.g., strontium-90) are not needed or are needed only in smaller quantities, they should be listed separately. The maximum quantities of nuclides with atomic numbers above 83 should be stated separately. Stored wastes should be included in establishing both individual nuclide and total maximum quantities. A typical entry for Items 8a, 8b, and 8c would be:

	8.a Radioactive material	8.b. Chemical or physical form	8.c. Maximum possession limit
1	Any radioactive material with atomic numbers 3 to 83 except as specified below.	Any	50 millicuries of each radionuclides with atomic numbers 3 to 83, with a total possession limit of 2 curies except as specifically listed below.
2	Hydrogen-3	Any	1 curie
3	Carbon-14	Any	500 millicuries
4	Iodine-125	Any	300 millicuries
5	Strontium-90	Any	1 millicurie
6	Cesium-137	Sealed Source XYZ Co. Model 123	5 curies

ITEM 9 - PURPOSE FOR USE OF LICENSED MATERIAL

Describe in general terms the purposes for which you will use licensed material and explain why you need a broad license rather than amendments to a specific license. The uses should be consistent with your prior licensed activities. Examples of appropriate uses are "research and development."

A broad license may include sealed sources for uses related to the basic purpose of the broad license (e.g., research and development or calibration of the licensee's instruments). If you desire to use an irradiator under a broad license, you should follow the guidance in separate regulatory guides that cover licenses for large sealed sources contained in irradiators. However, you may not use 10,000 curies or more of radioactive material in sealed sources for irradiation of material under a broad license.

A broad license does not authorize industrial radiography or commercial services unless these activities are specifically authorized. A broad license does not authorize the use of radionuclides in field studies that involve release of radioactive materials to the environment unless such studies are specifically authorized by a condition of the license. You should discuss proposals for such field uses with department licensing personnel before you submit an application for a license or license amendment.

ITEM 10 (AND 11) - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY--THEIR TRAINING AND EXPERIENCE

10.1 RADIATION SAFETY OFFICER

You are required to appoint a radiation safety officer (RSO) under section 38.17 of Code Rule 38. The RSO should have an academic degree in physical or biological science or engineering and specific training in radiation health science and should have considerable professional experience (generally about 5 years) with radioactive materials. The RSO's professional experience should include the application of this training to the management and administration of a radiation safety program related to the types, quantities, and uses of the radioactive material to be used under this license. List and describe the training and experience of the RSO.

10.2 RADIATION SAFETY COMMITTEE

You are required to establish a Radiation Safety Committee (RSC) to administer a broad license. The RSC should consist of such persons as the radiation safety officer, at least one representative of management, and technical persons representing the departments, groups, or activities that will use radioactive materials under the broad license. Each technical member of the RSC should have training and experience in the use of radioactive materials and radiation safety, but this background need not be as extensive as that of the RSO. The administrative member or members of the RSC should ensure management support of the radioactive materials program and due consideration of the financial, legal, and business interests of the organization. Administrative

members of the RSC need not have a background in radiation safety.

You should identify the chairman and members of the RSC and their positions in your organization. Describe each member's formal training and work experience with radioactive materials and radiation safety. Either a resume for each individual or a general description of the minimum requirements for these positions may serve to describe training and experience.

ITEM 12 – INSTRUMENTATION

List the equipment available for radiation surveys and for analyzing wipes. Equipment must also be provided that is appropriate for surveying wipes before transfer from off-site locations to ensure that gross contamination is not present.

Your list should specify for each instrument (1) the type of instrument, (2) the number of instruments available, (3) the type of radiation detected, (4) the sensitivity range, and (5) the specific use. The instruments listed should have sufficient sensitivity to accurately measure any radioactive contamination on leak-test samples obtained from your customer's sources and devices.

Describe the lower limit of detection of equipment to be used for analyzing wipes, and provide an example calculation for converting counting results to activity.

