Radioactive Material License Guide

Medical Use

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INTRODUCTION

General:

This guide describes the type and extent of information needed by the Radiation Licensing Section staff to evaluate an application for a specific license for the possession and use of radioactive material. This type of license is provided for under LAC 33:XV.324 and 325. The applicant should carefully study the regulations and this guide and submit all information requested. Please remember that any necessary information that is not submitted will delay completion of the review of your application.

The Radiation Licensing Section usually issues a single radioactive material license to cover an institution's entire radioisotope program. Separate licenses are not normally issued to different departments of a medical institution nor are they issued to individuals associated with the institution. A separate license may be issued for teletherapy or gamma stereotactic radiosurgery if it is necessary.

Purpose of Guide:

This guide is designed to describe the type and extent of information needed by the Department to evaluate an application for a medical use license and to describe the medical use byproduct material regulations. This guide does not apply to academic programs that do not use byproduct material for medical use.

Purpose of Appendices to Guide:

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through S to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for its specific radiation safety needs.

Applicable Regulations:

The following chapters of LAC 33:XV apply to medical programs and should be used in conjunction with this guide. The applicant should carefully study the regulations and this guide and submit all the information requested. This guide does not substitute for understanding the requirements of the regulations.

A. Chapter 1 - General Provisions

B. Chapter 3 - Licensing of Radioactive Material

C. Chapter 4 - Standards for Protection Against Radiation

D. Chapter 7 - Use of Radionuclides in the Healing Arts

E. Chapter 10 - Notices, Instructions and Reports to Workers; Inspections

Please note that this guide is intended only for general guidance in preparation of the license application and should not be considered a substitute for the applicant's safety evaluation of the proposed use of radioactive material. The applicant must insure that the application correctly and adequately describes the radiation safety measures and procedures to be followed in order to provide adequate protection.

AS LOW AS REASONABLY ACHIEVABLE: (ALARA)

The applicant should, in addition to complying with the requirements set forth in LAC 33:XV, make every reasonable effort to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as reasonably achievable (ALARA). The term "as low as in reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socio-economic considerations, and in relation to the utilization of ionizing radiation in the public interest.

ALARA in Medical Institutions:

Each medical licensee must have a formal ALARA program (see LAC 33:XV.705). The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of byproduct material is required by LAC 33:XV.707 to review uses for safety and ALARA considerations.

The Committee, the RSO and management should audit the byproduct material program to ensure the continued safe use of byproduct material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program.

A model ALARA management program is contained in Appendix G to this guide. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

Types of Medical Licenses:

A specific license may be issued to institutions detailing each radioisotope and clinical use performed by physicians named on the institution's license. If the physicians have met the training and experience criteria applicable for the intended program and the proposed radiation safety program is acceptable, a license will be issued.

Specific licenses of broad scope for medical use, such as licenses authorizing multiple quantities and types of radioactive material for unspecified uses, are issued to institutions that 1) have had previous experience operating under a specific institutional license of limited scope; and 2) are engaged in medical research as well as routine diagnostic and therapy procedures using radioisotopes. Such programs operate under the supervision of a medical isotopes committee. Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and procedures are approved by the institution's medical isotope committee. Physicians may obtain basic and clinical radioisotope training and experience in the use of radiopharmaceuticals in such programs. This type of license is not appropriate for most institutions using radioactive material in medical programs.

Chapter 7 divides byproduct material for medical use into different types of use. You may indicate only the types of use you want or if you do not want all the material listed in Chapter 7, you must identify the material you do want from that section.

Radioactive aerosols and gases may be used only if specific application is made to and approved by the Department.

License Fees:

A fee is required for all initial applications and for licenses that are required to be reissued. The applicant should refer to the Department's fee schedule LAC 33:XV.Chapter 25 to determine the amount of the fee that must accompany the application. Review of the application will not begin until the proper fee is received by the Department. If you have any questions concerning the fee or the amount to submit, please do not hesitate to contact the Department.

Filing an Application:

A license application for radioactive material should be submitted on Form DRC-11, "Application for Radioactive Material License". The applicant should complete all items on the application form in sufficient detail for the Department to determine that the applicant's equipment, facilities, personnel training and qualifications, and radiation protection program are adequate to protect health and to minimize danger to property.

Only a single copy of the application and all attachments needs to be submitted to the Department. The applicant should retain one copy, since the license will require as a condition that the institution follow the statements and representations set forth in the application and any supplements.

Since the space on Forms DRC-11 and 13 is usually not sufficient to contain all of the required information, additional sheets should be appended. A heading indicating the appropriate item number should identify each separate sheet or document submitted with the application. When completed, Form DRC-11 should be signed and dated by a representative of the institution's management.

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 applications and other correspondence with the Department (2) the terms and conditions of the license, and (3) the Department's regulations.

It is your obligation to keep your license current. Anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit an application or letter for a license amendment. Meanwhile, 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 based on a submission requesting an amendment to your license, except as allowed by notification.

Your amendment letter should state your license number and clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and identify the pertinent information by date, page, paragraph, or letter.

Renewal of a License:

Initial licenses are issued for a period of up to 5 years. Send an application for renewal (RAD-40 form) to address specified at top of the form. Licensees are required to submit a full license application and corresponding attachments every 9 years. A new application ensures that the program contains all needed information as requested in current licensing guidance.

In accordance with LAC 33:XV.332.C, you should file your application for renewal at least 30 days before the expiration date of your license. However, if you file an application less than 30 days before the expiration date and the Department cannot process it before that date, you will be without a valid license when your license expires.

Termination of a License:

You may request termination of your license at any time. This request may include a completed RAD-14, "Radioactive Material License Termination" form or a letter, with the appropriate documentation certifying that all sources have been disposed of in a manner authorized in LAC 33:XV.332. There is no fee for licensees who request to terminate their license and send in the appropriate documentation.

CONTENTS OF APPLICATION

This portion of the guide explains, item by item, the information requested on Form DRC-11. The appendices to this guide serve several different purposes, i.e., to provide additional information on certain subject areas, to provide a model procedure the licensee may adopt in response to an item on the application form, or to provide an outline the applicant may use to develop a procedure for review the Department staff.

Form DRC-11

Item 1 – Name of Applicant/Mailing Address/Telephone Number. The name provided must be the legal business name of the company with direct control over the proposed uses of radioactive material. A division or department within the business should not be identified as the primary business name. If a physician is requesting use of radioactive material at his office, then he is named as the applicant. If radioactive material is to be stored and used at an institution, the institution is named as the applicant.

Provide the mailing address where correspondence should be sent. A post office box number is acceptable. Provide a good telephone number and email address for the RSO or primary contact for this application.

Item 2 – License Action Type. Indicate whether this is an application for a new license, an amendment, or a renewal.

For a new license application, a pre-licensing site visit may be conducted prior to the issuance of the license.

Item 3 – Location or Address Where RAM Use/Or Stored. If the mailing address in Item 1 is a post office box or if different from the location where medical radioisotopes will be used and/or stored, then enter the physical address where medical radioisotopes will be primarily used. A post office box address is not acceptable. If appropriate, specify the department or location within the institution where medical radioisotopes will be used and/or stored. If radioactive material is to be

used at more than one location, you must give the specific address of each location. You can submit these locations in an attachment, if needed.

Temporary job site means a location, other than the specific location(s) of use authorized on the license, where mobile medical services are conducted for limited periods of time.

A license amendment is required before receiving, using, or storing licensed material at an address or location not already listed on the license.

An email is recommended for communication for the license application and information that may need to be given to licensees at any time. You may use an RSO for the email communication or anyone that would be a good radiation contact.

Item 4 – Radiation Program Personnel. Each applicant shall appoint a Radiation Safety Officer (RSO) in accordance with LAC 33:XV.706. The applicant may appoint one or more Associate Radiation Safety Officers (ARSO)s to support the RSO. The ARSO is delegated radiation safety duties and tasks by the RSO for the types of uses for which he/she is listed on the license. The training and experience requirements for the RSO and ARSOs are described in LAC 33:XV.763.A. See Appendix S.

Radiation Safety Officer:

The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in LAC 33:XV.708 to ensure that radioactive materials are used in a safe manner. Typical RSO duties are described in the list below and in Appendix F of this licensing guide. The department requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix F of this licensing guide also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO. Instructions for documenting training and experience can be found in Appendix S of this licensing guide. The RSO is often directly employed by the licensed facility. However, the department has authorized individuals who are not directly employed by the licensee, such as consultants, to fill the role of RSO or to provide support to the facility RSO. To fulfill the duties and responsibilities, the RSO should be onsite periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of LAC 33:XV.706 and 708.

RSO Responsibilities: Some of the typical duties and responsibilities of RSOs include the following:

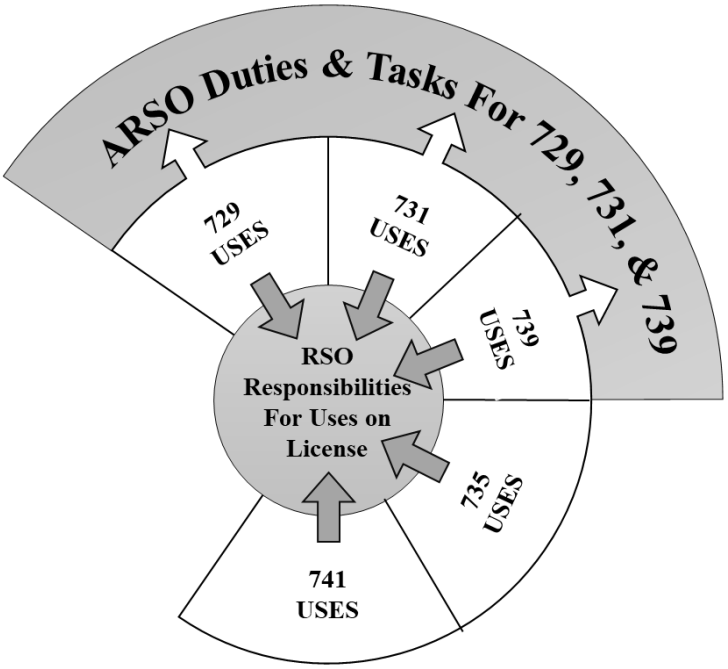
- stopping unsafe activities involving licensed materials
- developing and maintaining an ALARA program
- conducting material accountability and disposal
- interacting with the NRC
- providing timely and accurate reporting and maintenance of appropriate records
- conducting annual program audits
- ensuring proper use and routine maintenance
- monitoring inventory and leak tests of sealed sources
- ensuring personnel are trained
- overseeing ordering, receipt, surveys, and delivery of byproduct material
- packaging, labeling, surveying, etc., of all shipments of byproduct material leaving the institution
- overseeing the waste disposal program
- controlling monitoring programs, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- conducting investigations of incidents involving byproduct material (e.g., medical events) and notifying appropriate agencies
- assigning specific duties and tasks to an ARSO, restricted to the types of use for which the ARSO is listed on the license
- for licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, participating in the development and implementation of a security program for radioactive material in accordance with LAC 33:XV Chapter 16, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

Associate Radiation Safety Officer (ARSO):

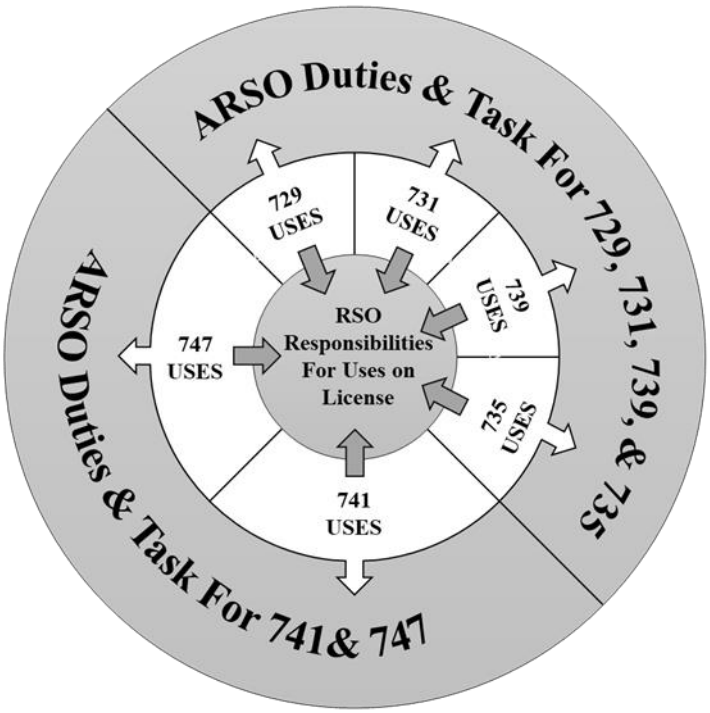
A licensee may choose to identify one or more individuals as ARSOs to support the RSO in accordance with LAC 33:XV.706. The ARSOs may be assigned duties and tasks in the oversight of the radiation safety operations of designated sections of the licensed program, but the RSO retains responsibility for all sections of the program. Figures (a) - (c) provides illustrative examples of potential ARSO duties and tasks with the RSO retaining overall responsibilities for all uses listed on a license in different size programs.

The ARSOs are required, per LAC 33:XV.763.A, to complete the same training and experience requirements as the named RSO for their assigned sections of the radiation safety program. The RSO, with written agreement from licensee management, may assign duties and tasks to each ARSO that are limited to the types of use for which the ARSO is listed on the license. The ARSOs would perform duties and tasks in the oversight of the radiation safety operations of their assigned sections of the program, while reporting to the named RSO. The regulations

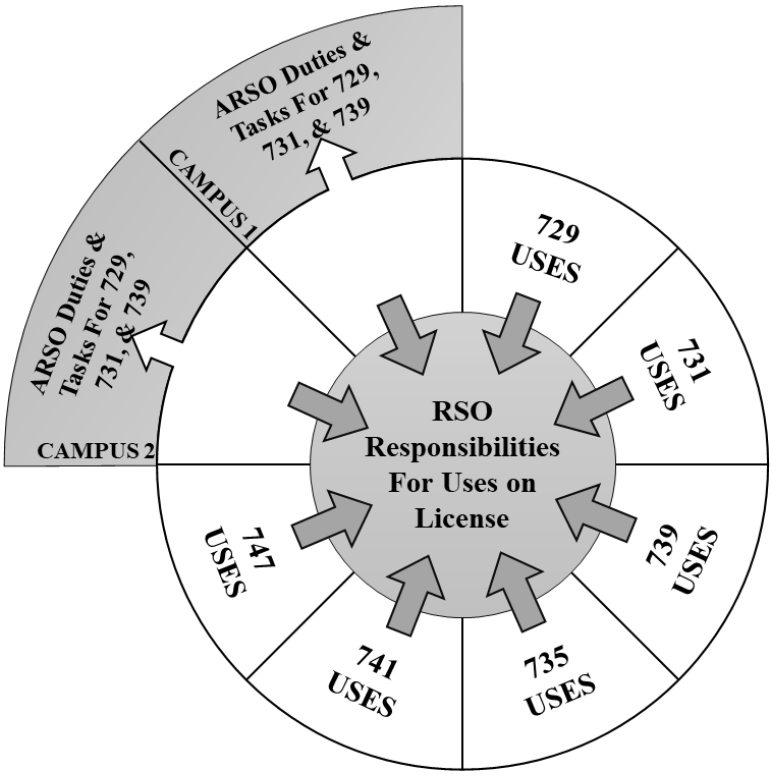
continue to allow a licensee to name only one RSO on a license. Licensees with multiple operating locations or multiple types of uses can appoint a qualified ARSO at each location or for each type of byproduct material used. These individuals will be listed on the license as ARSOs. Their assigned sections of the program will also be listed.



(a)


ARSO Duties & Task For 729, 731, 739, & 735
ARSO Duties & Task For 741& 747
729 USES
731 USES
739 USES
735 USES
741 USES
747 USES
RSO Responsibilities For Uses on License

(b)



(c)

(a) A moderate-sized program–the RSO is responsible for the entire program and has direct oversight over the LAC 33:XV.735 and LAC 33:XV.741 medical uses–a single ARSO has oversight duties and tasks for LAC 33:XV.729, LAC 33:XV.731, and LAC 33:XV.739 medical uses and reports to the RSO.

(b) A larger, single-campus program–the RSO is responsible for the entire program–there are two ARSOs with oversight duties and tasks over different sections of the program and both report to the RSO.

(c) A large, multi-campus program–the RSO is responsible for the entire program–there are two ARSOs with oversight duties and tasks over the two smaller campuses. Both ARSOs report to the RSO.

Before the ARSO may be assigned duties and tasks in the oversight of the radiation safety operations of a different section of the program, the licensee must amend the license and provide documentation that the individual meets the training and experience requirements for the new duties and tasks. As the ARSOs have the same training and experience requirements as an RSO,

the ARSOs will qualify to be named as the RSO on other licenses for the types of uses for which they are listed.

Individual(s) or Committee Responsible for Use:

List the names of physicians who will use, supervise, or direct the use of radioactive material. Acceptable training and experience for physicians is specified in Appendix S of this guide. This list should include the physicians who supervise other physicians in training and/or who direct technologists or other paramedical personnel who use radioactive material for human or non-human use. Non-physicians may only be authorized to use radioactive material for non-human use, e.g., instrument calibration or in vitro procedures.

Authorized physician users have the following responsibilities:

A. approving of procedures involving the administration of radiopharmaceuticals to patients or the application of radiation from radioisotope sources to patients;

B. prescribing the radiopharmaceuticals or source of radiation and the amount of or dosage to be administered;

C. determining the route of administration; and

D. interpreting the results of diagnostic procedures in which radiopharmaceuticals are administered.

Items A through D may be delegated to physicians who are in training under the supervision of authorized physician users.

Supervision means that the authorized user has adequately instructed the physician in training in the specific human use of radioactive materials and has also ascertained that safe use of these materials in humans has been properly emphasized to the physician in training. It also means that the physician user periodically reviews the work of those supervised and assures him that proper medical records are made of each use. It is required that the authorized user be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material).

