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

Radiation Guide 1.12

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR CYCLOTRON PRODUCTION OF RADIOACTIVE MATERIALS

Attachment(s): LLRW Guide

07/07

1. INTRODUCTION

A. PURPOSE OF GUIDE

This guide describes the type of information that should be submitted in applications for specific licenses of limited scope for the possession and use of radioactive material in unsealed form. It does not apply to applications for specific licenses of nuclear pharmacy (and related distribution licenses), broad scope, licenses for source or special nuclear materials, or licenses for kilocurie irradiation sources. It includes the general principles that will be considered in evaluating an applicant's proposed radiation safety program.

The applicant should carefully study Code Rule 38 and this guide, and should submit all required information in sufficient detail to allow a complete review. The Department will request additional information, when necessary to provide reasonable assurance that the applicant's proposed use, equipment, facilities, procedures and staffing are adequate to protect health and safety and minimize danger to life and property, from radiation hazards. Such requests will delay final action on the application.

Two general principles that will be considered in evaluating proposed radiation safety measures are recognition by the company of:

1) The management's responsibility for the safety of employees and the public; and

2) Its responsibility for maintaining all radiation exposures and releases as low as is reasonably achievable (ALARA).

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

B. APPLICABLE REGULATIONS

Licensees of the New York State Department of Health must comply with the provisions of Code Rule 38. It is your responsibility as an applicant and as a licensee to have copies of, to read, and to abide by these regulations. As a licensee, you are subject to all applicable provisions of the regulations as they pertain to operating a cyclotron.

C. AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

Part 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 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 11inches. 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

This guide contains appendices that present model procedures or programs acceptable to the Department. If you refer in your application to a section or appendix of this guide, that section or appendix will be incorporated as a part of the terms and conditions of your license. You will be inspected against the commitments contained in the referenced section, appendix, or document, just as you will be inspected against your more detailed responses. Accordingly, you must keep a copy of the referenced guide on hand at all times so that you can review your commitments as necessary.

The following paragraphs explain the information requested in Form DOSH 236.

Item 1. APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you may be the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address 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 five miles east on Highway 10, Anytown, State) to allow us to easily locate each of your facilities. A post office box address is not acceptable.

Item 3. NATURE OF BUSINESS

You should enter: Commercial Nuclear Pharmacy.

Item 4. PREVIOUS LICENSE NUMBER(S) AND ISSUING AGENCY

If you have ever had a license denied, suspended or revoked, you should describe the circumstances on an additional sheet and attach to the application.

Item 5 If applicable, identify the department(s) of your company that will be using radioactive materials.

Item 6 List all individuals who will use or directly supervise the use of radioactive material. Give the title or position of each person.

Item 7 Radiation Safety Officer - Part 38 requires that a Radiation Safety Officer be appointed. The Radiation Safety Officer is responsible for the day-to-day operation of the radiation safety program. A description of his/her training and experience in radiation protection and the use of radioactive material should be provided, along with a curriculum vitae.

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. If the radiation safety officer is assisted by a consultant or part-time employee, state the consultant's name and describe his/her duties, responsibilities, and the amount of time to be devoted to the radiation safety program.

The Radiation Safety Officer shall have, as minimum qualifications, a bachelors degree in health physics or radiological health and four years of the experience described below; or certification by the American Board of health Physics (Comprehensive), the American Board of Radiology in Medical Nuclear Physics, the American Board of Science in Radiation Protection or the American Board of Medical Physics in Medical Health Physics, and two years of the experience described below:

1. 200 hours of training in cyclotron physics and radiation safety, targetry, radiochemistry, use of automated and semi-automated chemical synthesis devices, quality control, airborne emissions verification and evaluation, and regulatory standards.

A statement must be included delineating the Radiation Safety Officer's duties, responsibilities and authority for carrying out the radiation safety program. The extent of the Radiation Safety Officer's responsibility and authority will depend on the scope of the proposed program; however, the following should be considered for inclusion in your statement:

(1) General surveillance over all activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is used.