Item 13 - CALIBRATION OF INSTRUMENTS

- (a) If survey meter calibrations are performed at your facility. You must submit your procedures. Appendix B to this Guide contains a model procedure. State that you will follow the model procedure or submit a copy of the Appendix with your changes indicated in red ink.

If your survey meters are sent out for calibration, submit a statement that calibrations will be performed by persons licensed to perform this service by the U.S. Nuclear Regulatory Commission or an Agreement State and that a copy of this license will be kept on file with the calibration certificates.

- (b) Quantitative Measuring Instruments - Instruments that will be used for quantitative analysis should be calibrated at six-month intervals. A description of the procedure for calibration of such instruments should be submitted and should include:
- (1) the manufacturer and model number of the source(s);
 - (2) the nuclide and quantity of radioactive material in the source(s);
 - (3) the accuracy of the source(s);
 - (4) the step-by-step procedures for calibration, including

associated radiation procedures; and

- (5) the name(s) and pertinent experience of person(s) who will perform the calibrations.

Item 14 - PERSONNEL MONITORING PROGRAM

Describe your personnel monitoring policies and procedures for staff who will collect leak test samples. This should include extremity and whole body monitoring, if a variety of sources are to be tested, and a monthly exchange interval should be used.

ITEM 15 - FACILITIES AND EQUIPMENT

Describe the facilities and equipment available in major areas of use including diagrams and locations. Include special considerations for iodination labs, hot cells, waste storage areas, hot labs, source storage areas, animal labs, etc. Your administrative procedures for internal control of uses under the broad license (discussed in Item 16) should include provisions for determination that your facilities and equipment are adequate for uses that may be approved by the Radiation Safety Committee.

You should also describe fire detection and suppression systems in use, storage and waste areas; and security systems and access controls. An explanatory sketch of buildings and facilities should be included to aid in review of this item.

ITEM 16 - RADIATION PROTECTION PROGRAM FOR BROAD LICENSES

Broad scope licenses will only be issued to organizations who have considerable experience in the use of radioactive material and have established administrative controls and provisions related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. You should describe these organizational matters and internal procedures of your proposed program. Your description should be in narrative form and should include the elements identified below.

16.1 PREVIOUS LICENSES

List the present and previous radioactive materials licenses for which this application requests a continuation or expansion of activities.

16.2 RADIATION SAFETY COMMITTEE

Your RSC should establish policies and overall guidance for your radioactive materials program and should review, approve, and record safety evaluations of proposed uses of radioactive material before such use. The RSC should conduct a periodic audit of the safety program and review the activities of the RSO and the records that must be maintained to ensure compliance with conditions of the license and applicable parts of the department's regulations. The RSC should meet as often as necessary to conduct its business (but not less than quarterly) and should keep minutes of committee meetings and activities.

You should describe the responsibilities and duties assigned to the RSC, the authority delegated to the RSC, and the frequency and quorum required for RSC meetings.

16.3 RADIATION SAFETY OFFICER

The RSO should be responsible for the day-to-day coordination and management of the radiation safety program within your organization and should ensure compliance with the conditions of your license and New York State Dept. of Health regulations. The RSO should report to top management in a staff capacity, should have ready access to all levels of the organization, and should have authority to immediately terminate a project that is found to be a threat to health, safety, or property. The RSO position for a broad-license program is usually a full-time assignment and is sometimes supported by a staff. You should indicate whether the RSO position is a full-time assignment and should state the size of the staff.