Properly trained technicians, technologists, or other paramedical personnel under an authorized user's direction may be delegated to the following activities:

A. the preparation and quality control testing of radiopharmaceuticals and sources of radiation;

B. the assay of radiopharmaceutical dosages prior to administration;

C. the use of appropriate instrumentation for the collection of data used by the physician; and

D. the administration of radiopharmaceuticals or radiation from radioisotope sources to patients if permitted under applicable federal, state or local laws. This delegation should be made in writing.

A qualified individual must be designated the responsibility for radiation protection (radiation safety officer). Such an individual may be a physician user or other qualified person. The name and title of the person designated by and responsible to the institution's management for the coordination of the institution's radiation safety program should be included under radiation program personnel. If the radiation safety officer is assisted by a consultant or part time employee, state the individual's name and describe his duties and responsibilities. If the radiation safety officer is not one of the physician users, submit a complete description of his training and experience.

The names of any technicians directly associated with the medical radioactive material program should be listed, and their qualifications and training should be given on the back of Form DRC-13, under radiological training and qualifications. For more details concerning training, please refer to Appendix A.

Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that, by hiring a contractor (e.g., consultant) to provide certain services, it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program, including the training of contractor staff, is effectively implemented by the appropriate individuals.

Item 5 - Personnel Monitoring:

External dose:
The use of individual monitoring devices for external dose is required, pursuant to LAC 33:XV.431.
In accordance with LAC 33:XV.410., licensees shall control occupational dose to individuals to the following limits:

1. an annual limit, which is the more limiting of:
   a. the total effective dose equivalent being equal to 0.05 Sv (5 rem); or
   b. the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem); and

2. the annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:
   a. a lens dose equivalent of 0.15 Sv (15 rem); and
   b. a shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

Personnel monitoring is required for all physicians and technicians associated with medical radioisotope programs utilizing either radioactive drugs or sealed sources, such as cesium, radium, cobalt, or iridium. In a sealed source program, there is the possibility that extremely high radiation exposures may occur in a short period of time; therefore, the use of pocket dosimeters or pocket chambers is encouraged as a means of an immediate indication of exposure. If pocket chambers or dosimeters are to be used, then complete the requested information in Item 5.B of Form DRC-11.

Internal dose:

Internal exposure monitoring is required, pursuant to LAC 33:XV.431.B for the following:

1. adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of LAC 33:XV.499.Appendix B; and
2. minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

If internal dose assessment is necessary, the applicant shall measure the following:
- concentrations of radioactive material in air in work areas
- quantities of radionuclides in the body
- quantities of radionuclides excreted from the body
- combinations of these measurements

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassays (both in vivo and in vitro) will be performed to evaluate intakes. The criteria should also describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments (i.e., the empirical models used to interpret the raw bioassay data). The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. If a commercial bioassay service will be used, the applicant should ensure that the service is licensed by the NRC or an Agreement State for that service or provide an alternative for review. Acceptable criteria that applicants may use in developing their bioassay programs are outlined in RG 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” July 1993.

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses, dosimeters must be processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited processor [LAC 33:XV.430.C)]. Most licensees use either OSLs, TLDs, or film badges. The

exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-accredited processor for its recommendations for exchange frequency and proper use of the dosimeter. The NIST maintains a directory of laboratories that are NVLAP-accredited.

See APPENDIX D of this guide for model procedures for monitoring external occupational exposure.

Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn in such a way that the part of the body likely to receive the greatest dose will be monitored.

Item 6 - Contamination Surveys and Area Surveys:

Licensees are required to make surveys of potential radiological hazards in their workplace.

For example, licensees must perform surveys to:

- Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 1 mSv/yr [100 mrem/yr] and that the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour from licensed operations in accordance with LAC 33:XV.421.

- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in LAC 33:XV.410.

- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.

- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in LAC 33:XV.406.

There are many different kinds of surveys performed by licensees:

- contamination (fixed, removable)
- personnel (during use, transfer, or disposal of licensed material)
- air effluent
- water effluent
- leak test
- bioassays
- air sample
- external radiation exposure levels
- restricted areas
- unrestricted areas

Surveys are required when it is reasonable under the circumstances to evaluate a radiological

hazard and when necessary for the licensee to comply with the appropriate regulations. Typical surveys may include:

- surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas (Refer to NRC RG 8.25, "Air Sampling in the Workplace," June 1992,)
- bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe.
- surveys of external radiation exposure levels in both restricted and unrestricted areas
- surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier)

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. Appendix N of this licensing guide contains model procedures that represent one acceptable method of establishing survey frequencies for medical use, ambient radiation levels, and contamination surveys.

For example, in accordance with LAC 33:XV.724, medical use licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals for which a written directive (WD) is required {diagnostic activities exceeding 1.11 MBq [30 µCi] of I-131 and all therapy treatments}. When the licensee administers radiopharmaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey within the patient's room. Licensees should be cognizant of the requirement to perform surveys to demonstrate that public dose limits are not exceeded in adjacent areas. In addition, licensees should perform surveys after the patient's release, in accordance with LAC 33:XV.737, and must perform surveys prior to the release of the room for unrestricted use.

As sealed sources (including within applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed, the licensee must perform surveys in accordance with LAC 33:XV.745:

- Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

- Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a survey of the patient or human research

subject with a radiation survey instrument to confirm that all sources have been removed.

In addition, the licensee should also consider surveying the following:

- the patient's bed linens before removing them from the patient's room
- the operating room and the patient's room after source implantation (e.g., radiation level and/or visual check)
- all trash exiting the patient's room or surgical recovery room
- areas of public access in and around the patient's room

In accordance with LAC 33:XV.725, the licensee must survey patients and the remote afterloader unit to confirm that the source has been removed from the patient and returned to the safe shielded position.

SEE APPENDIX N for model procedures.

Item 7 - Leak Test:

Licensees must perform leak testing of sealed sources possessed under 10 CFR Part 35 (LAC 33:XV.Chapter 7 e.g., calibration, transmission, reference, or brachytherapy sources), in accordance with LAC 33:XV.719, "Requirements for possession of sealed sources and brachytherapy sources." In addition, licensees must perform leak testing of all other sealed sources in accordance with LAC 33.XV.426.

Acceptable testing is conducted by an organization licensed by LDEQ, the NRC or an Agreement State or if it is conducted in accordance with procedures submitted by the applicant and approved by LDEQ, the NRC or an Agreement State. Leak test records shall be retained for 3 years after they are made or until the source in storage is removed.

Appendix H of this licensing guide provides model procedures that represent one acceptable method to perform leak testing for sealed sources. [LAC 33:XV.719] Licensees are required to perform leak tests at 6-month intervals or at other intervals approved by the Department, the NRC or an Agreement State and specified in the SSD registration certificate and before first use, unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq [0.005 µCi] of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The leak test may be performed in-house or by a contractor who is authorized by the Department, the NRC or an Agreement State to perform leak tests as a service to other licensees.

The licensee or contractor does not need to leak test sources if:

- Sources contain only byproduct material with a half-life of less than 30 days.
- Sources contain only byproduct material as a gas.
- Sources contain 3.7 MBq [100 µCi] or less of beta emitting or gamma-emitting material, or 0.37 MBq [10 µCi] or less of alpha emitting material. Sources contain iridium-192 seeds in nylon ribbon.
- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer, unless it has been leak-tested within 6 months before the date of use or transfer

Item 8 - Waste Disposal:

Licensed material must be disposed of in accordance with department requirements by:

- Transfer to authorized recipients (LAC 33:XV.465)
- Decay in storage (LAC 33:XV.728)
- Release in effluents within limits in LAC 33:XV.421
- As authorized under LAC 33:XV.461.462.463.464 or 465.F

Licensees are required to develop, document, and implement a radiation protection program in accordance with LAC 33:XV.406, which must contain provisions for waste disposal of licensed material. See Appendix R for model waste disposal procedures.

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. The Department requires medical licensees to dispose of radioactive waste generated at their facilities in accordance with regulations in LAC 33:XV.460-465, and LAC 33:XV.728. Generally, medical licensees dispose of radioactive waste by one or both of the following methods:

- decay-in-storage (DIS)
- transfer to an authorized recipient

Licensees may choose any one or both of these methods to dispose of their radioactive waste.

Decay-in-Storage (DIS): The Department has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS and interim storage. The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as in-house trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with LAC 33:XV.453.B, all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within

containers and that will be managed as biomedical waste after they have been released in accordance with LAC 33:XV.728. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of such disposals.

Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with LAC 33:XV.460, LAC 33:XV.465, or in applicable regulations in LAC 33:XV.301 or LAC 33:XV.1303. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.

When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location and appropriately posted in accordance with LAC 33:XV.451. In addition, all storage containers must be appropriately labeled in accordance with LAC 33:XV.453.

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Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. Check and calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153) may not be held for DIS and must be disposed of in accordance with LAC 33:XV. Most medical licensees only dispose of radioactive waste with half-lives greater than 120 days by transfer to authorized recipients (e.g., low-level radioactive waste disposal facilities or manufacturers).

Other Waste Management Issues

- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under LAC 33:XV.422, “Compliance with dose limits for individual members of the public,” and LAC 33:XV.462, “Disposal by Release into Sanitary Sewerage,” respectively.

    — Regulations for disposal in sanitary sewerage appear in LAC 33:XV.462. Material must be readily soluble or dispersible in water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. [Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations.]

    — Limits on permissible concentrations in effluents to unrestricted areas are enumerated in LAC 33:XV.499.Appendix B. These limits apply at the boundary of the restricted area.

— Liquid scintillation-counting media containing 1.85 kBq [0.05 µCi] or less per gram of tritium (H-3) or carbon-14 may be disposed of without regard to its radioactivity [LAC 33:XV.464].

- Waste from in vitro kits (except mock I-125) that are generally licensed under LAC 33:XV.322.I is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

- Applicants who wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their response to Section 8.9.1, Facility Diagram:

  — Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations.

  — Provide manufacturer's specifications, annotated sketches or photographs, and other information about the compactor design.

  — Describe the type, quantities, and concentrations of waste to be compacted. — Provide an analysis of the potential for airborne release of radioactive material during compaction activities.

  — Provide the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtration systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.

  — Discuss the methods used to monitor worker breathing zones and/or exhaust systems.

  — Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area.

  — Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

Nuclear pacemakers:

Medical facilities are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted

pacemaker dies. In such cases, and when the medical facility is not responsible for control or disposal of the pacemaker, notify the Department and attempt to contact the hospital (licensee) where the pacemaker was implanted to address any removal or disposal concerns. The licensee that implanted the device is responsible for the follow-up, removal, and return of the pacemaker to the manufacturer for proper disposal. NRC's Information Notice 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

Item 9 - Health Physics Program:

a. **Radiation Safety Committee/Radiation Safety Officer**

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. Each medical institution licensee must establish a Radiation Safety Committee. If you are not an institution, you only need to submit the Radiation Safety Officer delegation of authority. SEE APPENDIX F.

b. **ALARA Program**

The As Low As Is Reasonably Achievable (ALARA) requirement in LAC 33:XV.406, "Radiation Protection Programs," regulations state that "each licensee shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Chapter." and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are…ALARA." This section also requires that licensees review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

References and Resources:
Applicants should consider the ALARA philosophy detailed in the following reports when developing plans to work with licensed radioactive materials. The following documents and resources contain information, methods, and references useful to those who are establishing radiation protection programs to maintain radiation exposures at ALARA levels in medical facilities:

- Regulatory Guide (RG) 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," August 2016.
- RG 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," February 1996.
- RG 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Is Reasonably Achievable," April 2011.

- NUREG–1736, "Consolidated Guidance: 10 CFR Part 20–Standards for Protection Against Radiation," contains information directly related to radiation protection standards in 10 CFR Part 20.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," December 31, 1990.
- NCRP Report No. 127, "Operational Radiation Safety Program," June 12, 1998.

See Appendix G for sample ALARA program.

c. **Training Program**

Individuals working with or in the vicinity of licensed material must have adequate safety instructions, as required by LAC 33:XV.705 and 1012. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide safety instructions, as required by LAC 33:XV.1012, "Instruction to Workers." Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in LAC 33:XV.736, 742 and 750. Under LAC 33:XV.709, the licensee's AUs and ANPs are required to provide safety instruction to all personnel using byproduct material under their supervision. Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in LAC 33:XV.Chapter 16) must implement a training program for those individuals implementing the security program.

Licensees must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instructions commensurate with their assigned duties, and if it is likely that they could receive doses over 1 mSv [100 mrem] in a year, they must receive instructions, as specified by LAC 33:XV.1012. For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 1 mSv [100 mrem], should be informed of the nature of the licensed material and the meaning of the radiation symbol and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security) may assist in controlling abnormal events, such as loss of radioactive material. In addition, licensees should ensure that contractor staff receives safety instructions.

In addition to safety instructions required by LAC 33:XV.1012, and in accordance with LAC 33:XV.736, 742 and 750, the licensee must provide radiation safety instructions to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with 10 CFR 35.75. This safety instruction should be commensurate with the duties of the personnel and include safe

handling of byproduct material, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU, if the patient has a medical emergency or dies. A licensee must retain a record of individuals receiving instruction in accordance with LAC 33:XV.750.F.

In accordance with LAC 33:XV.709.B, individuals working with licensed material under the supervision of an AU must receive instructions on the licensee's written radiation protection procedures, WD procedures, LDEQ regulations, and LDEQ license conditions, with respect to the use of byproduct material. In accordance with LAC 33:XV.709.C, a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an ANP or an AU, as allowed by LAC 33:XV.702, shall instruct the supervised individual in the preparation of byproduct material for medical use and require the individual to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and LDEQ regulations. Under LAC 33:XV.709.D, a licensee that permits supervised activities is responsible for the acts and omissions of the supervised individuals.

Appendix A of this licensing guide provides a model training program that provides one way to satisfy the requirements referenced above. In addition, the NRC Medical Uses Licensee Toolkit Web page provides guidance for training suggested for emerging technologies [e.g., yttrium(Y) -90 microsphere brachytherapy].

d. Operating and Emergency Procedures

Before using licensed material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of licensed material. The radiation protection program that licensees are required to develop, document, and implement in accordance with LAC 33:XV.406, must include provisions for responding to spills or other contamination events to prevent the spread of radioactive material. Appendix J of this licensing guide contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, State and local authorities, and LDEQ Radiation Section, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, and containment of spills and other releases, as well as appropriate methods for reentering and decontaminating facilities (when necessary).

e. <u>Spill Procedures</u>

Before using licensed material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of licensed

material.

The radiation protection program that licensees are required to develop, document, and implement in accordance with LAC 33:XV.406, must include provisions for responding to spills or other contamination events to prevent the spread of radioactive material. Appendix J of this licensing contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, State and local authorities, and LDEQ, Radiation Section, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, and containment of spills and other releases, as well as appropriate methods for reentering and decontaminating facilities (when necessary).

Submit a copy of your spill procedures.

f. Emergency Procedures for Therapy Devices Containing Sealed Sources

Before using materials under LAC 33:XV.747, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery (GSR) unit," the applicant must develop, document, implement, and submit written emergency procedures in accordance with LAC 33:XV.702. Regulations in LAC 33:XV.750, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a GSR unit. The procedures needed to meet LAC 33:XV.750 must include

- instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions
- the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure
- the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally

A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room. Regulations in LAC 33:XV.751, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require the physical presence of certain

individuals for therapy units to ensure that safety precautions are appropriately implemented. The following documents provide useful information regarding physical presence requirements:

- IN 2012-08, "High Dose-Rate Remote Afterloader (HDR) Physical Presence Requirements," April 10, 2012

- RIS 2005-23, "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments," October 7, 2005

When sources are placed within the patient's body, LAC 33:XV.751.E requires that licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source.

The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. The licensee must provide instructions, initially and annually, to include responding to an abnormal situation described in LAC 33:XV.750.A.4. Practice drills, using nonradioactive (dummy) sources when possible, must be practiced at least annually and may be conducted more frequently, as needed. Team practice is important for adequate emergency coordination. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators, if applicable, and emergency procedures for removing the patient from the radiation field. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.

- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing the safety of the patient.

- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.

- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should

include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.

- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).

- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.

- Specifying who is to be notified.

- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Provide procedures required by LAC 33:XV.750.

g. **Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources**

Applicants requesting authorization to install, maintain, adjust, repair, and inspect their own therapy devices containing sealed sources must develop, document, submit, and implement those procedures, in accordance with LAC 33:XV.406 and LAC 33:XV.324. In accordance with 10 CFR 35.605, "Installation, maintenance, adjustment, and repair," and LAC 33:XV.748, "Maintenance and Repair Restrictions," licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSD registration certificate. In addition, LAC 33:XV.762 requires that teletherapy and GSR units be fully inspected and serviced during source replacement. The interval between each full-inspection servicing shall not exceed 5 years for teletherapy and gamma stereotactic radiosurgery units to ensure that the source exposure mechanism and other safety components function properly. Maintenance is necessary to ensure that source integrity and safety components are not compromised and that the device functions as designed.

Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s). The Department requires that maintenance and repair (as

defined above) be performed only by persons specifically licensed by the Department, the NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review LAC 33:XV.748 before responding to this item. Regulations in LAC 33:XV.748 allow for an AMP to perform certain service activities with regard to LDR remote afterloader units.

No response is required if the licensee contracts with personnel who are licensed by the NRC or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee. However, if the applicant requests that one of its own employees, who is trained by the manufacturer, be authorized to perform the aforementioned activities, the applicant must provide sufficient information to allow the NRC to evaluate and approve such authorization in accordance with LAC 33:XV.748 and LAC 33:XV.762. This should include the following:

- name of the proposed employee(s) and types of activities requested AND
- description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested AND
- copy of the manufacturer's training certification and an outline of the training in procedures to be followed AND
- written commitment from the licensee that the trained employee will follow manufacturer procedures.