(2) Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the radiation safety committee.

(3) Monitoring and maintaining filter systems associated with the use, storage or disposal of radioactive material.

(4) Furnishing consulting services on all aspects of radiation safety to personnel at all levels of responsibility.

(5) Receiving, delivering and opening all shipments of radioactive material arriving at the company and receiving, packaging and shipping all radioactive material being shipped out.

(6) Distributing and processing personnel monitoring equipment, determining the need for bioassays, keeping personnel exposure and bioassay records, and notifying individuals

and their supervisors of exposures approaching ALARA levels and recommending appropriate remedial action.

(7) Conducting training programs and otherwise instructing personnel in the proper procedures for the use of radioactive material prior to use, annually (refresher training), and as required by changes in procedures, equipment, regulations, etc.

(8) Supervising and coordinating the radioactive waste disposal program, including keeping waste storage and disposal records, and monitoring effluents.

(9) Storing all radioactive materials not in current use, including wastes.

(10) Performing leak tests on all sealed sources.

(11) Maintaining an inventory of all radioisotopes and limiting the quantity of radionuclides to the amounts authorized by the license. The inventory should include the name of the person responsible for each quantity of radioisotope, where it will be used or stored, and the date the quantity was delivered to that person. Items are removed from the inventory by showing how and when the radioisotope was disposed of.

(12) The authority to terminate immediately a project that is found to be a threat to health or property.

(13) Maintaining other records not specifically designated above (e.g., receipt, transfer and survey records).

Item 8a List radioactive materials (nuclides) to be possessed and used (e.g., any nuclide with atomic numbers 3-83, carbon-11, fluorine 18, gallium 67 and co-produced nuclides).

Item 8b List physical/chemical form (e.g., solid activation products, carbon monoxide and carbon dioxide as gases, F18-FDG as specified in IND#_____, solids as plated accelerator targets).

List possession limits for each nuclide.

Item 9 List uses (e.g., for use and storage as incidental products of cyclotron operations; for preparation, from bombarded targets, of radiochemicals and radiopharmaceuticals; for research in diagnostic studies conducted in accordance with an IND that has been accepted by the USFDA and has been approved by the (institution's name) Radiation Safety and Human Subjects Review Committees.

Items10 & 11 TRAINING AND EXPERIENCE

A. Qualified Expert - A qualified expert must be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the

accelerator is first capable of producing radiation and before routine operation. A qualified expert must also perform a radiation survey after changes in shielding or major changes in occupancy of surrounding areas, operations, etc. The person should have the following training and experience:

1. A baccalaureate degree, a master's degree or a doctorate in radiological physics or a closely related field such as physics or health physics; and who has participated in the design and radiation survey of at least two facilities which are similar in design complexity, intended uses and beam characteristics (including energies), and who has had primary responsibility for the design and radiation survey of at least one similar facility.

2. The design experience described above must have included calculation and specification of shielding requirements; design and layout of any ancillary equipment such as hot cells and radionuclide handling and transport systems; and design of monitoring, warning and safety systems.

   For new installations, submit the training and experience of the qualified expert who will or has consulted on the design of your installation and approved it, and a copy of that approval.

   For all applicants, confirm that a qualified expert will be called upon to perform a radiation survey after changes in shielding or other major changes.

B. Authorized Users (non-human use) – Staff who will operate the cyclotron or process cyclotron products without direct supervision must have any requisite professional training and experience (e.g., nuclear pharmacist or radiochemist) as well as specific training and experience relevant to work in a cyclotron/PET facility. This should include:

2. 200 hours of training in cyclotron physics and radiation safety, targetry, radiochemistry, use of automated and semi-automated chemical synthesis devices, quality control, airborne emissions verification and evaluation, and regulatory standards.

3. Hands-on experience with the relevant equipment and chemistry at a similar facility, and there should be a documented evaluation of individual knowledge and performance.

Submit the training and experience of persons who will be designated as authorized users (those who will produce or use cyclotron products without direct supervision).