You should list the responsibilities and duties of the RSO in your application. The extent of these responsibilities and duties will depend on the scope of the proposed broad license; however, the following should be considered and included, if applicable:

1. Coordinating the RSC's review of safety evaluations of all proposed uses of radioactive material.
2. Generally overseeing all activities involving radioactive material, including conducting routine monitoring and special surveys of all areas in which radioactive material is used. The RSO generally conducts periodic surveys of work areas to supplement and audit routine monitoring by authorized users. You should indicate the types and frequencies of monitoring and surveys to be performed by the RSO.
3. Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the RSC.
4. Receiving, opening, and delivering all shipments of radioactive material arriving at the facility and receiving, packaging, and shipping all radioactive material leaving the facility.
5. Maintaining an inventory of all radionuclides at the facility and limiting the quantities of radionuclides to the amounts authorized by the license. The inventory record should include the name of the person responsible for each quantity of radionuclide, where it will be used or stored, and the date the quantity was delivered to that person. When items are removed from the inventory, it should show how and when the radionuclide was disposed of.
6. Supervising and coordinating the radioactive waste minimization and management program, including keeping waste storage and disposal records and monitoring effluents.
7. Storing all radioactive materials not in current use, including wastes.

8. Distributing personnel monitoring devices and arranging for their processing, determining the need for and evaluating bioassays, notifying individuals and their supervisors of exposures that are approaching maximum permissible amounts, and recommending and supervising appropriate remedial action.
9. Performing or arranging for calibration of instruments.
10. Performing leak tests on sealed sources.
11. Conducting training programs and otherwise instructing personnel in the proper procedures before they are allowed to use radioactive material and as required by changes in procedures, equipment, regulations, etc. All individuals working in or frequenting a restricted area must receive instructions according to section 38.27(c) of Code Rule 38. These individuals include not only radiation workers but also others such as clerical, custodial, and maintenance personnel.
12. Furnishing consulting services on all aspects of radiation safety to personnel at all levels of responsibility.
13. Monitoring and maintaining special filter systems associated with the use, storage, or disposal of radioactive material.
14. Supervising decontamination in case of contaminating accidents.
15. Maintaining other records not specifically designated above, e.g., records of surveys, radiation monitoring, and disposal; records of receipts and transfers of material; and records necessary to eventual decommissioning.

16.4 ADMINISTRATIVE PROCEDURES

You should establish administrative procedures to ensure control of procurement and the use of radioactive material and to ensure completion of safety evaluations of proposed uses of radioactive material. The safety evaluations should include a determination of the adequacy of facilities and equipment, training and experience of the users, and operating or handling procedures.

16.5 CONTROL OF PROCUREMENT AND USE

Your application should describe the administrative procedures you have established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. Licensees usually have a procedure that centralizes all purchases or other procurement through an authorized purchasing agent in order to verify that the procurement and use are authorized under the license. If you do not use such a centralized procedure, describe how your procedure prevents unauthorized procurement and use.

16.6 SAFETY EVALUATIONS OF PROPOSED USES

Your application should describe in detail the procedures and criteria for conducting the safety evaluations for approving uses and users. Some licensees with broad licenses use application forms and guidance adapted from department forms and radiation guides to do the equivalent of a licensing review of each proposed use. A copy of your request and approval forms, if available, would be helpful to the department in its review of your application. Your procedures and criteria should include the evaluation and approval of:

1. Training and experience requirements for project supervisors and individual users who will use material without direct supervision.
2. Facilities and equipment for each specific use. The following should be considered:
 - a. Shielding,
 - b. Containment (hoods, filters, glove boxes),
 - c. Restricted area controls and posting,
 - d. Remote handling equipment, and
 - e. Survey and monitoring procedures, frequency and instrumentation.

You should also include a commitment to keep, for the duration of your license, records of proposed uses approved by the Radiation Safety Committee.

ITEM 17 - WASTE MANAGEMENT

Using the enclosed guidance, submit your LLRW minimization and management plan.

ITEM 18 - CERTIFICATION

If you are an individual applicant acting in a private capacity, you are required to sign the form. Otherwise, your application should be dated and signed by the Chief Executive Officer of the corporation or legal entity applying for the license, or 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.

OTHER PROCEDURES AND INFORMATION TO BE SUBMITTED

Please see other enclosed guides and submit the information requested, unless it has been covered above.

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 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 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. 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.

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 (DOSH 236) 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 this guide.