Note: The applicant should specify only those installation, maintenance, inspection, adjustment, and repair functions, as described in a certificate or letter from the manufacturer of the device, that document the employee's training in the requested function(s).

h. **Leak Test**

The Department requires testing to determine if there is any radioactive leakage from sealed sources. The Department finds testing to be acceptable if it is conducted by an organization licensed by the Department, the NRC or an Agreement State or if it is conducted in accordance with procedures submitted by the applicant and approved by the Department, the NRC or an Agreement State. Leak test records shall be retained for 3 years after they are made or until the source in storage is removed.

See Appendix H for example procedures for leak-testing sealed sources.

i. **Safe Use of Radiopharmaceuticals**

Before using licensed material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed licensed material.

The radiation protection program that licensees are required to develop, document, and implement, in accordance with LAC 33:XV.406, must include provisions for safe use of licensed material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material, from the time it arrives at their facilities until it is used, transferred, and disposed of. The written procedures should provide reasonable assurance that only appropriately trained personnel would handle and use licensed material without undue hazard to themselves, other workers, or members of the public. In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- use of syringe shields and/or vial shields, specific to the energy emitted (e.g., PET shields should be used when handling high-energy fluorine-18)
- wearing laboratory coats and gloves when handling unsealed byproduct material
- monitoring hands after handling unsealed byproduct material
- designing equipment and facilities to protect health and minimize danger to life or property in accordance with LAC 33:XV.325.A.2. Appendix I of this licensing guide contains model procedures that provide one acceptable method for the safe use of unsealed licensed material.

Submit a copy of your rules for the safe use of radiopharmaceuticals. SEE APPENDIX I.

j. **Ordering and Receiving**

The requirements for receiving packages containing licensed material are found in LAC 33:XV.455, "Procedures for receiving and opening packages." Additionally, the security of licensed material, required by LAC 33:XV.455.A and LAC 33:XV.455.B, must be considered for all receiving areas.

Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized. Appendix K of this licensing guide contains model procedures that represent one acceptable method for ordering and receiving licensed material.

Submit a copy of your procedure for ordering and receiving radioactive material.

k. **Opening Packages**

Licensees must establish, maintain, and retain written procedures for safely opening packages, to ensure that the monitoring requirements of LAC 33:XV.455 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. Appendix L of this licensing guide contains model procedures that represent one acceptable method for safely opening packages containing radioactive materials. Applicants are reminded that LAC 33:XV.455.C requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Submit your procedure for opening packages that contain radioactive material.

l. **Material Receipt and Accountability**

To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material. (LAC 33:XV.455.A and B)
- Maintain records of receipt, transfer, and disposal of licensed material. (LAC 33:XV.342, LAC 33:XV.340, and LAC 33:XV.478)
- Conduct physical inventories at required frequencies to account for licensed material. Ensure that material received does not exceed license possession limits.
- Update transactions in the NSTS, including an annual inventory reconciliation. (LAC 33:XV.493)
- Conduct physical inventories at intervals not to exceed 3 months) to account for all sealed sources containing byproduct material and retain records for 5 years. (LAC 33:XV.719). Individual GSR sources are exempt from this physical inventory requirement. However, in accordance with LAC 33:XV.342, the licensee must maintain records of GSR source receipt, transfer, and disposal to indicate the current inventory of sources at the licensee's facility.
- Maintain accountability for brachytherapy sources in storage or use and retain records for 5 years.
- Maintain access control and surveillance to Category 1 and Category 2 quantities of radioactive material in accordance with LAC 33:XV.1629.
- Before transferring aggregated Category 1 or Category 2 quantities of radioactive

material listed in LAC 33:XV.1699. Appendix A, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material.

- Preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in LAC 33:XV.1699. Appendix A.

Licensed materials must be tracked from "cradle to grave," from receipt (from another licensee or from its own radionuclide production facility) to its eventual transfer/disposal, to ensure accountability at all times; identify when licensed material may be lost, stolen, or misplaced; and ensure that the possession limits listed on the license are not exceeded. For aggregated Category 1 and Category 2 quantities of radioactive material listed in LAC 33:XV.1699.Appendix A, licensees must fully implement the requirements of LAC 33:XV.Chapter 16 before receipt of the radioactive material. Additionally, according to LAC 33:XV.1629.A.1, licensees must continuously monitor and detect, without delay, all unauthorized entries into security zones. Additionally, for Category 1 quantities of radioactive material, LAC 33:XV.1629.A.3.a requires immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. For Category 2 quantities of radioactive material, 10 LAC 33:XV.1629.A.3.b requires weekly verification through physical checks, tamper-indicating devices, use, or other means to ensure that the radioactive material is present.

Licensees are required under LAC 33:XV.445.A and B to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified LAC 33:XV.342 and 719. Typically, these records contain the following types of information:

- radionuclide and the activity (in units of becquerels or curies) of byproduct material in each sealed source, and assay date

- manufacturer's or distributor's name, model number, and serial number (if appropriate) of each device containing byproduct material

- location of each sealed source and device

- for inventories, the date of the inventory, and name and signature of the individual conducting the inventory

- for materials transferred or disposed of, the date of the transfer or disposal, the

name and license number of the recipient, a description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's or distributor's name and model number, serial number), and method of disposal (e.g., decay-in-storage return to pharmacy, return to manufacturer)

Note: Category 1 and Category 2 sources listed in LAC 33:XV.499.Appendix G (i.e., nationally tracked sources) must be tracked in the National Source Tracking System (NSTS) in accordance with LAC 33:XV.493. The regulations in LAC 33:XV.493 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NSTTR) to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that tracks Category 1 and Category 2 nationally tracked sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays to below Category 2.

Security Note: There are additional security requirements for shipment and transfer of a Category 1 and Category 2 quantity of radioactive material listed in LAC 33:XV.1699.Appendix A. Prior to transferring Category 1 or Category 2 quantities of radioactive material, licensees must use NRC's license verification system (or contact the licensing authority) to verify that the recipient licensee is authorized to possess the radioactive material. Licensees that ship Category 1 or Category 2 quantities of radioactive material must preplan and coordinate such shipments in accordance with LAC 33:XV.1645. Shipments of Category 1 quantities are also subject to the LAC 33:XV.1647 advance notification requirements. For additional guidance on implementing LAC 33:XV.Chapter 16 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material." Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Provide the following statements:

- "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

  — license possession limits are not exceeded
  — licensed material in storage is secured from unauthorized access or removal
  — licensed material not in storage is maintained under constant surveillance and control
  — records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

AND

- If applicable, "We will comply with the NSTS reporting requirement, as described in LAC 33:XV.493."

m. **Unit Dosage Records**

Submit your procedure for keeping records of unit dosage use. SEE APPENDIX M.A.

n. **Multidose Vial Records**

Submit your procedure for keeping records of multidose vial use. SEE APPENDIX M.B.

o. **Molybdenum Concentration Records**

Submit your procedure for measuring and recording molybdenum concentration. SEE APPENDIX M.C.

p. **Implant Source Use Records**

Submit your procedure for keeping an inventory of implant sources. SEE APPENDIX M.D.

q. **Air Concentration Control**

Submit your procedure for calculating spilled gas clearance times. SEE APPENDIX O.

r. **Radiopharmaceutical Therapy**

Submit your procedure for radiation safety during radiopharmaceutical therapy. See Appendix P.

s. **Safety Procedures for Treatment When Patients are Hospitalized**

Applicants must develop and implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public within regulatory limits.

Under LAC 33:XV.745.B and LAC 33:XV.745.C, licensees are required to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is performed to confirm that all sources have been removed and accounted for. In addition, applicants must take the following steps for patients who cannot be released under LAC 33:XV.725:

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage. (Note: LAC 33:XV.737.A.1.b allows for a room shared with another radiopharmaceutical therapy patient.)

- Provide a private room for patients implanted with brachytherapy sources.

- Visibly post a "Caution: Radioactive Materials" sign on the patient's room and a note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room (LAC 33:XV.737.A.2).

- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings) with a radiation survey meter set on its most sensitive scale with no interposed shielding to determine that residual radioactivity cannot be distinguished from the natural background radiation level or handle the material and items as radioactive waste (10 LAC 33:XV.737.A.5).

- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies (LAC 33:XV.737.B).

Licensees are required to perform adequate surveys to evaluate the extent of radiation levels in accordance with LAC 33:XV.430. Therefore, licensees must evaluate the exposure rates around patients who cannot be released under the requirements of LAC 33:XV.725 and are hospitalized following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

Licensees are required to secure licensed material in storage from unauthorized access or removal in accordance with LAC 33:XV.445.A. Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material temporarily stored in the patient's room and unnecessary personnel exposures. To control exposures to individuals, in accordance with LAC 33:XV.410 and LAC 33:XV.421, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items, as applicable, to be consistent with good medical care.

t. **Release of Patients or Human Research Subjects**

Licensees may release from its control patients or human research subjects (patients) who have been administered licensed material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv [0.5 rem]. Licensees must provide radiation safety instructions to patients released (or to their parent or guardian) in

accordance with LAC 33:XV.725.

Under LAC 33:XV.725, the licensee is required to provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv [0.1 rem]. If the dose to a breastfeeding infant or a child could exceed 1 mSv [0.1 rem], assuming there was no interruption of breastfeeding, the instructions also must include:

- guidance on the interruption or discontinuation of breastfeeding
- information on the potential consequences of failure to follow the guidance

Appendix V of this licensing refers the applicant to Regulatory Guide 8.39 for guidance when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material.
- Instructions to the patient are required by LAC 33:XV.725.B.

Regulatory Guide 8.39 lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in LAC 33:XV.725. The NRC has issued additional information on controlling exposures to members of the public. Licensees should review RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," January 25, 2011, and RIS 2008-11, "Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administration of Iodine-131," May 12, 2008.

u. **Implant Therapy**

Submit your procedure for radiation safety during implant therapy. See Appendix Q.

v. **Physical Facilities**

Submit a drawing of the room or rooms and adjacent areas where radioactive material will be used. Note the following:

A. Room numbers and principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet, hallway).

B. Any shielding available.

C. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors.

D. The diagram should show the proximity of radiation sources to unrestricted areas.

w. **Written Directives Program (LAC 33:XV.777)**

This section is applicable for any licensee administering: any teletherapy radiation dose; any gamma stereotactic radiosurgery radiation dose; any brachytherapy radiation dose; any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.

A medical use licensee preparing WDs must develop, implement, and maintain written procedures to provide high confidence that, among other things, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met.

Licensees are required to determine if a medical event, as defined in LAC 33:XV.712, has occurred. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered or activity implanted to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive. Licensees are required for permanent implant brachytherapy, to determine, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

Additionally, under LAC 33:XV.755.D, the licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. The procedures do not need to be submitted to the Department. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining Department approval. Appendix U of this licensing guide provides guidance on developing the procedures.

Item 10 - Health Physics Instrumentation:

List all radiation monitoring or measuring instruments that will be available. List the

manufacturer's name and model number of each instrument, number of instruments available, the type of radiation detected (e.g., beta, gamma) the range (mR/hour, counts per minute), window thickness if applicable, and how used (measuring or surveying). Describe the method, frequency, and standard used for the maintenance and calibration of radiation detection and survey instruments. These procedures should be included even if the services of an individual or company is employed. SEE APPENDIX B for model procedures.

Item 11 - General Instrumentation:

List the manufacturer and model number of all instruments used in conjunction with the requested procedures. This would include rectilinear scanners, gamma cameras, and dose calibrators. Submit your procedure for calibrating the dose calibrator. SEE APPENDIX C for requirements.

Item 12 - Medical Supplements:

See Appendices P and Q for additional information. Attach approvals from hospitals where radioactive materials are used and hospitals that admit patients containing radioactive materials.

Item 13 - Industrial Radiography Supplement

Not applicable.

Item 14 – Addendum to Permit Applications per LAC33:1.1701

Item 15 - List the name and company affiliation of any individuals who assisted in the completion of the license application.

THE APPLICATION MUST BE DATED AND SIGNED BY THE INDIVIDUAL AUTHORIZED TO SIGN ON BEHALF OF THE INSTITUTION. SUBMIT ONLY THE ORIGINAL.

FORM DRC-13

Sealed Sources:

In the space provided or on a separate attachment, give the proposed inventory of calibration, reference, and medical radioisotopes in the form of sealed sources. Indicate if the sources will be owned or leased either on a long term or case-by-case basis. If the model numbers of the sealed sources are not available, then indicate the type of sources such as plaques, needles, seeds, tubes, or wire.

Radiological Qualifications and Training:

Complete the required information for all technologists listed under Item 4 of Form DRC-11. This information may be submitted on a separate attachment if desired, but the attachment should be clearly referenced.

Schedule of Radioactive Materials:

For routine human use, if you have met the minimum training requirement for diagnostic procedures, you may state only the section number of Chapter 7 of LAC 33:XV (LAC 33:XV.729 and/or 731) for which you are requesting licensure.

Indicate specific therapy procedures that you wish to perform and are qualified to perform in accordance with the submitted preceptor statements. Evidence of board eligibility or certification provides qualification for the use of sealed sources in therapy procedures.

For routine human use not listed in LAC 33:XV.729 and 731, and for non-human use, list each radionuclide to be used. Provide the chemical and physical form and the maximum quantity in millicuries and/or microcuries to be possessed. List the manufacturer, model number, and quantity for all sealed sources.

Describe the intended use of each isotope listed above.

For additional requirements for the use of radioactive gases or aerosols, please refer to Appendix O. Also submit the following information to support a request to use Xenon-133.

1. Describe the procedures to be followed for routine uses of Xe-133. If you plan to use a special apparatus for administration and collection of Xe-133, such as charcoal traps, please specify the manufacturer's name and model number and include a description of its design characteristics. Inclusion of a brochure will be helpful.

2. Describe any special procedures that you plan to employ to reduce leakage. Example: use of nose clamps or special enclosures.

3. Describe the emergency procedures to be used in case of an accidental release of Xe-133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area.

4. Please describe the method of disposal for Xe-133 that will be employed. One method for disposal is release to the atmosphere through an air exhaust system. Licensees are required to perform surveys to ensure that they are in compliance with regulatory requirements for release of radioactive material to unrestricted areas.

   The disposal method of choice is absorption on charcoal traps. The traps are then stored for decay. If a charcoal trap is used, please describe how you will handle the problem of

leakage from such trapping devices and how you will handle saturated filters.

Your discussion should include a description of the area, available shielding and ventilation.

TERMINATION OF ACTIVITIES

The licensee must do the following:

• Notify the department, in writing, within 60 days of the occurrence of any of the following:

— expiration of its license

— a decision to permanently cease principal activities at the entire site

— for licensees subject to LAC 33:XV.332, a decision to permanently cease principal activities in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to the department or NRC requirements

— no principal activities under the license have been conducted for a period of 24 months

— no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to the department or NRC requirements

• Submit a decommissioning plan, if required by LAC 33:XV.332.D.2

• Conduct decommissioning, as required by LAC 33:XV.332.D.6.e.

The licensee's obligations in this matter begin when the license expires or at the time the licensee ceases operations, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit decommissioning information, and to perform any other actions summarized in "Criteria" above.

APPENDIX A

Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and background knowledge of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet Louisiana DEQ requirements. Guidance on requirements for training and experience for authorized medical physicists (AMP), ophthalmic physicists (OP), and authorized users (AU) for medical use who engage in certain specialized practices is also included.

Model Training Program for Medical and Nonmedical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for 3 years. The training records will include the date of the instruction or training, a brief outline of subjects covered, and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Medical Use of Byproduct Material

Training for professional staff [e.g., AU, AMP, ophthalmic physicist, authorized nuclear pharmacist, radiation safety officer (RSO), associate radiation safety officer (ARSO), nurse, dosimetrist, technologist, therapist] will contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, as commensurate with their duties:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues).
- Basic radiation protection to include concepts of time, distance, and shielding.
- Concept of maintaining exposure as low as is reasonably achievable (ALARA).
- Risk estimates, including comparison with other health risks.

- Posting requirements.
- Proper use of personnel dosimetry (when applicable).
- Access control procedures.
- Proper use of radiation shielding, if used.
- Patient release procedures
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care.
- Occupational dose limits and their significance.
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy.
- Worker's right to be informed of occupational radiation exposure.
- Each individual's obligation to report unsafe conditions to the RSO.
- Worker's right to contact the regulatory agency with concerns.
- Applicable regulations, license conditions, information notices, bulletins, etc.
- Where copies of the applicable regulations, the LDEQ license, and its application are posted or made available for examination.
- Proper recordkeeping required by LDEQ regulations.
- Appropriate surveys to be conducted.
- Proper calibration of required survey instruments.
- Emergency procedures.
- Decontamination and release of facilities and equipment.
- Dose to individual members of the public.
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste

management, sealed-source leak testing).

- Hazardous Materials (HAZMAT) training for preparing shipments of radioactive material. (49 CFR Part 172)

- Security for Category 1 or Category 2 sources or aggregated quantities of material.

Training for Individuals Involved in Nonmedical Use of Byproduct Material

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material will include, as appropriate, the elements that are listed above for medical uses. All training should be commensurate with the individual's duties.