C. Other Users – Other staff who will participate in operation of the cyclotron or processing of cyclotron products under the supervision of authorized users must also have appropriate training and experience.

Staff must be instructed in radiation safety precautions and procedures, regulatory and license requirements, operating and emergency procedures, cyclotron operation, use of related equipment and of survey and monitoring equipment as appropriate to their assigned tasks.

Confirm that staff who will participate in licensed activities will receive the instruction described above before beginning work under the license and that this instruction will include hands-on experience. Also confirm that there will be a documented evaluation of each individual's knowledge and performance after instruction, and that only those that meet or exceed a pre-determined passing score will be allowed to begin work under the license.

Submit a description of the training program that will be provided to these individuals.

Item 12 INSTRUMENTATION

A. Area Monitors

Radiation levels in high radiation areas must be continuously monitored with readout at the cyclotron controls.

Area monitors must be on separate circuits from control and interlock systems, and must give an audible warning when pre-set radiation levels are exceeded.

Submit a description of the area monitors installed in high radiation areas and other areas and what the pre-set alarm point for each monitor is. Also, describe fail-safe features in case of malfunction or radiation damage.

Area badges can be used to assess exposures over time in other areas such as those adjacent to transport tubing, filter banks, etc., to demonstrate compliance with Part 38 limits.

Describe any actual or anticipated use of area badges for monitoring purposes.

B. Survey Meters

You must provide appropriate survey instruments for contamination surveys, measuring exposure rates in work and storage areas, and on incoming and outgoing packages and for personnel frisking.

These should include meters with thin window pancake probes and audible signals for surface contamination surveys, a high range ion chamber that will measure up to 1R/hr and microrem meters for frisking personnel and "cold" waste.

Please list the instruments that will be provided by make, model, type, range and quantity.

C. Analytical Equipment

You must also have a well counter for analysis of wipe tests.

List the make, model and type of each analytical instrument and the lower limit of detection for nuclides of interest.
Also, submit procedures for annual calibration of equipment, and for QC on days of use.

Item 13 CALIBRATION AND OPERATIONAL CHECKS FOR INSTRUMENTATION

Describe your program for performing operational checks of all equipment listed in Item 12.

Include frequencies, methods, criteria and actions to be taken when equipment is found to be malfunctioning.

Item 14. PERSONNEL MONITORING AND BIOASSAYS

You must establish and implement procedures for a personnel monitoring and bioassay program. At a minimum, these procedures must include the following requirements:

A. Whole body badges will be provided to all staff who handle radioactive materials on a regular basis. They will be exchanged for processing on a monthly basis, by a processor accredited by NVLAP.

B. Finger badges will be provided to all staff who handle radioactive materials on a regular basis.

C. Finger badges issued to Nuclear Pharmacists and authorized users that manipulate large quantities of loose radioactive materials will be exchanged for processing on a weekly basis, as will finger badges for any other staff who elute generators.

D. Finger badges issued to other staff will be exchanged for processing on a monthly basis.

E. Provide audible dosimeters (chirpers) to staff who will work around or handle large quantities of material, especially during the early stages of facility operation.

F. Provide personnel monitoring for visitors to your facility. If you envision large numbers of visitors, this may involve considerable planning in advance.

G. If pregnant staff will be permitted to work in controlled areas, you must describe how they will be monitored and what criteria you will use for exposure to the worker and to the fetus.

Item 15. FACILITIES AND EQUIPMENT

You must provide a detailed description of the facilities at which you propose to conduct your program, and the equipment you will have available for shielding, handling, storage and processing of radioactive materials.

A. Facility layout should be shown on scaled drawings, clearly showing the overall layout and use of all areas within, and contiguous to, your facility. Drawings of each use and storage area should also be submitted, and should clearly show the location of all equipment, including: hot cells, remote handling equipment, radionuclide transport systems, effluent monitors, filters, traps and hold-up systems, interlocks, ventilation systems, hoods, scram buttons, warning lights and audible warning devices, fixed monitoring systems and viewing/communication systems. The drawings should also indicate areas for receipt of radioactive materials both during and after hours, and how security will be maintained.