Training for Staff Directly Involved in Administration to or Care of Patients Administered Byproduct Material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131); Training for Staff Involved in Therapeutic Treatment Planning

In addition to the topics identified above, the following topics will be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), commensurate with their duties:

- leak testing of sealed sources

- emergency procedures (including emergency response drills)

- operating instructions

- computerized treatment planning system

- dosimetry protocol

- detailed pretreatment quality assurance checks

- safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources

- patient control procedures

- visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room)

- licensee's written directive (WD) Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources, applicators, and collimators to ensure that treatment is to the correct site

- proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources)

- size and appearance of different types of sources and applicators

- previous incidents, events, and/or accidents for remote afterloaders, teletherapy units, and GSR units

- licensee operational safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes

    — vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operation and safety of the unit)

    — design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms

    — hands-on training in actual operation of the device under the direct supervision of an experienced user, including "dry runs" (using dummy sources) of routine patient set-up and treatment and implementation of the licensee's emergency procedures

    — a method, such as practical examinations, to determine each trainee's competency to use the device for each type of proposed use

Additional Training for Authorized Medical Physicists and Ophthalmic Physicists

Applicants for licenses to include AMPs and OPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in LAC Title 33 Part XV. Radiation 763.J and 719,N and that the OP is trained in the activities specific to 719.N. Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of strontium-90 sources used for ophthalmic treatments and assisting the licensee in developing, implementing and maintaining written procedures to provide high confidence that the administration is in accordance with the WD (719.N). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device

operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 763.J.

Additional Training for Authorized Users for Medical Uses of Byproduct Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of LAC 33:XV.763.E.1, LAC 33:XV. 763.E.3, LAC 33:XV. 763.E.4, LAC 33:XV. 763.F, LAC 33:XV. 763.G, and LAC 33:XV. 763.I, as applicable, attention should be focused on the additional training and experience necessary for treatment planning, quality control systems, and clinical procedures.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/or housekeeping, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 1 millisievert [100 millirem] will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel.

Topics of instruction will include the following, as commensurate with the individuals duties:

- storage, transfer, or use of radiation and/or radioactive material
- potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding)
- the applicable provisions of LDEQ regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material)
- responsibility to report promptly to the licensee any condition that may lead to or cause a violation of LDEQ regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues)
- appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material
- radiation exposure reports that workers may request, as per LAC 33:XV.1013, “Notifications and reports to individuals”

APPENDIX B

Model Procedure for Calibrating Survey Instruments

The following provides acceptable guidelines for radiation survey instrument calibrations.

Radiation Monitoring Instrument Specifications

The specifications in Table B–1 may help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies). Except where indicated by an asterisk below, the information in Table B–1 was extracted from "The Health Physics and Radiological Health Handbook," Revised Edition, 1992. Additional information about instruments and their uses also can be found in NUREG–1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," Chapter 6 and Appendix H.

Table B-1. Typical Survey Instruments

Portable Instruments Used for Contamination and Ambient Radiation Surveys

Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	microroentgen (µR)-roentgen (R)	N/A
Count Rate Meters			
Geiger-Mueller (GM)	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples

Detectors	Radiation	Energy Range	Efficiency
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High

	Gamma		Moderate
Gamma Counter [Sodium iodide (NaI0)]*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Equipment Selection

Licensees should possess and use calibrated and operable radiation detection and measurement instruments that are sufficiently sensitive to detect and measure the type and energy of the radiation used. Applicants should determine the number and type of instruments necessary to support licensed activities by considering the scope of activities that will be performed at their facilities. Licensees typically possess one or more portable or handheld instruments to monitor radiological conditions, detect contamination, and perform package preparation and receipt surveys. Portable instrumentation includes ionization chambers as well as other instrumentation, such as count-rate meters that are supported by a variety of handheld probes or detectors that can be used to detect various types of radiation. These include Geiger-Mueller (GM) detectors, sodium iodide [NaI(Tl)] scintillation detectors, and plastic scintillation detectors. Additionally, licensees may possess stationary or fixed instrumentation, such as well-type scintillation counters (LSCs), area monitors, stack monitors, or continuous air monitors. When deciding which types of instruments are appropriate for the intended use, licensees may wish to consult with the instrumentation or equipment manufacturer or vendor to obtain specifications. The instrument should be capable of detecting the type of radiation (e.g., beta or gamma) and be sensitive to the energy or energy range of the radiation to be measured (e.g., keV, MeV). The characteristics of the instrument, including principles of operation and expected efficiency for the type and energy of the radiation being measured, should be understood by the licensee before use.

Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with GM probes. The detection efficiency generally is about 2 percent for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys.

Medium- to high-energy beta emitters, such as phosphorus-32 and calcium-45, can be detected with a pancake GM. The efficiency ranges from 15 percent to 40 percent, depending on the beta energy.

Low-energy gamma emitters, such as iodine-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the NaI probe possesses a thin window and thin crystal, the detection efficiency is approximately 20 percent. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.

Medium- to high-energy gamma emitters, such as iodine-131 (I-131), can be detected with either GM or NaI probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for NaI probes.

Model Radiation Survey Instrument Calibration Program

Training

Before independently calibrating radiation survey instruments, an individual shall have sufficient training and experience to perform independent radiation survey instrument calibrations in accordance with LAC 33:XV.716.

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
    - — principles and practices of radiation protection
    - — radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
    - — mathematics related to the use and measurement of radioactivity
    - — biological effects of radiation
- On-the-job training will be considered complete if the individual has completed both of the following:
    - — observing authorized personnel performing radiation survey instrument calibration
    - — conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations

Facilities and Equipment for Calibration of Dose and Dose Rate Measuring Instruments

To reduce doses received by individuals not calibrating radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.

The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.

The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.

Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20, "Precautionary Procedures." Individuals conducting radiation survey instrument calibrations will wear assigned dosimetry. Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Frequency of Calibration of Radiation Measurement Instruments and Equipment

A licensee committed to a routine or emergency radiation survey program should perform an acceptable calibration of all radiation measurement instruments and equipment at the frequency specified in LDEQ regulations, annually, or at the frequency recommended by the manufacturer, whichever period is shorter.

Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a radiation measurement instrument have changed, by repair or alteration, or whenever system performance is observed to change significantly. (Battery changes are not considered as a repair or alteration.)

Routine maintenance of radiation measurement instruments should be performed as recommended by the manufacturer.

Primary or secondary standard instruments used to calibrate radiation measurement instruments should be inspected frequently for consistency of performance.

Calibration Sources for Dose and Dose Rate Measuring Instruments

Radiation survey instruments will be calibrated with a radioactive source in accordance with LAC 33:XV.716. Electronic calibrations alone are not acceptable. Radioactive sealed sources will be used for calibrating dose and dose rate measuring radiation survey instruments; these sources will have the following characteristics:

- The sources should approximate a point source.

- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microGray/h (µGy)/h [0.1 millirad (mrad)/h] and 10 percent for dose rates less than 1.0 µGy/h [0.1 mrad/h].

- The sources should contain a radionuclide that emits radiation of identical or similar type and energy [e.g., cesium-137 (Cs-137), cobalt-60] as the environment in which the calibrated device will be used.

- The sources should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of cobalt-60].

Note: Inverse square and radioactive decay laws should be used to correct for changes in exposure rate due to changes in distance or source decay.

Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose or dose-rate survey meters. These are calibrated as follows:

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings shall be within ± x (noted below) of the conventionally true value for the following ranges:

  — Background to 10 µGy/h [1.0 mrad/h]; ±x = ±30% — 10 µGy/h [1.0 mrad/h] to 1.0 milliGray (mGy)/h [100 mrad/h]; ±x = ±20% — 1.0 mGy/h [100 mrad/h] to 10 Gray/h [1,000 Rad/h]; ±x = ±10%

- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.

- **Digital readout instruments** should be calibrated the same as linear readout instruments. Digital readout instruments without scale switching for indicating exposure rates shall be checked at two points on each decade.

- **Integrating instruments** shall be checked at two dose rates at approximately 20 percent and 80 percent of the stated dose rate range. Instrument readings shall be within the same ± x of the conventionally true value as described for linear readout instruments.

Note: Readings above 2.58 × 10−4 coulomb/kilogram/hour [1R/h] need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales may be checked for operation and response to radiation.

Note: Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured.

Calibration of Surface Contamination Measurement Instruments

Instruments used to detect surface contamination usually consist of a count-rate meter and a detector that is appropriate for the type of radiation(s) being measured.

The efficiency of radiation survey meters must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

If each scale has a calibration potentiometer, the reading should be adjusted to respond to the calibration source at approximately 80 percent of full scale, and the response at approximately 20 percent of full scale should be observed. If only one calibration potentiometer is available, the response should be adjusted at mid-scale on one of the scales, and response on the other scales should be observed. The instrument efficiency factor [e.g., counts per minute (cpm)/disintegrations per minute (dpm)] thus obtained should have a signal-to-noise ratio, including the compilation of source and instrument uncertainties, of ±x for the following ranges:

- alpha measurement
  0.01 becquerel (Bq)/square centimeter (cm2) to 2.0 Bq/cm2 [60 to 12,000 dpm/100 cm2]; ±x = ±20%
  2.0 Bq/cm2 to 200 Bq/cm2 [12,000 to 1,200,000 dpm/100 cm2]; ±x = ±10%

- beta measurement
  0.05 Bq/cm2 to 2.0 Bq/cm2 [300 to 12,000 dpm/100 cm2]; ±x = ±20%
  2.0 Bq/cm2 to 200 Bq/cm2 [12,000 to 1,200,000 dpm/100 cm2]; ±x = ±10%

Calibration of Analytical Instruments Such As Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

Analytical instruments used to determine radioactivity in a sample may be specialized equipment according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small, and can be difficult to measure. Sample collection and preparation may differ for the various analytical instruments, so manufacturer procedures and industry standard practices should be followed. Such analytical instruments should be calibrated in accordance with the manufacturer's instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

As with calibration of other radiation measurement instruments, calibration of analytical instruments use a radioactive sealed source(s). These should be suitable for the geometry of the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the samples type, and other environmental conditions.

Model procedures for the calibration of LSC, well-type LSC, gas-flow proportional counters, and single or multi-channel analyzers are not provided in this document. For compliance with LAC 33:XV.430, users should refer to manufacturers' instructions and/or nationally recognized standards for instrument calibration information. In general, manufacturers' instructions typically specify that for these types of instruments, calibration is expected to produce readings within plus or minus 20 percent of the actual values over the range of the instrument. The minimum detectable activity (MDA) for instruments used should be a fraction (10 to 50 percent) of the criteria that is to be met.

Calibration Records

A record must be made of each radiation survey instrument calibration and retained for 3 years after each record is made (LAC 33:XV.472 and 716.E).

Calibration records for all radiation survey instruments should indicate the procedure used and the results of the calibration. The records should include the following:

- the owner or user of the radiation survey instrument

- a description of the radiation survey instrument that includes the manufacturer's name, model number, serial number, and type of detector

- a description of the calibration source, including the exposure rate at a specified distance or activity on a specified date

- for each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the radiation survey instrument

- the efficiency of the radiation survey instrument, for each radionuclide the instrument will be used to measure (if efficiency is not calculated before each use) the exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)

- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)

- for radiation survey instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument

- for radiation detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure

- the exposure rate or count rate from a check source, if used

- the name and signature of the individual who performed the calibration and the date on which the calibration was performed

The following information will be attached to the radiation survey instrument as a calibration sticker or tag:

- for dose and dose rate measuring instruments, the source radionuclide that was used to calibrate the instrument (with correction factors) for each scale

- for surface contamination measurement instruments, the efficiency of the radiation survey instrument, for each radionuclide the instrument will be used to measure (if efficiency is not calculated before each use)

- the proper deflection in the battery check mode, unless this is clearly indicated on the instrument

- special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated)

- for each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated • the date of calibration and the next calibration due date

- the apparent exposure rate or count rate from the check source, if used

- sensitivity of counting system

Follow the procedures in Appendix H of this licensing guide to determine MDA, if there is a question concerning the ability to measure small quantities of radioactivity.

Calculating the Efficiency of Sodium Iodide (Thallium Doped) Uptake Probes

Sodium iodide (thallium doped) uptake probes are commonly used for bioassays of personnel administering I-131 radionuclides in the form of liquid NaI. Refer to LAC 33:XV.499, Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage” for the

ALIs and DACs for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, μCi) when performing bioassays to determine thyroid burdens of radioiodine.

Use the following procedure to calibrate the probe for uptake measurements:

- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by the National Institute of Standards and Technology (NIST).

- Calculate the efficiency of the instrument.

For example:

$$Eff_a = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ microcuries)}$$

where: Eff_a = efficiency[1],
cpm = counts per minute,
std = standard, and
bkg = background.

Operational and calibration checks, using a dedicated check source, should be conducted each day the instrument is used. The date of the efficiency test should be attached to the instrument as a calibration sticker or tag, and the following information should be included:

- the due date of the next efficiency test

- results of efficiency calculation(s)

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation

standard such as those maintained by NIST.

- Calculate the efficiency of the instrument.

For example:

$$Eff = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ microcuries)}$$

where *Eff* = efficiency, in cpm/microcurie,
cpm = counts per minute,
std = standard, and
bkg = background.

Operational and calibration checks, using a dedicated check source, should be conducted each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- the due date of the next efficiency test
- results of efficiency calculation(s)

References:

- Detailed information about portable radiation survey instrument calibration may be obtained by referring to American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments," 2013. Copies may be obtained from the ANSI eStandards Store.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 112, "Calibration of Survey Instruments Used in Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination," 1991.

APPENDIX C

Model Procedure for Calibrating Dose Calibrator

The model procedure provides acceptable methods for dose calibrator testing when measuring photon emitting radionuclides. Applicants may either adopt this model procedure or develop an alternative procedure in accordance with manufacturer's instructions or a nationally recognized standard pursuant to LAC 33:XV.715. For instance, ANSI N42.13 2004—Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Radionuclides may be ordered at ansi.org

1. Test for the following at the indicated frequency.

    a. Constancy, at least once each day prior to assay of patient dosages (±10 percent).

    b. Linearity, at installation and at least quarterly thereafter (±10 percent).

    c. Geometry dependence, at installation (±10 percent).

    d. Accuracy, at installation and at least annually thereafter (±10 percent).

    Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.) For example, a licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 1.11 megabecquerels (MBq) or 30 microcurie (μCi)] if the geometry or linearity error exceeds 10 percent. In addition, after repair, adjustment, or relocation to another building, the dose calibrator tests will be repeated before use

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a longer period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

    a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

c. For each source used, record (e.g., plot, log) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the name of the individual who performed the test.

d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Record the results.

e. Notify the radiation safety officer (RSO) or the authorized user if the test results fall outside +/− 10% of the expected results. For instance, the Cs-137 value should be compared to the reference activity, corrected for decay. Other radionuclides (e.g., Tc-99m) should be compared to the value determined during the last accuracy test, corrected for the reference standard's decay.

4. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use G–2 between the maximum activity administered and 1.11 MBq [30 μCi]. This test will be performed using a vial or syringe of technetium-99m (Tc-99m) or other readily available radionuclide whose activity is at least as large as the maximum activity normally assayed for administration. Tc-99m is routinely used due to its ready availability and lower energy, and therefore lower exposure to licensee personnel, as compared to higher energy radionuclides like those used in Positron Emission Tomography and Iodine-131.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form. This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 10 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. Record the measured activities, the calculated activities, the time elapsed between

measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

e. Notify the RSO, if the deviation is more than +/− 10%.

Shield Method

"Sleeves" of various thicknesses are used to test for linearity. However, they must first be calibrated. The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves:

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through e above.

f. From the data recorded in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

g. Notify the RSO if the greatest deviation is more than +/− 10%.

6. Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections or administrations, and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials and the predetermined safety margin is +/−10%. If 5 cc syringes, 10 cc glass vials, or any other geometric variations are used, the geometry testing will include these.

Note: If these volumes are not used, change the procedure so that the syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity indicated.

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and activity indicated.

d. Repeat the process until you have assayed a 2.0 cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."

f. Record the model number and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/− 10% error lines.

g. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume the activity indicated.

i. Repeat the process until you have assayed a 19.0 cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."

k. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.

l. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines..

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from the NIST and from many radionuclide suppliers. At least one source with a principal photon energy between 100 kiloelectron-volts (keV) and 500 keV (e.g.,

Co-57 or barium-133) will be used. At least one reference source whose activity is within the range of activities normally assayed will be used.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

b. The measurement should be within +/− 10% of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the name of the individual who performed the test.

e. Notify the RSO if the test results do not agree, within +/− 10%, with the certified value of the reference source(s).

f. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings.

8. The RSO will review and sign the records of all geometry, linearity and accuracy tests.

APPENDIX D

Model Personnel External Exposure Monitoring Program

This model provides acceptable procedures for an external occupational dose monitoring program and references and resources for developing an internal occupational dose monitoring program. Applicants may either adopt these model procedures for an occupational dose monitoring program or develop alternative procedures to meet the requirements of LAC 33:XV.406 and 410 ("Occupational Dose Limits") and Subchapter C ("Surveys and Monitoring") of LAC 33:XV.Chapter 4. The model includes guidance as well as a discussion of regulatory requirements that are to be reflected in the elements of an occupational dose monitoring program.

The licensee must consider the dose that an individual may receive in the current year from all sources of employment where the individual's assigned duties involve exposure to sources of radiation. See RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.

If an individual may receive more than 10 percent of the annual dose limit, the NRC requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his or her dose.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits for radiation dose and to help demonstrate that doses are maintained at ALARA levels.

Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring as part of the overall requirements for radiation protection.

Under LAC 33:XV.431, the use of individual monitoring devices is required for the following:

- Adults likely to receive, in a year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in LAC 33:XV.410. Monitoring devices are accordingly required for adults likely to receive an annual dose in excess of

    — 0.5 rem [0.005 Sv] DDE
    — 1.5 rem [0.015 Sv] lens (of the eye) dose equivalent
    — 5 rem [0.05 Sv] SDE to the skin
    — 5 rem [0.05 Sv] SDE to any extremity

- Minors who are likely to receive an annual dose in excess of:

  — 0.1 rem [1.0 millisievert (mSv)] DDE
  — 0.15 rem [1.5 mSv] lens (of the eye) dose equivalent
  — 0.5 rem [5 mSv] SDE to the skin, or
  — 0.5 rem [5 mSv] SDE to any extremity

- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem [1.0 mSv] DDE during the entire pregnancy.