B. Provisions for security, fire detection and fire suppression should also be described. This should include the type of doors and locks, any window barriers, sprinkler systems, alarms, etc.

C. The location of the facility, the uses of surrounding buildings and the zoning should also be described. The Department will only license the use of radioactive materials for nuclear pharmacy in an appropriate, commercially zoned location. Areas with heavy public traffic such as office buildings or large shopping centers are not appropriate due to the potential for an accident involving a large airborne release, or the spread of radioactive contamination in significant quantities.

D. The ventilation system for your facility must be designed by a qualified individual, experienced in the design of ventilation systems for facilities using large quantities of radioactive materials; and must be tested in-place prior to the start of licensed operations. Areas where volatile or gaseous materials are used or stored, or where radiopharmaceutical preparations are heated, should be at negative pressure and equipped with fume hoods.

In a multi-tenant building, you must also provide assurance that air from your premises will not be circulated to other areas of the building.

Submit a diagram of your ventilation system showing measured air supply and exhaust data and exhaust points (you may submit calculated or design values if the system is not yet completed, and submit actual measurements before operations begin). You should also submit a commitment to repeat such measurements at six month intervals and make any necessary repairs or adjustments to maintain the airflow as designed.

E. Interlocks

Each safety interlock must be on a circuit which is independent of all other safety

interlocks, and must be designed so that interlock failure will prevent operation of the cyclotron. In addition, interlocks must require manual re-set at the interlock and lastly at the controls after a trip.

1. Vault doors must be interlocked to cyclotron controls so that operation of the cyclotron is not possible unless doors are closed (in a fully shielded configuration) and so that operation will be interrupted if an interlock is tripped.

2. Stack monitors should be interlocked to cyclotron operation so that cyclotron operation is not possible unless monitors are operating.

3. Supply and exhaust fans for hood and hot cells should be interlocked.

4. Other areas which will be high radiation areas during cyclotron operation must have barriers to prevent access during operation. Such barriers must be interlocked to prevent cyclotron operation if the barrier is not in place and to interrupt operation if the barrier is penetrated.

Describe all interlocks by location and function, confirm that they meet the criteria above and describe any fail-safe features for interlocks that could be degraded in high radiation areas.

F. Warning Lights

1. Above each cyclotron vault entrance there must be a flashing or rotating red light that is activated automatically and only when radiation is being produced. Confirm that such a warning light will be installed at each entrance and that it will have a back-up feature such as an audible alarm that will sound if radiation is produced and the light does not function.

2. Similar warning lights must be installed at the entrance to all areas accessible to humans which will be high radiation areas when the cyclotron is operated.

Describe all warning lights by location and function and confirm that those that signify high radiation areas meet the criteria above.

G. Safety Devices

1. Stack monitors should have alarms that signal when pre-set radiation levels have been exceeded.

Describe these alarms and how the set-points will be chosen.

2. Scram switches must be located in all high radiation areas accessible to humans. Each switch must be clearly identified and have a positive indication

of the operative position. Each switch must require manual reset at the switch before the cyclotron can be re-started at the main control.

3. Audible warning devices must be provided in all areas with scram switches. The audible signal must give warning at least 15 seconds before radiation is produced in the area.

Describe scram switches and audible warning devices by location and function; including any fail-safe features for scram switches that could be degraded in high radiation fields.

H. Shielding must be provided to maintain staff exposures ALARA below regulatory limits. Describe the shielding you will provide for:

1. Irradiated components (targets, windows, collimators, etc.);

2. Storage of other radioactive materials including calibration check sources;

3. Radioactive materials handling areas; and

4. Radioactive waste storage, both in use areas and storage rooms. Waste containers should also have shielded covers to reduce workers exposure.

Item 16. RADIATION PROTECTION PROGRAM

You are required by section 38.17 of Code Rule 38 to develop, document and implement a radiation protection program commensurate with the scope and extent of the radioactive materials use authorized by the license. Responses to the following sections will be evaluated to determine if your program is adequate to protect health and safety.