- Individuals entering a high- or a very-high-radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10 percent of the applicable limits. In these cases, the NRC does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10 percent of regulatory limits:

- Prior Experience: Reviews of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10 percent of the limits.

- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys [e.g., using a radiation survey meter or area thermoluminescent dosimeters (TLDs)] in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10 percent of the limits (exposures associated with reasonable “accident” scenarios should also be evaluated).

- The licensee performs a reasonable calculation, based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10 percent of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters, or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program-approved, as required by LAC 33:XV.430.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year [LAC 33:XV.410]. When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly nonuniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head. For additional guidance, see RG 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," July 2010.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

Under LAC 33:XV.476, individual monitoring must be recorded on DRC-5, "Occupational Dose Record for a Monitoring Period," or equivalent. DRC-5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years. For additional guidance, see RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees should be thorough in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and add it to the employee's dose record, to demonstrate compliance with occupational dose limits in LAC 33:XV.410. Sometimes the most reliable method for estimating an individual's dose is to use his or her recent dose history. In other cases, particularly if the individual does nonroutine types of work, it may be better to use doses of coworkers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in International Commission on Radiological Protection (ICRP) Report 26, "Recommendations of the International Commission on Radiological Protection," Investigational Levels serve as check points above which the results are considered sufficiently important to justify investigation.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table D–1 (i.e., 10 percent of the annual limit for occupational exposure), the radiation safety officer (RSO) or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds the Investigational Level II in Table D–1 (i.e., 30 percent of the annual limit for occupational exposure), the RSO or the RSO's designee should investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table D-1. Investigational Levels

Part of Body	Investigational Level I (mrem/yr)	Investigational Level II (mrem/yr)
Whole body, head, trunk including male gonads, arms above the elbow, or legs above the knee	500 [5 mSv]	1,500 [15 mSv]
Hands, elbows, arms below the elbow, feet, knees, legs below the knee, or skin	5,000 [50 mSv]	15,000 [150 mSv]
Lens of the eye	1,500 [15 mSv]	4,500 [45 mSv]

Review and record on DEQ DRC Form 5, "Occupational Dose Record for a Monitoring Period," or an equivalent form (e.g., dosimeter processor's report), the results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table D–1 are reached:

- Personnel dose less than Investigational Level I Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken, if an individual's dose is less than Table D–1 values for Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II

When the dose of an individual equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required, unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements or additional safety measures are needed to reduce exposures. Evaluate, in the context of ALARA program quality, and record the results of investigations and evaluations.

- Personnel dose equal to or greater than Investigational Level II

The RSO should investigate, in a timely manner, the causes of all personnel doses equaling or exceeding Investigational Level II. The RSO should consider actions to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

• Reestablishment of Investigational Level II to a level above that listed in Table D–1

In cases where a worker's dose or the dose for a group of workers needs to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

Declared Pregnancy and Dose to Embryo/Fetus

Regulations in LAC 33:XV.417, "Dose equivalent to an embryo/fetus," state that the licensee shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem [5 mSv]. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo or fetus shall be taken as the sum of

- the DDE to the declared pregnant woman, and

- the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman

Licensees should reference RG 8.13, "Instructions Concerning Prenatal Radiation Exposure," June 1999, for information to help pregnant women and other personnel make decisions regarding radiation exposure during pregnancy and RG 8.36, "Radiation Dose to the Embryo/Fetus," July 1992, for calculating the radiation dose to the embryo/fetus.

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in a year. (LAC 33:XV.431). Values for radionuclide intakes by means of inhalation and ingestion (i.e., derived air concentration (DAC) and ALI) are provided in Table 1 of Appendix B of 10 CFR Part 20.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem [0.05 Sv] or a committed dose equivalent of 50 rem [0.5 Sv] to any individual organ or tissue; again, with no consideration for the contribution of external dose.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in microcurie (μCi)/milliliter that, if an occupational worker were to be continuously exposed to it for 2,000 hours [1 year], would result in one ALI.

The TEDE concept makes it possible to combine both the internal and external doses. The ALI and DAC numbers in LAC 33:XV.499 reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (WT), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per LAC 33:XV.499, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities, require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established. If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

- adequate equipment to perform bioassay measurements
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or μCi units
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue)
- the interval between bioassays, differentiating between routine and special bioassays
- action levels
- the actions to be taken at those levels

For additional guidance on developing occupational dose-monitoring programs, refer to the following:

- Regulatory Guide (RG) 8.2, "Administrative Practices in Radiation Surveys and Monitoring," May 2011.
- RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," May 2018.
- RG 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," July 1993
- RG 8.20, "Applications of Bioassay for Radioiodine," September 2014.
- RG 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," July 1992.
- RG 8.40, "Methods for Measuring Effective Dose Equivalent from External Exposure," July 2010.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 87, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition," February 1987.
- NUREG/CR–4884, "Interpretation of Bioassay Measurements," July 1987.
- NUREG–1400, "Air Sampling in the Workplace," September 1993

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by LAC 33:XV.476.

APPENDIX E

Model Procedure for Mobile Nuclear Medicine Service

The Department normally limits its review of equipment quality assurance programs to those programs developed for radiation safety equipment. However, when delicate imaging equipment is transported from one location of use to another, e.g., by a mobile nuclear medicine service, it is reasonable to assume that it may suffer damage in transit. Therefore, the Department requires that mobile nuclear medicine services have an imaging equipment quality assurance program to ensure that the use of radioactive material will not be inimical to the public health and safety. Mobile nuclear medicine services should also check ventilation equipment if gases will be used.

Model Procedure

Survey Meter

Check the survey meter with the dedicated check source at each location of use. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Camera

1. Perform the following checks daily at each location of use before administering radioactive material:

    a. Peak each camera according to the manufacturer's instructions.

    b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.

    c. Do not administer material until an authorized user or a designated technologist approves the camera for use.

    d. You do not have to make a permanent record of these daily checks.

2. Perform the following checks weekly:

    a. With the same frequently used collimator in place, image a flood source and either a

parallel-line-equal-space (PLES), bar, orthogonal-hole (OH) or resolution-quadrant phantom with the flood field as a source.

b. If a PLES or bar phantom is used, rotate it 90 degrees so that the camera is tested for both vertical and horizontal geometric linearity.

c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.

d. Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.

e. Retain the images for 2 years.

3. Perform the following safety checks after repairs and quarterly:

a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.

4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for 2 years.

Ventilation - If gases or aerosols will be used, check the ventilation supply, exhaust vents, and collection devices for operation with tissue paper or a velometer. There is no need to keep a record of these checks.

APPENDIX F

Model Radiation Safety Committee Charter and Radiation Safety Officer Responsibilities & Delegation of Authority

Model Radiation Safety Committee Charter (if applicable)

Applicants that fit the criteria listed below shall establish a Radiation Safety Committee to oversee the use of radioactive materials:

- Medical Institutions as defined as an organization in which several disciplines are practiced and that has inpatient facilities.

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review, as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with the Louisiana Radiation Regulations and the institutional license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent regulations, the license application, the license, and amendments;

2. Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the authorized medical physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassay, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required.

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with radiation regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of the Department's inspections, written safety procedures, and the adequacy of the management control system;

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

10. Ensure that the radioactive material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as X-ray radiation safety, quality assurance oversight, and research project review and approval.

Radiation Safety Officer (RSO) Responsibilities

Typical Duties and Responsibilities of the Radiation Safety Officer

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety, security, and compliance with both Louisiana Department of Environmental Quality (LDEQ or Department) and U.S. Department of Transportation (DOT) regulations and the conditions of the license. Typically, these duties and responsibilities include ensuring the following:

- Stop activities involving licensed material that the radiation safety officer (RSO) considers unsafe.

- Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).

- Oversee all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used or stored.

- Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed, as appropriate.

- An inventory of all radioactive material is maintained, as required. Ensure that possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the Sealed Source and Device (SSD) registration certificate(s), and the manufacturer's recommendations and instructions.

- The receipt, opening, and delivery of all packages of radioactive material arriving at the facility are overseen and coordinated. Also, radiation surveys of all shipments arriving or leaving the facility, as well as packaging and labeling of radioactive material leaving the facility are overseen.

- Ensure individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license.

- Ensure personnel training is conducted and is commensurate with the individual's duties regarding licensed material.

- Ensure documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits or that personnel monitoring devices are provided.

- When necessary, ensure personnel monitoring devices are used and exchanged at the proper intervals, and personnel radiation exposure and bioassay records are monitored, reviewed, and maintained. Individuals are notified when radiation exposures are approaching established limits and appropriate corrective actions are taken.

- Properly secure radioactive material from unauthorized use or access.

- If the licensee possesses an aggregated Category 1 or Category 2 quantity of radioactive material, support development and implementation of a security program for radioactive material in accordance with LAC 33:XV.Chapter 16, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

- Ensure documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in LAC 33:XV.421, "Radiation Dose Limits for individual members of the public."

- Notify proper authorities of incidents, such as damage to or malfunction of sources/devices, excess breakthrough values for Mo-99/Tc-99m or Sr-82/ Rb-82 generators, loss of licensed material, fire, and theft.

- Serve as a point of contact for the Department's and licensee's management during routine operations, emergencies, or incidents.

- Medical events and precursor events are investigated and reported to the Department, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.

- Perform and document periodic audits, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable Department regulations and the terms and conditions of the license.

- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for 3 years after the record is made) and provided to management for review; ensure that prompt action is taken to correct deficiencies.

- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.

- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, ensure corrective action(s) are developed, implemented, and documented.

- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of LAC 33:XV limits are investigated, their cause(s) are identified, appropriate corrective action(s) are implemented, and reports are submitted to the Department and other appropriate authorities, if required, within the required time limits.

- Ensure that licensed material is transported, or offered for transport, in accordance with all applicable Department and DOT requirements.

- Ensure that radioactive waste is disposed of in accordance with Department regulations and license conditions. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records. Oversee the storage of radioactive material not in current use, including waste.

- Perform/oversee the inventory and leak testing on all sealed sources.

- Oversee the calibration of radiation survey instruments.

- Supervise decontamination operations.

- Maintain up-to-date copies of LDEQ regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the Department during the licensing process.

- Submit amendment and renewal requests in a timely manner.

- Assign tasks and duties to an ARSO, if applicable

Model Delegation of Authority

Memo to: (Name of Radiation Safety Officer)

From: (Name of Chief Executive Officer or other ranking official)

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe and secure use of radiation and radioactive material. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations when justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Louisiana Department of Environmental Quality at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____ _____

Signature of Management Representative Date

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

cc: Names of affected department heads

Model Appointment of ARSO

Memo To: Associate Radiation Safety Officer

From: Chief Executive Officer
Radiation Safety Officer

Subject: Appointment of ARSO

You, _____, have been appointed an Associate Radiation Safety Officer. The Radiation Safety Officer, with written agreement from management, will assign specific oversight duties and tasks to you. These duties and tasks are restricted to the types of use for which you are listed on our license.

You are free to raise issues with the Louisiana Department of Environmental Quality at any time. It is estimated that you will spend _____ hours per week conducting Associate Radiation Safety Officer duties and tasks.

You will report to the Radiation Safety Officer, who retains responsibility for oversight of the entire radiation safety program.

_____ _____
Signature of Management Representative Date

_____ _____
Signature of Radiation Safety Officer Date

cc: Names of affected department heads

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA

ALARA Program

_____

(Licensee's Name)

_____

(Date)

1. **Management Commitment**

   a. We, the management of this (medical facility, hospital, etc.) are committed to the program described hereby for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is

reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. **Radiation Safety Committee**

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. **Delegation of Authority**

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. **Review of ALARA Program**

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded

(see Section 6 below for a discussion of investigational levels).

Table 1

Investigational Levels

		Investigational Levels (mRems per calendar quarter)	
		Level I	Level II
1.	Whole body; head and trunk active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	375	1125
3.	Skin of whole body*	1250	3750

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. **Radiation Safety Officer**

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures**.**

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. **Authorized Users**

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Individuals Who Receive Occupational Radiation Doses**

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses**

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form DRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than

Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II, and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form DRC-5, or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official (The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____

Signature

_____

Name and Title (print or type)

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources

This model program provides acceptable procedures for sealed-source leak testing and analysis. Applicants may either adopt these model procedures or develop alternative procedures.

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently in accordance with LAC 33:XV.325.A.1. Records for training on the applicable leak test procedures should be maintained.

Classroom training may be in the form of lecture, online, video, or self-study, and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

Appropriate on-the-job training consists of the following:

- observing authorized personnel collecting and analyzing leak test samples
- collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak test and sample analysis

Facilities and Equipment

- To ensure the required sensitivity of measurements is achieved, analyze leak tests in a low-background area.
- Use a calibrated and operable radiation survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (e.g., sodium iodide well-counter system for gamma emitters, liquid scintillation detector for beta emitters, or gas-flow proportional counters for alpha emitters).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 becquerels (Bq) [0.005 microcuries (μCi)] of radioactivity. If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{bkg \times t}}{t \times E}$$

where *MDA* = minimum detectable activity in disintegrations per minute (dpm)
bkg = background count rate in counts per minute (cpm)
t = background counting time in minutes
E = detector efficiency in counts per disintegration

For example:

where *bkg* = 200 cpm
E = 0.1 counts per disintegration (10 percent efficient)
t = 2 minutes

$$MDA = \frac{2.71 + 4.65\sqrt{200 \text{ cpm} \times 2 \text{ minutes}}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{400}}{0.2}$$

$$= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= \frac{478.55 \text{ disintegrations}}{\text{minute}}$$

$$\text{becquerels (Bq)} = \frac{1 \text{ disintegration}}{\text{second}}$$

$$MDA = \frac{478.55 \text{ disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 7.976 \text{ Bq}$$

Note: The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for nonequal counting times, as well as derivations of equations and discussions of limitations, can be found in "Decommissioning Health Physics—A Handbook for MARSSIM Users," Eric W. Abelquist, published by Taylor & Francis Group, 2001.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device registration certificate. If a sealed source is not registered, leak tests should be conducted at 6 month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Procedure for Performing Leak Testing and Analysis

[on all sealed sources except individual radium-226 (Ra-226) sealed sources]

- Follow the manufacturer's instructions for performing the leak test.
- For each sealed source to be tested, list identifying information, such as sealed source serial number, manufacturer, model number, radionuclides, and activity of the sealed source.
- Use a radiation survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking, but do not wipe the surface of a plated or foil source (see manufacturer's instructions).

Procedure for Performing Gaseous Emanation Test for Individual Ra-226 Sealed Sources (ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification," Appendix A, Section A.2.1.5)

- For each source to be tested, list identifying information, such as sealed source serial number, manufacturer, model number, radionuclide, and activity.
- Number each container to correlate information for each source.
- Wear gloves.
- Put each Ra-226 sealed source into a separate small, gas-tight container with activated carbon or two cotton filters.
  - — Leave source in an airtight container for 24 hours.
  - — Remove source.
  - — Close container.
- Measure immediately the activity of the Absorber. (See "Model Procedure for Analysis of Gaseous Emanation and Leak Test" below for (i) how to analyze the absorber, (ii) required records, (iii) leakage determination, and (iv) required response to a leaking source.)
- If the wipe test reveals 37 Bq [1 nanocurie (nCi)] or greater of radon or daughter products
  - — Notify the RSO.
  - — Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired.
  - — File a report within 5 days of the leak test, in accordance with LAC 33:XV.719.E.

Procedure for Analysis of Leak Test and Gaseous Emanation

- Select an instrument that is sensitive enough to detect 185 Bq [0.005 μCi] of the radionuclide and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same

radionuclide as the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by the National Institute of Standards and Technology.

- Calculate the counting efficiency of the detector.

$$\text{Efficiency in cpm/Bq} = \frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}}$$

where cpm = counts per minute
std = standard
bkg = background
Bq = Becquerel

- Count each wipe (or absorber for a Ra-226 sealed source) sample; determine net count rate.
- For each sample, calculate and record activity in Bq (or µCi).
- The activity of the sample in becquerels may be calculated using the following formula:

$$\text{Activity of sample [Bq]} = \frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}}$$

- Leak test records (which include the gaseous emanation test) will be retained in accordance with LAC 33:XV.719.D.
  Licensees should include the following in records:
  — the model number and serial number (if assigned) of each source tested
  — the identity of each source radionuclide and its estimated activity
  — the measured activity of each test sample expressed in Bq (or µCi)
  — a description of the method used to measure each test sample
  — the date of the test
  — the name of the individual who performed the test
- If the wipe test reveals 185 Bq [0.005 µCi] [or 37 Bq [1 nCi] of radon or daughter products] or greater:
  — Notify the RSO.
  — Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired.
  — File a report within 5 days of the leak test, in accordance with LAC 33:XV.719.E or standard license condition.

APPENDIX I
MODEL PROCEDURES FOR SAFE USE OF UNSEALED LICENSED MATERIAL

This model provides acceptable procedures for safe use of unsealed licensed material. Applicants may either adopt these model procedures or develop their own procedures. Some of the health physics practices listed below may also apply to sealed sources.

Model Procedure

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with a crystal probe or camera.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

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 in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear extremity dosimeters, if required, when handling radioactive material.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. Survey all areas of licensed material use, including the generator storage, kit preparation, and injection areas, for contamination using a survey instrument each day of use. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with LAC 33:XV.724 (except when administering therapy dosages in patients' rooms when patients are confined).

13. Store radioactive solutions in shielded containers that are clearly labeled.

14. Radiopharmaceutical multi-dose diagnostic and therapy vials, syringes, and unit dosages must be labeled in accordance with LAC 33:XV.721, "Labeling of vials and syringes," and LAC 33:XV.453, "Labeling containers." Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in LAC 33:XV.499.Appendix C, "Quantities of Licensed Material Requiring Labeling," the syringe or vial need only be labeled to identify the radioactive drug. To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.

15. For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (LAC 33:XV.717).

16. Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.

17. When measuring the dosage, licensees need not consider the radioactivity that adheres to the syringe wall or remains in the needle.

18. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive (WD), the patient's identity must be verified, and the administration must be in accordance with the WD (LAC 33:XV.777).

19. Always keep calibration, transmission, and reference sources, syringes, waste, and other radioactive material in shielded containers.

20. Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under LDEQ license, NRC license or Agreement State license (or such individual's designee).

APPENDIX J
General Topics for Safe Use of Radiopharmaceuticals and Model Emergency Procedures

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

This model provides acceptable procedures for responding to emergencies involving spills or patients administered therapeutic amounts of radionuclides. These model procedures also include instructions for autopsy or cremation of patients who have permanent implants or handling a deceased individual with a nuclear pacemaker. Applicants using unsealed licensed material may either adopt this model or develop alternative procedures to meet the requirements of LAC 33:XV.406. Applicants using therapeutic sealed sources should develop procedures specific to each use. Applicants using permanent implants can use the sample procedure in conjunction with facility-specific therapeutic sealed source emergency procedures.

General Safety Procedures to Handle Spills

The name and telephone number of the radiation safety officer (RSO) should be posted conspicuously in areas of use, so that they are readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill/contamination kits should include the following items:

- disposable gloves
- disposable lab coats
- disposable head coverings
- disposable shoe covers
- roll of absorbent paper with plastic backing
- masking tape
- plastic trash bags with twist ties
- "radioactive material" labeling tape
- marking pen
- prestrung "Radioactive Material" labeling tags
- contamination wipes
- instructions for "Emergency Procedures"
- clipboard with a copy of Radioactive Spill Report Form
- pencil
- appropriate survey instruments, including batteries

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material.

For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest annual limit on intake (ALI), an alternative spill/contamination procedure may be to restrict access, pending complete decay. In most cases, determination of a major versus minor spill should be based on the lowest ALI for the radionuclide(s) involved in the spill or contamination.

The licensee should estimate the amount of radioactivity spilled and initiate a major or minor spill/contamination procedure. Use Table J–1 as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. Spills above these millicurie (mCi) amounts should be considered major, and spills below these levels should be considered minor.

Table J–1. Relative Hazards of Common Radionuclides

Radionuclide	mCi	MBq	Radionuclide	mCi	MBq
nitrogen-13	100	3700	technetium-99m	100	3700
carbon-14	10	370	indium-111	10	370
oxygen-15	100	3700	iodine-123	10	370
fluorine-18	100	3700	iodine-125	1	37
phosphorus-32	1	37	iodine-131	1	37
gallium-67	10	370	samarium-153	10	370
rubidium-82	10	370	ytterbium-169	10	370
strontium-82	1	37	mercury-197	10	370
strontium-85	10	370	gold-198	10	370
strontium-89	1	37	thallium-201	100	3700
yttrium-90	1	37	Alpha emitters	*	*
*For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions					

Minor Spills of Liquids and Solids

Instructions to Workers

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Wear gloves and protective clothing, such as a lab coat and booties, and clean up the spill using absorbent paper. Clean up the spill by wiping from the perimeter of the spill to the center of the spill.

4. Carefully fold the absorbent paper with the clean side out g labeled "caution radioactive material" for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposal material in the bag.

5. Survey the area with an appropriate low-range radiation detector survey meter. Survey for removable contamination to ensure contamination levels are below trigger levels (see Appendix N for more information regarding trigger levels). Check the area around the spill.

6. Continue to clean up the spill and re-survey until radiation levels and removable contamination are below trigger levels.

7. Survey your hands, clothing, and shoes for contamination prior to leaving the area.

8. Report the incident to the Radiation Safety Officer (RSO).

9. Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, requested documentation).

Reminders to RSO

1. Follow up on the decontamination activities and document the results.

2. As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

3. If necessary, notify the LDEQ/Radiation Section.

Major Spills of Liquids and Solids

Instructions to Workers

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper "caution radioactive material," but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.

5. Notify the RSO immediately.

6. Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. Document personnel decontamination efforts.

7. Cooperate and follow the instructions of the RSO and the RSO's staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, requested documentation).

Reminders to RSO

1. Supervise and confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

2. Document decontamination results, including all surveys, location of surveys, and decontamination results.

3. Evaluate and determine personnel radiation exposure. Beta emitting radionuclides could have a potential for resulting in a shallow-dose exposure in excess of regulatory limits from μCi quantities of contamination.

4. Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

5. If necessary, notify the LDEQ/Radiation Section.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

For emergency surgery or autopsy of patients administered byproduct material, National Council on Radiation Protection and Measurements (NCRP) Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, or Industrial Facilities," 1991, may contain helpful information.

If emergency surgery is performed within the first 24 hours following the administration of iodine-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.

Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).

The radiation safety staff will direct personnel in methods to keep doses as low as reasonably achievable (ALARA) during surgical procedures.

If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

1. Immediately notify the authorized user (AU) in charge of the patient and the RSO upon death of a therapy patient.

2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures to keep doses ALARA during the autopsy.

3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta rays in cases involving therapy with phosphorus-32 and yttrium-90.

4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accordance with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.

5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

Autopsy or Cremation of Patients Who Have Permanent Implants

Patients treated with seed implants will not usually represent a radiation hazard to persons dealing with the body unless there is to be an autopsy or cremation. For autopsy or cremation of patients with permanent implants, NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information.

If an autopsy or cremation is to be performed

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.

2. Consult and get permission from the RSO.

3. Instruct pathologist to excise tissue containing radioactive seeds.

   — Make pathologist aware seeds may have migrated and additional tissue may need to be removed.
   — Instruct pathologist to consult with RSO about the possibility of slicing through a seed and contaminating the facility.

4. Seek municipal approval, if required, because the very high temperatures used in modern crematoria may cause seeds to burst, releasing radioactivity into the plume.

Nuclear Pacemakers

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the licensee is not responsible for control or disposal of the pacemaker, notify the NRC and attempt to contact the hospital where the pacemaker was implanted to arrange for explantation. The licensee that implanted the device is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. Information Notice (IN) 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

APPENDIX K

Model Guidance for Ordering and Receiving Radioactive Material

This model provides acceptable procedures for ordering and receiving packages containing licensed material. Applicants may either adopt this model or develop alternative procedures.

Model Guidance

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

    a. For routinely used materials

        (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

        (2) The above records will be checked to confirm that material received was ordered through proper channels.

    b. For occasionally used materials (e.g., therapeutic dosages)

        (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

        (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO or designee will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO or designee will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: CHIEF OF SECURITY

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package _____, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____, at extension _____.

Radiation Safety Officer: _____

Chief of Nuclear Medicine: _____

Chief Nuclear Medicine Technologist: _____

Nuclear Medicine Technologist on call
(call page operator at extension _____)

Nuclear Medicine Physician on call

(call page operator at extension _____)

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of LAC 33:XV.455.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in LAC 33:XV.1599. Such packages must be received expeditiously when the carrier offers them for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt, if received during working hours, or no later than 3 hours from the beginning of the next working day, if received after working hours, in accordance with the requirements of LAC 33:XV.455.C.

Notify the final delivery carrier and LDEQ/Radiation Section, 225-765-0160, by telephone, when

- removable radioactive surface contamination exceeds the limits of LAC 33:XV.1516.B.9.
- external radiation levels exceed the limits of LAC 33:XV.1513, "External radiation standards for all packages."

Model Procedure

1. For packages received under the specific license, the following procedure for opening each package will be followed:

    a. Put on gloves to prevent hand contamination.

    b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO) or designee.

    c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface; the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from

packages with "White I" labels should be less than 0.5 millirem per hour at the package surface.

d. Open the package with the following precautionary steps:

(1) Remove the packing slip.

(2) Open the outer package following the supplier's instructions, if provided.

(3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Notify the RSO or the RSO's designee of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material or anything is found other than expected.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI (Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement). Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in-house trash.

h. Make a record of the receipt, package survey and wipe results.

i. Notify the final delivery carrier and, LDEQ/Radiation Section at 225-765-0160, by telephone, when removable radioactive surface contamination exceeds the limits of

10 CFR 71.87(i), or external radiation levels exceed the limits of 10 CFR 71.47, "External radiation standards for all packages."

j. If applicable, comply with the National Source Tracking System reporting requirement, as described in LAC 33:XV.493, "Reports of Transactions Involving Nationally Tracked Sources."

APPENDIX M

Records of Radioactive Material Use

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

A. Records of Unit Dosage Use

You may use the following model procedure to keep a record of unit dosage use.

Model Procedure

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
    a. Prescribed dosage (unless already recorded in clinical procedure manual),
    b. Measured activity in millicuries or microcuries and date and time of measurement,

c. Patient name and identification number if one has been assigned;

9. If discarded, the date and method of disposal; and

10. Initials of the individual who made the record.

B. Records of Multidose Vial Use

You may use the following model procedure to keep a record of multidose vial use.

Model Procedure

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,

   a. Prescribed dosage (unless already recorded in clinical procedure manual),

   b. Date and time dosage was drawn and measured,

   c. Calculated volume that is needed for the prescribed dosage,

   d. Measured activity in millicuries or microcuries,

   e. Patient name and identification number if one has been assigned;

7. If discarded, the method of disposal and date; and

8. Initials of the individual who made the record.

C. Measuring and Recording Molybdenum Concentration

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration and alumina contamination. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution.

Model Procedure

Each time a generator is eluted, make a record of the:

1. Date the generator was received;

2. Date and time of elution;

3. Measured Mo-99 activity in microcuries;

4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. The licensee must notify the Department if a leaking generator is detected). (The 0.07 action level allows for the quicker decay of the Tc through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.)

7. Initials of the person who made the record.

D. Keeping an Inventory of Implant Sources

Model Procedure

1. Use a locking installed cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX N

Model Procedure for Area Surveys

Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of LAC 33:XV.406, 430, and 724. Guidance for developing alternate trigger levels for contamination in restricted areas is included below. Before use of survey instrumentation, perform a daily check with a dedicated check source and battery checks.

Ambient Dose Rate Surveys (reference LAC 33:XV.406, 430 and 724)

1. Appropriate surveys will be conducted to ensure that the requirements of LAC 33:XV.421 are met.

2. Perform surveys of dose rates in locations where

    a. Workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits **or**

    b. An individual is working in an environment with a dose rate of 0.025 millisievert (mSv)/h [2.5 millirem/hour (h)] or more [5 rem/year (yr) divided by 2,000 h/yr].

3. Perform radiation level surveys with a radiation survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR)/h in the following areas, at the frequency specified:

    a. **Survey at the end of each day of use** all radiopharmaceutical elution, preparation, and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of the day of administration). If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

    b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), **survey monthly** with a radiation detection survey meter.

    c, In all radionuclide use, storage and waste storage areas, **survey weekly**

    d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

4. Regulations in LAC 33:XV.421.E, "Dose limits for individual members of the public," require that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 millisievert (mSv) [0.1 rem] in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv [0.002 rem] in any one hour. Appropriate surveys will be conducted to ensure that the requirements of LAC 33:XV.742 are met.

5. If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted and unrestricted areas are presented in Table N–1.

Table N-1. Ambient Dose Rate Trigger Levels

Type of Survey	**Area Surveyed**	**Trigger Level**
Ambient Dose Rate	Unrestricted	0.1 mR/h
Ambient Dose Rate	Restricted	5.0 mR/h

Contamination Surveys

Facilities and equipment for contamination surveys:

To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area. The section of Table B–1, entitled "Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples," provides examples of appropriate instruments.

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of byproduct materials are used:
    - to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
    - after any spill or contamination event
    - when procedures or processes have change
    - to evaluate contamination of users and the immediate work area, at the end of the

day or before leaving the area of use, when licensed material is used

- in unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly

- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment

- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables N–2 for restricted areas and Table N–3 for unrestricted areas [e.g., 200 disintegrations per minute (dpm)/100 square centimeters (cm2) for isotopes of I-131 in unrestricted areas]. Table N–3 for unrestricted areas is based on NRC's "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material" (August 1987). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:

  - **Survey weekly** for removable contamination in radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
  - **Survey monthly** for removable contamination in laboratory areas where only small quantities of photon emitting radioactive material are used (less than 200 µCi at a time).
  - **Survey weekly** for removable contamination in radionuclide storage and radionuclide waste storage areas.

- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in counts per minute) to dpm.

- Contamination found in unrestricted areas should be immediately decontaminated to background levels using appropriately sensitive equipment. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table N–3.

- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for

restricted areas are presented in Table N–2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table N-2. Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)	
Area, clothing	**Restricted areas, protective clothing used only in restricted area**
Alpha emitters	200
P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	2,000
Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201	20,000

Table N-3. Acceptable Surface Contamination Levels in Unrestricted Areas (per 100 cm^2)			
Nuclide[1]	**Average[2, 3, 4]**	**Maximum[2, 4, 5]**	**Removable[2, 4, 6]**
U-nat, U-235, U-238, and associated decay products	83.3 Bq 5,000 dpm	250 Bq 15,000 dpm	16.7 Bq 1,000 dpm
Transuranics, I-125, I-129, Ra-226, Ra-228, Pa-231, Ac-227, Th-230	1.7 Bq 100 dpm	5.0 Bq 300 dpm	0.3 Bq 20 dpm
-126, I-131, I-133, Ra-223, Ra-224, Sr-90, U-232, Th-nat, Th-232	16.7 Bq 1,000 dpm	50.0 Bq 3,000 dpm	3.3 Bq 200 dpm
Other alpha emitters[1]	8.33 Bq 500 dpm	25 Bq 1,500 dpm	1.67 100 dpm
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except those noted above.	83.3 Bq 5,000 dpm	250 Bq 15,000 dpm	16.7 Bq 1,000 dpm

[1]Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting radionuclides should apply independently.
[2]As used in this table, disintegrations per minute (dpm) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
[3]Measurements of average contaminants should not be averaged over more than 1 square meter.

For objects of less surface area, the average should be derived for each such object.
[4]The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/h at 1 cm and 1.0 millirad/h at 1 cm, respectively, measured through not more than 7 milligram/cm2 of total absorber.
[5]The maximum contamination level applies to an area of not more than 100 cm2.
[6]The amount of removable radioactive material per 100 cm2 of surface area should be determined by wiping that area with a filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally, and the entire surface should be wiped.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

    a. The date, area surveyed, and equipment used, serial number, and calibration date.

    b. The name or initials of the person who made the survey.

    c. A diagram of the areas surveyed with contamination and dose rate action levels as established by the RSO.

    d. Background levels

    e. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2 as appropriate.

    f. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

3. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

APPENDIX O

Model Procedure for Monitoring, Calculating, and Controlling Air Concentrations

WORKER DOSE FROM NOBLE GASES

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure checking trap effluent, you may respond by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix 0.3 to the Guide.

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation.

WORKER DOSE FROM AEROSOLS

If you collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the monitor manufacturer's instructions for checking for accuracy and constancy, you may respond by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation.

0.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:

   a. Estimated number of studies per week;

   b. Activity to be administered per study;

   c. Estimated activity lost to the work areas per study (you may assume 20 percent loss);

   d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);

   e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);

   f. Measured airflow exhaust at the storage site (e.g., a fume hood); and

   g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} μCi/ml in restricted areas and 5×10^{-7} μCi/ml in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 6×10^{-5} μCi/ml in restricted areas and $2 \times E^{-7}$ μCi/ml in unrestricted areas.

2. The following calculations must be made:

   a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.

   b. The estimated average concentration in restricted areas.

      (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.

(2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

0.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.

2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

0.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.

    1. If you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, the trap is breaking down and must be replaced.

4. Follow the trap manufacturer's instructions for replacing the trap.

SPILLED GAS CLEARANCE TIME

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix 0.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

0.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

    a. A, the highest activity of gas in a single container, in microcuries;

    b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;

    c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;

    d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-5} μCi/ml in restricted areas and 3×10^{-7} μCi/ml in unrestricted areas.

    e. V, the volume of the room in milliliters.

2. For each room make the following calculations:

    a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.

    b. The evacuation time $t = \frac{-V}{Q} \times 1n\ (C \times V/A)$.

APPENDIX P

Model Procedure for Radiation Safety during Iodine Therapy Over 30 Millicuries

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

    a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

    b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.

    c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

        (1) Containers should be unbreakable and closable.

        (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

        (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

        (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

        (5) Supply a wide-mouth antisplash funnel.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131, P-32, or Gold-198", or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line", and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter sign-out form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsulated I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. A licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mRem. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside

with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2/

    d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

APPENDIX Q

Model Procedure for Radiation Safety during Implant Therapy

You may use the following procedure to reduce worker and public dose during implant therapy.

Model Procedure

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It should be a private room.

2. Supply the nurses with film badges, TLDs, OSLDs, or pocket ionization chambers.

3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Temporary Implant Sources," or your own nursing instruction form as an outline. Allow time for questions an answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. Mark a visitors "safe line" on the floor with tape as far from the patient as possible.

7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

APPENDIX R

Model Procedure for Waste Disposal

The following general guidance and procedure may be used for disposal of radioactive waste. Most licensees will dispose of material that fall within these procedures. Note that some short half-life radionuclide products [e.g., technetium (Tc)-99m/molybdenum (Mo)-99 generator columns and some yttrium (Y)-90 microspheres] may contain long half-life contaminants that may preclude disposal by decay-in-storage and may require disposal by alternate methods, such as return to the manufacturer. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of LAC 33:XV.Subchapter H. "Waste Disposal" and LAC 33:XV.728.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer and release to in-house waste. With the exception of the patient excreta and generally licensed in vitro kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material

Model Procedure for Decay-In-Storage

Regulations in LAC 33:XV.728, "Decay-in-storage," describe the requirements for decay-in-storage. Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at as low as is reasonably achievable (ALARA) levels. Storage areas must be in a secure location.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

- Liquid and solid wastes should be stored separately.