A. Submit a commitment to conduct, or have conducted, an annual review of the radiation protection program content and implementation, and of the performance of your radiation safety officer. You should include the qualifications of the person or persons who will conduct the audit and what will be covered. The latter can be satisfied by submitting a copy of the form to be used.

B. All survey and monitoring procedures must be in accordance with protocols established by a qualified expert (see **NOTE**) or the Radiation Safety Officer (RSO) and contained in a manual. The manual must be updated on an annual basis, made readily available to staff and included in initial and annual instruction given to facility staff who will be engaged in work under the license. Confirm that this will be done.

Submit your procedures for:

1. Surveys of personnel for contamination before leaving use areas. Describe equipment provided (friskers for hands, large area monitors for shoes, portable

instruments for clothing, etc.) and locations where each piece of equipment will be available.

2. Surveys for ambient radiation levels (including use of fixed monitors). Describe the surveys or monitoring to be performed in each area; including equipment to be used, frequencies and action levels. Be sure to include procedures and equipment for neutron surveys; and survey procedures for transport tubing, rabbit systems, filters, etc., to ensure compliance with Part 38 limits for controlled and non-controlled areas and ALARA considerations.

3. Surveys for radioactive contamination. Describe the areas to be surveyed, equipment to be used, frequencies, and action levels. Be sure to include surveys of storage areas for QC sources and phantoms to detect any leakage early.

4. Surveys for airborne radioactive materials. Describe the areas to be surveyed, equipment to be used, frequencies, action levels and assessment of internal doses to staff. Your procedures should also address documentation of data sufficient to demonstrate compliance with Part 38 limits on airborne concentrations in controlled and non-controlled areas within your facility (your releases to the environment will be regulated by the NYSDEC).

NOTE: The surveys described here are for routine operations. A survey must be performed <u>prior</u> to routine operation of the cyclotron or after changes in shielding (or other major change), by a qualified expert who has the following training and experience:

a. A baccalaureate degree, a master's degree or a doctorate in radiological physics or a closely related field such as physics or health physics; and who has participated in the design and radiation survey of at least two facilities which are similar in design complexity, intended uses and beam characteristics (including energies), and who has had primary responsibility for the design and radiation survey of at least one similar facility.

b. The design experience described above must have included calculation and specification of shielding requirements; design and layout of any ancillary equipment such as hot cells and radionuclide handling and transport systems; and design or monitoring, warning and safety systems.

C. General rules for Safe Use of Radioactive Materials.

Appendix A contains a set of general rules acceptable to the Department. You may respond to this section by <u>stating</u> that you will adopt and implement the procedures in Appendix A of NYSDOH Radiation Guide 1.12 (Rev. 2007).

D. <u>Submit</u> your procedures for:

1. Responding to a minor spill or release of radioactive materials (define a "minor" quantity), with procedures to address both surface and airborne release pathways.

2. Responding to a major spill or release of radioactive materials (define a ""major" quantity), with procedures to address both surface and airborne release pathways.

   You should specifically discuss possible accidental releases of radioactive liquids and gases to non-controlled areas and any provisions you will make to enable early detection and measurement of such releases. This should include establishing time limits for delivery of liquids or gases that are transported via tubing so that a time action level is set for assuming leakage and beginning emergency procedures.

3. Confirm that these procedures will be included in initial and annual instruction given to staff who will engage in work under this license, and that this instruction will include annual exercises of emergency procedures.

4. Confirm that outlines of emergency procedures will be posed at the cyclotron control panel and in all areas which could be impacted in the event of a release.

E. Submit your procedures (including to the extent possible, identification by title only of the staff who will perform various functions) for:

1. Physical inspection before each cyclotron operation, of all areas that will be high radiation areas during operation to be sure they are unoccupied.