- If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.

- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container.

- The container should be labeled in accordance with LAC 33:XV.453 and LAC 33:XV.454. The container may be transferred to the DIS area. When large quantities are held for DIS, measurable activities may be present even after many half lives and persons performing surveys should be aware of the potential for measurable radiation.

- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.

- Prior to disposal as ordinary or biomedical waste, monitor and record the results of monitoring of each container as follows:

    — Use a survey instrument on the lowest setting that is appropriate for the type and energy of the radiation being measured.
    — Check the radiation survey meter for proper operation and current calibration status.
    — Monitor in a low-level background radiation area away from all sources of radioactive material, if possible.
    — Remove any shielding from around the container or generator column.
    — Monitor, at contact, all surfaces of each individual container.
    — Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee, as described in LAC 33:XV.728).
    — Discard as in-house ordinary or biomedical waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
    — Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.
    — Short half-life radionuclide products, such as samarium-153 (Sm-153), Tc-99m/Mo-99 generator columns, and Y-90 microspheres may contain long half-life contaminants that may preclude disposal by decay-in-storage. Licensees need to perform surveys and dispose of long half-life contaminants.

Note: Check for any calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153), as these may not be held for decay-in-storage and must be

disposed of in accordance with LAC 33:XV.Chapters 4 and 6.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m, strontium-82/rubidium-82, or germanium-68/gallium-68 generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with LAC 33:XV.Chapter 15 and U.S. Department of Transportation (DOT) regulations. Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with LAC 33:XV.342, "Records."

Model Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with LAC 33:XV.340.C, confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's LDEQ License, U.S. Nuclear Regulatory Commission license or Agreement State license that authorizes the byproduct material).
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.

- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in LAC 33:XV.499. Appendix B.

- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in LAC 33:XV.462.A.4 and LAC 33:XV.499. Appendix B, Table 3.

- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of each radionuclide to the corresponding limit for each radionuclide in LAC 33:XV.499, Appendix B, Table 3 must not exceed unity.

- Confirm that the total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of tritium (H-3), 37 GBq [1 Ci] of carbon (C)-14, and 37 GBq [1 Ci] of all other radioactive materials combined. Note: LAC 33:XV.462.A.4 further limits the disposal of H-3, C-14, and "other radioactive material" to the limits noted above even when sewerage totals determined under LAC 33:XV.462.A.3, and as noted in the bullet above, may have allowed a higher sanitary sewerage disposal activity.

- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.

- Liquid waste should be discharged only via designated sinks, toilets, or other release points.

- Discharge liquid waste slowly, to minimize splashing, with water running to be sure that the material moves out of the sink and into the sewer system.

- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.

- Decontaminate all areas or surfaces if found to be contaminated.

- Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual

discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility

APPENDIX S

Acceptable Training and Experience for Medical Uses of Radioactive Material

Radiation Safety Officer

Except as provided in LAC 33:XV.763.B, an individual fulfilling the responsibilities of the radiation safety officer as provided in LAC 33:XV.706 shall:

1. who is certified by a specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Paragraphs A.4 and 5 of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.); or

2. who has completed a structured educational program consisting of both:

a. 200 hours of classroom and laboratory training in the following areas:
   i. radiation physics and instrumentation;
   ii. radiation protection;
   iii. mathematics pertaining to the use and measurement of radioactivity;
   iv. radiation biology; and
   v. radiation dosimetry; and

b. one year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a commission or agreement state license or permit issued by a commission master material licensee that authorizes similar type(s) of use(s) of byproduct material; or

3. is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has radiation safety officer responsibilities; and

4. who has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in Paragraph A.5 and in Clauses A.1.a.i and ii or Clauses A.1.b.i and ii or Paragraph A.2 or Subparagraph A.3.a or b of this Section, and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

5. who has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Training for Experienced Radiation Safety Officer

An individual identified as a radiation safety officer on an agreement state, licensing state, the Radiation Control Section or U. S. Nuclear Regulatory Commission license on February 20, 1991, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of LAC 33:XV.763.

Training for Uptake, Dilution, or Excretion Studies

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user of a radiopharmaceutical listed in LAC 33:XV.729 to be a physician who:

1. who is certified by a specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Paragraphs A.4 and 5 of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.); or

2. a. has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include:
    i. classroom and laboratory training in the following areas:
        (a). radiation physics and instrumentation;
        (b). radiation protection;
        (c). mathematics pertaining to the use and measurement of radioactivity;
        (d). chemistry of byproduct material for medical use; and
        (e). radiation biology; and
    ii. work experience, under the supervision of an authorized user who meets the requirements in Subsection C or D or Paragraph E.1 of this Section, or equivalent agreement state requirements;

and

3.. has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Subsection C or D or Paragraph E.1 of this Section, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in Subparagraph C.1.a or C.3.a of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in LAC 33:XV.729.

Training for Imaging and Localization Studies

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in Section 731 to be a physician:

1. who is certified by a medical specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Subparagraph D.3.b of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.) ; or

2. who meets the following requirements:
   a. has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum:
      i. classroom and laboratory training in the following areas:
         (a). radiation physics and instrumentation;
         (b). radiation protection;
         (c). mathematics pertaining to the use and measurement of radioactivity;
         (d). chemistry of byproduct material for medical use; and
         (e). radiation biology; and
   b. work experience, under the supervision of an authorized user, who meets the requirements in this Subsection, or Subclause D.3.a.ii.(f) and Paragraph E.1 of this Section, or equivalent agreement state requirements,

and

3. has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this Subsection, or Paragraph E.1 and Subclause D.3.a.ii.(f) of this Section, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in Subparagraph D.1.a or D.3.a of this Section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in LAC 33:XV.729 and LAC 33:XV.731.H.

Training for Therapeutic Use of Radiopharmaceuticals

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user of a radiopharmaceutical listed in LAC 33:XV.735 for therapy to be a physician:

1. who is certified by a medical specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Division E.1.b.i.(b).(vii) and Clause E.1.b.ii of this Section. (Specialty boards whose certification processes have been recognized by the commission or an agreement state will be posted on the NRC's web page.)

OR

2. who meets the following requirements:
    i. has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include:
    (a). classroom and laboratory training in the following areas:
        (i). radiation physics and instrumentation;
        (ii). radiation protection;
        (iii). mathematics pertaining to the use and measurement of radioactivity;
        (iv). chemistry of byproduct material for medical use; and
        (v). radiation biology; and
    (b). work experience, under the supervision of an authorized user who meets the requirements in this Paragraph, or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in Subparagraph E.1.b of this Section, must also have experience in administering dosages in the same dosage category or categories (i.e., Division E.1.b.i.(b).(vii) of this Section) as the individual requesting authorized user status. The work experience must involve:
        (i). ordering, receiving, and unpacking radioactive materials safely and

performing the related radiation surveys;

(ii). performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii). calculating, measuring, and safely preparing patient or human research subject dosages;

(iv). using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (v). using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(vi). Reserved.

(vii). administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

[a]. oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I–131, for which a written directive is required;

[b]. oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 (Experience with at least three such cases also satisfies the requirement in Subdivision E.1.b.i.(b).(vii).[a] of this Section.);

[c]. parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

[d]. parenteral administration of any other radionuclide, for which a written directive is required;

AND

2. has obtained written attestation that the individual has satisfactorily completed the requirements in Clause E.1.a.i and Division E.1.b.i.(b).(vii) or Clause E.1.b.i of this Section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in LAC 33:XV.735.C. The written attestation must be signed by a preceptor authorized user who meets the requirements in this Paragraph or equivalent agreement state requirements. The preceptor authorized user who meets the requirements in Subparagraph E.1.b of this Section must have experience in administering dosages in the same dosage category or categories (i.e., Division E.1.b.i.(b).(vii) of this Section) as the individual requesting authorized user status.

Training for Therapeutic Use of Manual Brachytherapy Sources

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user using a brachytherapy source specified in LAC 33:XV.741, for therapy to be a physician:

1. who is certified by a medical specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the

requirements in Subparagraph F.2.c of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.)

OR

2. who has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
   i. 200 hours of classroom and laboratory training in the following areas:
      (a). radiation physics and instrumentation;
      (b). radiation protection;
      (c). mathematics pertaining to the use and measurement of radioactivity; and
      (d). radiation biology; and
   ii. 500 hours of work experience under the supervision of an authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements at a medical institution, involving:
      (1) ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

      (2) checking survey meters for proper operation;

      (3) preparing, implanting, and removing sealed sources;

      (4) using administrative controls to prevent the misadministration of radioactive material; and

      (5) using emergency procedures to control radioactive material.and

   iii. has completed three years of supervised clinical experience in radiation oncology under the supervision of an authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in Subparagraph F.2.a.ii of this Section;

AND

3. has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in Subparagraph F.1.a, or Paragraph F.2.a and b of this Section, and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized in LAC 33:XV.741.

Training for Ophthalmic Use of Strontium-90

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

1. who is an authorized user in accordance with Subsection F of this Section, or equivalent agreement state requirements;

OR

2. who meets the following requirements:
   a. has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:
      i. radiation physics and instrumentation;
      ii. radiation protection;
      iii. mathematics pertaining to the use and measurement of radioactivity; and
      iv. radiation biology; and
   b. supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
      i. examination of each individual to be treated;
      ii. calculation of the dose to be administered;
      iii. administration of the dose; and
      iv. follow-up and review of each individual's case history;

AND

3. has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Subsections F and G of this Section, or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in Paragraphs G.1 and 2 of this Section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Training for Use of Sealed Sources for Diagnosis

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user using a sealed source in a device specified in LAC 33:XV.739 to be a physician, dentist, or podiatrist:

1. who is certified by a specialty board whose certification process includes all of the requirements in Paragraphs H.2 and 3 of this Section and whose certification process has been recognized by the commission or an agreement state. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.);

OR

2. who has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:
    a. radiation physics and instrumentation;
    b. radiation protection;
    c. mathematics pertaining to the use and measurement of radioactivity; and
    d. radiation biology;

AND

3. who has completed training in the use of the device for the uses requested.

Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Sterotactic Radiosurgery Units

Except as provided in LAC 33:XV.763.B, the licensee shall require the authorized user of a sealed source specified in LAC 33:XV.747 in a teletherapy unit to be a physician:

1. who is certified by a medical specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Subparagraph I.2.c and Paragraph I.3 of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.)

OR

2. who meets the following requirements:
    a. has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
        i. 200 hours of classroom and laboratory training in the following areas:
            (a). radiation physics and instrumentation;
            (b). radiation protection;
            (c). mathematics pertaining to the use and measurement of radioactivity;

and

(d). radiation biology; and

ii. 500 hours of work experience under the supervision of an authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements at a medical institution, involving:

(a). reviewing full calibration measurements and periodic spot-checks;

(b). preparing treatment plans and calculating treatment doses and times;

(c). using administrative controls to prevent a medical event involving the use of byproduct material;

(d). implementing emergency procedures to be followed in the event of the abnormal operation of a medical unit or console;

(e). checking and using survey meters; and

(f). selecting the proper dose and how it is to be administered; and

b. has completed three years of supervised clinical experience in radiation therapy under the supervision of an authorized user who meets the requirements in this Subsection, or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in Subparagraph I.2.a.ii of this Section;

AND

3. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraph I.1.a or Subparagraph I.2.a and b and Paragraph I.3 of this Section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in this Subsection or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status;

AND

4. who has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Training for an Authorized Medical Physicist

Except as provided in Subsection B of this Section, the licensee shall require the authorized medical physicist to be an individual:

1. who is certified by a specialty board whose certification process has been recognized by the commission or an agreement state, and who meets the requirements in Subparagraph J.2.b and Paragraph J.3 of this Section. (The names of board certifications that have been recognized by the commission or an agreement state will be posted on the NRC's web page.)

OR

2. who meets the following requirements:
    a. holds a master's or doctor's degree in physics, medical physics, another physical science, engineering, or applied mathematics from an accredited college or university, and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in a clinical radiation facility that provides high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services, and must include:
        i. performing sealed source leak tests and inventories;
        ii. performing decay corrections;
        iii. performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
        iv. conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable;

AND

    b. has obtained written attestation that the individual has satisfactorily completed the requirements in Subparagraphs J.1.a and b and Paragraph J.3, or Subparagraph J.2.a and Paragraph J.3, of this Section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this Subsection, or equivalent agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status;

AND

3. who has training for the type(s) of use for which authorization is sought that

includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Recentness of Training

The training and experience specified in Subsections A-K of this Section shall have been obtained within the seven years preceding the date of application, or the individual shall have had continuing applicable experience since the required training and experience was completed.

ADDENDUM TO PERMIT APPLICATIONS:

The "ADDENDUM TO PERMIT APPLICATIONS PER LAC 33:I.1701. This form must be completed before a license can be issued. This form can be found at: http://www.deq.louisiana.gov/portal/tabid/240/Default.aspx

APPENDIX T
MODEL PROCEDURES FOR REMOTE AFTERLOADER SPOT-CHECKS

This model provides acceptable procedures for performing spot-checks of Remote Afterloader units, equipment, and facilities as required in LAC 33:XV.757.B. This procedure applies to high dose-rate, medium dose-rate, pulsed dose-rate, or low dose-rate (LDR) remote afterloader units. Applicants may either adopt these model procedures or develop alternative procedures.

Periodic Spot-Checks for Remote Afterloader Units

Before the first use on a given day (or before each patient treatment for LDR remote afterloaders) and after each source installation, the following spot-checks will be performed:

- Electrical Interlocks at Each Room Entrance

Proper functioning of the treatment room door interlock will be performed using the remote afterloader source.

Expose the remote afterloader source inside the treatment room, open the treatment room door, and verify that the source retracts. The source should retract immediately, the area radiation monitor should alarm, and the control console should indicate that the door is open. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Source Exposure Indicator Lights

    — Treatment Console Indicators and Status Lamps

        Turn on the remote afterloader unit and verify that the indicator lights flash to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the treatment console are lit to indicate an exposed source.

    — Remote Afterloader Indicators and Status Lamps

        Turn on the remote afterloader unit and verify that the indicator lights flash on the remote afterloader to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the remote afterloader are lit to indicate an exposed source.

- Viewing and Intercom Systems

    — Viewing System

Turn on the camera(s). Check that the camera(s) is (are) operable and that the treatment area can be viewed from the treatment console. Adjust, if necessary.

— Intercom System

Turn on the intercom system. The intercom system will be tested using a two-person method. One person will be at the treatment console while another person is in the treatment room. Both individuals will speak and confirm that the other is heard.

- Emergency Response Equipment

Verify the presence of the emergency equipment within the treatment room. This equipment includes but is not limited to a mobile lead container large enough to hold the largest applicator, long-handled forceps, wire cutter, flashlight, suture removal kit, and timer (timer located at unit console). If a portable radiation survey meter is included, verify the presence, current calibration of the meter and check the operability using a radioactive check source.

- Radiation Monitors Used to Indicate the Source Position

Verify that the area radiation monitor located inside the treatment room is on with the indicator light flashing green. Expose the remote afterloader source inside the treatment room with the door closed and verify that the indicator light flashes red; indicating the presence of radiation. This test will be performed with the area radiation monitor on A/C power and on battery backup power.

- Timer Accuracy

Expose the remote afterloader source inside the treatment room with the door closed. Immediately start a stopwatch when the control console indicates that the source is exposed. Stop the stopwatch when the control console indicates that the source is retracted. Compare the stopwatch measured time to the irradiation time indicated on the control console. Verify that the comparison is within 1 percent.

- Clock Date and Time in the Computer for the Remote Afterloader

Verify clock date and time printed on the control console documentation of the pretreatment checks against the actual date and time. The date must be exact, and the time may be within 1 hour.

- Decayed Source Activity in the Computer for the Remote Afterloader

Verify the source activity (or decay factor) displayed on the remote afterloader control

console matches to within 0.5 percent of the manufacturer's provided decay table for today's date.

Note: If the results of the above checks indicate the malfunction of any system, the control console shall be locked in the off position, as required by LAC 33:XV.757.B, and not used except as may be necessary to repair, replace, or check the malfunctioning system.

In addition, consideration will be given to testing the following before the first use of the remote afterloader unit on a given day:

- Treatment Interrupt Button

  Press the "Interrupt" button on the control console while source is exposed. Verify that the source retracts immediately, and the control console indicates an alarm. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Emergency Off Button

  Press the "Stop" button on the control console while the source is exposed. Verify that the source retracts immediately, and the control console indicates an alarm. Repeat the test for all wall-mounted "Stop" buttons. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Dual Use Switch

  An X-ray unit is also used in the remote afterloader treatment room, and a selector switch to limit operation to only one unit at a time is installed.

  With the key switch on the wall set to X-ray, attempt to expose the remote afterloader source. Verify that the area radiation monitor and the control console source indicator lights do not illuminate; indicating that the source did not expose. Switch the key to remote afterloader. Expose the remote afterloader source and confirm that the area radiation monitor illuminates. With the remote afterloader source still exposed, switch the key back to X-ray, and confirm that the remote afterloader source retracts and the area radiation monitor flashes green. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Misconnected or Missing Transfer Tube and/or Applicator

Misconnect a transfer tube to the remote afterloader. This may either be performed by connecting the transfer tube to the wrong channel or by not fully inserting the transfer tube into the correct channel. Attempt to expose the remote afterloader source and verify that the source does not expose as indicated by the area radiation monitor. Additionally, verify that an error is indicated on the control console for the misconnection. Repeat the test with an applicator intentionally misconnected to a transfer tube that is correctly inserted into the remote afterloader.

- Mechanical Integrity of Applicators, Transfer Tubes, Connectors

  Perform a visual inspection of all applicators, transfer tubes, and connectors to be used for patient treatments that day. Check for any potential mechanical defects. Replace if a defect is noted.