2. Securing cyclotron controls and access to radiation areas during both the normal workday and after hours, to prevent unauthorized use or entry. You should consider possible inadvertent entry by patients, housekeeping staff, etc., into radiation areas, and possible unauthorized use of the cyclotron or cyclotron products by staff.

3. Operating, testing, and servicing of traps, filters and hold-up systems (including exchange procedures) and the frequency for each action described. You should include relevant calculations and any assumptions made.

4. Testing tubing used for radionuclide transport for leaks (including frequencies). Also, indicate whether spare tubes will be installed as back-ups in case leaks are detected and whether such spare tubes will be included in regular testing.

5. Testing alarms, non-passive warning and access restrictions systems, interlocks, scram switches, monitoring devices, etc., for proper operation. You

should include the equipment that will be tested, test method, frequency and criteria for action.

6. Monitoring to ensure that airflow and pressure differences within the facility are maintained in accordance with a ventilation plan approved by a Certified Industrial Hygienist with experience in airborne radioactive materials hazards.

   Your procedures should include a monitoring plan, equipment to be used, frequencies and action levels. If any seals or other devices necessary to maintenance of the intended ventilation pattern require testing, describe the tests that will be performed along with frequencies and action levels.

   If this is an original application, submit the credentials of the Certified Industrial Hygienist who has approved your ventilation plan system.

F. Procedure Manuals for Operation of the Cyclotron and for handling and processing of cyclotron produced radioactive materials.

1. You must have operating manuals which clearly describe procedures to be followed by persons who will be involved in operation of the cyclotron and/or the handling and processing of cyclotron produced radioactive materials.

2. The manuals must be updated on an annual basis, included in initial and annual instruction to staff who will be engaged in work under the license and copies must be available in the relevant work areas.

3. The manuals must include at a minimum:

   a. Actions to be taken prior to cyclotron operation such as physical checks for occupancy of controlled areas, locking access doors, operational checks of radiation monitors, etc.

   b. Criteria for entry into the cyclotron and target vaults after cyclotron operation.

   c. Use of shielding, personnel monitoring, protective devices and contamination safeguards.

   d. Use of “rabbit” transport systems in accordance with facility policies, such as: using only for cyclotron produced materials, calling ahead to received before each transport, use of tracking system, reporting of problems, care and maintenance of rabbit containers, etc.

   e. Procedures for operation and maintenance of the cyclotron.

   f. Procedures for handling and/or processing of cyclotron produced

radioactive materials.

Submit your operating manuals.

Item 17 WASTE DISPOSAL (SEE ITEM _____)

Item 18 CERTIFICATION

The application should be signed by the President or CEO of the company and countersigned by the chief operating officer or general manager of the specific location being licensed. Identify the titles of the signators.

Please enter the name and telephone number of a person to be contacted about the contents of the application.

4. ADDITIONAL DOCUMENTS TO BE SUBMITTED

In addition to the foregoing, you must 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. 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 (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, representation, 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 II 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.

APPENDIX A

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used or stored (e.g., processing, packaging, and waste areas).

2. Always wear disposable gloves when handling radioactive materials, or articles that may be contaminated with radioactive materials (such as empty containers), or surfaces where radioactive materials have been used.

3. Monitor hands and clothing for contamination after each handling procedure or when leaving an area where radioactive materials are used or stored.

4. Always use syringe shields, vial shields and tongs for preparing, dispensing and assaying radiopharmaceuticals.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects with radioactive material.

7. Always wear your personal monitoring badges in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. When not being worn to monitor occupational exposures, badges should be stored in the designated low-background area.

8. Always wear finger badges when handling millicurie quantities of radioactive material. Finger badges must also be worn when removing the contents of returned radiopharmaceutical cases.

9. Never pipette by mouth.

10. Waste from use and storage areas must be surveyed with a microrem meter to determine whether it is radioactively contaminated before disposal. Dispose of radioactive waste only in specifically designated and properly shielded receptacles.

11. Confine radioactive solutions in covered containers that are clearly identified and labeled with the name of the compound, radionuclide, date and activity.

12. Always transport radioactive material in appropriately shielded containers.