- Position of Remote Afterloader Within the Treatment Room

  For some remote afterloader units located within minimally shielded rooms, the location of use within the room may have been specified in the application to ensure that the regulatory limits in LAC 33:XV.421 will not be exceeded. If this is the case, verify that the positioning of the remote afterloader unit within the treatment room is in accordance with the commitments made in the application.

References and Resources:

AAPM Report No. 41, "Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41)," 1993

APPENDIX U
Model Procedures for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives (WD). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of LAC 33:XV.777.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a high dose-rate treatment, the delivery process may involve a team of medical professionals, such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, and film verifications to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be completed before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, ophthalmic physicist, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each such modality for which LAC 33:XV.777 requires, or would require, a WD, the licensee should develop, implement, and maintain written procedures to meet the requirements and objectives of LAC 33:XV.777, outlined below:

- Confirm that the WD is signed and dated by the AU prior to the administration, in accordance with LAC 33:XV.777, and includes the name of the patient or human research subject.

- Verify the identity of the patient or human research subject prior to each administration.

- Verify that the administration is in accordance with the treatment plan, if applicable, and the

WD.

- Check both manual and computer-generated dose calculations.

- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by LAC 33:XV.747.

- Determine if a medical event, as defined in LAC 33:XV.712, has occurred.

- Determine, for permanent implant brachytherapy, within 60 calendar days from the date of implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the written directive.

- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 Microcuries of Iodine-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of LAC 33:XV.777:

- An AU must date and sign a WD prior to the administration of any dose or dosage. WDs may be maintained in patients' charts and must be available for inspection and retained for 3 years.

- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or other forms of identification. Asking or calling the patient's name does not constitute positive patient identity verification.

- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (e.g., radionuclide, total source strength, total dose, or dosage) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include
  (i) measuring the activity in the dose calibrator,
  (ii) checking the serial number of the sealed sources behind an appropriate shield,
  (iii) using color-coded sealed sources, or

(iv) using clearly marked storage locations

Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Complete the WD in accordance with LAC 33:XV.777. For temporary implants, before implantation, record the treatment site, radionuclide, and dose, and after implantation but before completion of the procedure, record the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date, as required by as required by LAC 33:XV.777.B.7.. For permanent implants, before implantation, record the treatment site, radionuclide, and total source strength and after implantation but before the patient leaves the post-treatment recovery area, record the treatment site, the number of sources implanted, the total source strength implanted, and the date, as required by LAC 33:XV.777.B.6. The WD may be maintained in the patient's chart.

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

- for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)

- for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)

- for manually-generated dose calculations, verifying

— no arithmetical errors
— appropriate transfer of data from the WD, treatment plan, tables, and graphs
— appropriate use of nomograms (when applicable)
— appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment-planning or dose-calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment-planning or dose-calculating computer program for therapy dose calculations. Each treatment-planning or dose-calculating computer program will be assessed, based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot-check measurements indicate that the source output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay.

Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either

1. an individual who did not perform the full calibration (the individual will meet the requirements specified in LAC 33:XV.763.J) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in LAC 33:XV.755), or

2. an AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5 percent.

For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient’s skull match those of the treatment plan.

For emerging technologies (e.g., Yttrium-90 Microsphere Brachytherapy, Leksell Gamma Knife Perfexion), the licensee should review the applicable guidance on the NRC Medical Uses Licensee Toolkit Web page to ensure the written directive contains all necessary components.

A physical measurement of the teletherapy output will be made under applicable conditions prior to

administration of the first teletherapy fractional dose, if the patient's treatment plan includes (i) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (ii) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, ophthalmic physicist, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

Treatment-planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused and must be relabeled in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

As required by LAC 33:XV.777, determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable, and whether a medical event, as defined in LAC 33:XV.712, has occurred.

For permanent implant brachytherapy, determine, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the WD, to evaluate whether a medical event, as defined in LAC 33:XV.712, has occurred. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Conduct periodic reviews of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). The number of patient cases to be sampled should be based on the number of treatments performed and be representative of each treatment modality performed in the institution.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

Reports of Medical Events

Notify by telephone LDEQ/Radiation Section 24-hour hotline at 225-765-0160 no later than the next calendar day after discovery of a medical event and submit a written report to LDEQ/Radiation Section within 15 days after the discovery of the medical event, as required by LAC 33:XV.712. Also, notify the referring physician and the patient as required.

APPENDIX V
Release of Patients or Human Research Subjects
Administered Radioactive Materials

LAC 33:XV.725 permit a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv [0.5 rem]." However, a patient who meets the release criteria in LAC 33:XV.725 is not required to leave the hospital immediately following administration of radioactive materials and may be hospitalized for other medical reasons. The licensee can release the patient from its radiological controls while the patient remains hospitalized for other medical reasons if the licensee ensures LAC 33:XV.725 is met for that patient's specific situation.

Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Materials," provides guidance for releasing patients under LAC 33:XV.725. Licensees should use the most current version of RG 8.39 when developing procedures for the release of patients who are administered radioactive materials.

- Information Notice (IN) 2017-02, "Best practice concepts for patient release," issued May 17, 2017.

- Regulatory Issue Summary (RIS) RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," issued January 25, 2011.

- RIS 2008-11, "Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administrations of Iodine-131," issued in May 12, 2008.

- IN 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations," issued on December 9. 2003 and its Supplement issued July 29, 2009.

APPENDIX W
MODEL MEDICAL LICENSEE AUDIT

Annual Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Also, the audit notes may not be complete for nonmedical uses authorized on the license.

Date of this audit: _____

Date of last audit: _____

Date of next audit: _____

Auditor: _____
Signature Date

Management review: _____
Signature Date

All references are to LAC 33:XV.Radiation Protection Parts unless noted otherwise.

License (License Condition)

1. License Number.

2. Current Amendment Number.

3. Are all of the tie-down documents on file?

4. Has the Legal Entity having control over licensed activities changed since the last audit?
   Are materials, uses, and locations of use confined to those specifically described in the license?

Audit History
1. Were previous audits conducted annually [LAC 33:XV.406.C.]?
2. Were records of previous audits maintained [LAC 33:XV.471.A.2]?
3. Were any deficiencies identified during previous audit?
4. Were corrective actions taken? (Look for repeated deficiencies.)
5. Any previous problem/deficiency not corrected or repeated?

6. What corrective actions from previous audits, if any, are still in progress?

Organization and Scope of Program

1. Radiation Safety Officer (RSO)

    a. If the RSO was changed, was the license amended [LAC 33:XV.703]

    b. Does the new RSO meet LDEQ training requirements [LAC 33:XV.763.A]?

    c. If the scope of the program expanded, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [LAC 33:XV.763.A]?

    d. Is the RSO fulfilling all duties and responsibilities [LAC 33:XV.706]?

    e. If the scope of the program expanded, have the RSO duties been updated to reflect the scope of the program [LAC 33:XV.706]?

    f. Is the written agreement in place for the new RSO [LAC 33:XV.706]?

    g. Has the Department been notified about a temporary RSO [LAC 33:XV.703]?

    h. Are the written agreements and duties and responsibilities in place for the temporary RSO [LAC 33:XV.706]?

2. Associate Radiation Safety Officer (ARSO):

    a. If the ARSO was changed, was the license amended [LAC 33:XV.703]?

    b. Does the new ARSO meet the Department training requirements [LAC 33:XV.763.A]?

    c. If the scope of the program expands, did the RSO assign duties for the expanded program and does the ARSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses?

    d. Is the ARSO fulfilling all duties and tasks?

    e. Is the written appointment in place for a new ARSO?

3. Multiple places of use? If yes, list locations. [License Condition (L/C)]

4. Are all locations listed on license? (L/C)

5. Were annual audits performed at each location? If no, explain.

6. Describe the scope of the program (e.g., staff size, number of procedures performed)

7. Licensed Material: (L/C)

    a. Isotope, chemical form, physical form, quantity, and use as authorized?

    b. Does the total amount of radioactive material possessed require financial assurance? If so, is financial assurance current?

    c. Calibration, transmission, and reference sources?

        i. Sealed sources manufactured and distributed by a person licensed pursuant to LAC 33:XV.328.L, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 1.11 gigabecquerel (GBq) [30 millicuries (mCi)] each [LAC 33:XV.717]?

        ii. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq [15 mCi]?

        iii. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq [200 microcuries (µCi)] or 1,000 times the quantities in LAC 33:XV.499.Appendix C?

        iv. Technetium-99m (Tc-99m) in individual amounts as needed?

        v. The sources are not used for medical use except in accordance with the requirements in LAC 33:XV.739?

        vi. The sealed sources are not combined (bundled or aggregated) to create an activity greater than the maximum activity listed above [LAC 33:XV.718]?

    d. Unsealed materials used under LAC 33:XV.729, LAC 33:XV.731, and LAC 33:XV.735 are:

        i. Obtained from a manufacturer or preparer licensed under LAC 33:XV.328.J?

        OR

        ii. Obtained from a producer of Positron Emission Tomography radioactive

drugs under LAC 33:XV.324?

OR

iii. Prepared by a physician authorized user (AU), an authorized nuclear pharmacist (ANP), or an individual under the supervision of an ANP or physician AU?

OR

iv. Obtained and prepared for research in accordance with LAC 33:XV.729, LAC 33:XV.731, and LAC 33:XV.735, as applicable?

8. Are the sealed sources possessed and used under LAC 33:XV.741.B, 10 CFR 35.500, and 10 CFR 35.600 approved in the Sealed Source and Device Registry? Are the sealed sources used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

9. Are the actual uses of medical devices consistent with the authorized uses listed on the license? (L/C)

10. If places of use/storage changed, was the license amended [LAC 33:XV.703]?

11. If control of the license was transferred, was the Department's prior consent obtained or notification made [LAC 33:XV.331.B.1]?

12. If bankruptcy was filed, was the Department immediately notified [LAC 33:XV.331.E]?

Radiation Safety Program

1. Minor changes to program?

2. Records of changes maintained for 5 years?

3. Content and implementation reviewed annually by the licensee?

4. Records of reviews maintained?

Nationally Tracked Sources

1. Reports of transactions involving nationally tracked sources submitted to National

Source Tracking System?

Use by Authorized Individuals (L/C)

1. Authorized Nuclear Pharmacist?

    a. Listed on facility license?

2. Authorized User:

    a. Listed on facility license?
    b. Each AU only uses material for which they are authorized?

3. Authorized Medical:

    a. Listed on a facility license?
    b. Each AMP only uses material for which they are authorized?
    c. If applicable, performs tasks described in LAC 33:XV.719.N and 756, as appropriate?

4. Ophthalmic Physicist

    a. Listed on facility license?
    b. Only uses material for which they are authorized?
    c. Performs tasks described in LAC 33:XV.719.N?

5. Nonmedical use authorized users:

    a. Listed on facility license for same materials and uses?

Mobile Medical Service

1. Operates services per LAC 33:XV.726?

2. Compliance with public dose limits evaluated and met?

3. Are all base locations listed on the license? (L/C)

4. Mobile Medical Agreement letter signed by management of each client?

5. Licensed material not delivered to client's address, unless client was authorized?

6. Dosage measuring instruments checked for proper function before use at each address of use or on each day of use, if more frequent?

7. Survey instruments checked for proper operation before use at each address of use?

8. Survey all areas of use prior to leaving each client address?

9. Adequate security maintained for mobile trailer? Keypad codes changed, or keys retrieved when an employee terminates employment?

10. AUs briefed on responsibilities for supervising the use of licensed material?

11. Compliance with additional technical requirements for mobile remote afterloaders evaluated and met, including record retention?

Amendments since Last Audit [LAC 33:XV.703]

1. Any Amendments since last audit?

2. Security-related sensitive information was properly marked?

Notifications since Last Audit [LAC 33:XV.704]

1. Any Notifications since last audit?

2. Appropriate documentation provided to the Department for ANP, AMP, ophthalmic physicist, or AU, no later than 30 days after the individual starts work?

3. The Department notified within 30 days after: AU, ANP, AMP, ophthalmic physicist, or RSO/ARSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for LAC 33:XV.729 or 731 use; the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number.

Training, Retraining, and Instructions to Workers

1. Briefly describe the training program.

2. Is the training program implemented? Have workers been provided with required instructions?

3. Is the individual's understanding of current procedures and regulations adequate?

4. Do appropriate individuals have adequate understanding of appropriate:

   a. Operating procedures?
   b. Emergency procedures?

5. Do appropriate individuals have an up-to-date copy of the licensee's operating use and emergency procedures?

6. Periodic training required and implemented?

7. Vendor operational and safety training provided prior to first patient treatment of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit?

8. Were all workers who are likely to exceed 1 millisievert (mSv) [100 millirem (mrem)] in a year instructed and was refresher training provided, as needed?

9. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives (WD), as appropriate?

10. Are initial and periodic training records maintained for each individual?

11. Hazardous Materials (HAZMAT) training [49 CFR Part 172]

12. Do additional therapy device instructions/training include:

    a. Unit operation, inspection, associated equipment, survey instruments?
    b. License conditions applicable to the use of the unit? c. Emergency drills?

13. Are workers cognizant of requirements for:

    a. Radiation Safety Program [LAC 33:XV.706, LAC 33:XV.406]?
    b. Annual dose limits [LAC 33:XV.410, 421 and 422]?
    c. 10 percent monitoring threshold [LAC 33:XV.431]?
    e. Dose limits to embryo/fetus and declared pregnant worker [LAC 33:XV.417]?
    f. "Grave Danger" Posting [LAC 33:XV.451)]?
    g. Procedures for opening packages [LAC 33:XV.455]?

14. Is supervision of individuals by AU and/or ANP in accordance with LAC 33:XV.709?

15. Was training provided for workers involved with emerging technologies in accordance with the Department license and tie-downs?

Training for Manual Brachytherapy and Use of Unsealed Byproduct Material for Which a Written Directive Is Required

1. Does safety instruction to personnel include [LAC 33:XV.736, LAC 33:XV.742]:

    a. Control of patient and visitors?
    b. Routine visitation to patients in accordance with LAC 33:XV.421?
    c. Contamination control and size/appearance of sources?
    d. Safe handling and shielding instructions?
    e. Waste control?
    f. RSO and AU notification, if patient had a medical emergency or died?
    g. Records retained?

Facilities

1. Facilities, as described in license application? (L/C)

2. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?

3. Emergency source recovery equipment available [LAC 33:XV.743, LAC 33:XV.751]?

4. Storage areas:

    a. Materials secured from unauthorized removal or access [LAC 33:XV.445.A]?
    b. Licensee controls and maintains constant surveillance of licensed material not in storage [LAC 33:XV.445.B]?
    c. Locations appropriately shielded to control public and occupational exposures in accordance with LAC 33:XV?

5. Therapy unit operation:

    a. Unit, console, console keys, and treatment room controlled adequately [LAC 33:XV.445.A, B and, 750]?
    b. Restricted to certain source orientations and/or gantry angles? (L/C)
    c. Ceases to operate in restricted orientation(s)? (L/C)
    d. Only one radiation device can be placed in operation at a time within the treatment room [LAC 33:XV.750)]?

Dose or Dosage Measuring Equipment

1. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [LAC 33:XV.715]:

   a. Types of equipment listed?
   b. Approved procedures for use of instrumentation followed?
   c. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
   d. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., ±10 percent)?
   e. Records maintained and include required information?

2. Determination of dosages of unsealed byproduct material [LAC 33:XV.717]?

   a. Each dosage determined and recorded prior to medical use ? Or transfer?
   b. Measurement of unit dosages of alpha, beta, or photon emitting radionuclides made either by direct measurement, or by decay correction of the activity provided by the licensed producer?
   c. For other than unit dosages of alpha, beta, or photon emitting radionuclides, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation using the activity provided by the licensed producer?

3. Licensee uses generators?

   a. Each eluate tested for molybdenum-99 (Mo-99) breakthrough [LAC 33:XV.732?
   b. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 kilobecquerel (kBq) per MBq [0.15 µCi per mCi] of Tc-99m?
   c. Before first patient use of day eluate tested for strontium (Sr)-82 and strontium-85 (Sr-85) when eluting rubidium (Rb)-82?
   d. No radiopharmaceuticals administered with Sr-82 concentrations over 0.02 kBq per MBq [0.02 µCi per mCi] of Rb-82 or Sr-85 concentrations over 0.2 kBq per MBq [0.2 µCi per mCi] of Rb-82?
   e. Each measurement that exceeds the limits in paragraph b or d above reported to the department and distributor of the generator in accordance with LAC 33:XV.732.D?
   f. Records maintained?

4. Confirmation of source output or activity for manual brachytherapy sources? Alternatively, the manufacturer's measurements may be accepted, if the criteria in LAC 33:XV.719 have been met.

5. Dosimetry Equipment [LAC 33:XV.755]:

a. Calibrated system available for use?
b. Calibrated by National Institute of Standards and Technology or an American Association of Physicists in Medicine (AAPM)-accredited lab within previous 2 years and after servicing or calibrated by intercomparison?
c. Calibrated within the previous 4 years?
d. Licensee has available for use a dosimetry system for spot-check measurements?
e. Record of each calibration, intercomparison, and comparison maintained?

Radiation Protection and Control of Radioactive Material

1. Use of radiopharmaceuticals:

a. Protective clothing worn?
b. Personnel routinely monitor their hands?
c. No eating/drinking in use/storage areas?
d. No food, drink, or personal effects kept in use/storage areas?
e. Proper dosimetry worn?
f. Radioactive waste disposed of in proper receptacles?
g. Syringe shields and vial shields used and are specific to the energy emitted?
h. Proper use of remote-handling tools and radiation shields?

2. Leak tests and inventories:

a. Leak test performed on sealed sources and brachytherapy sources at appropriate intervals or leak test license condition?
b. Inventory of sealed sources and brachytherapy sources performed semiannually?
c. If applicable, transactions associated with nationally tracked sources entered into the NSTS, including annual reconciliation?
d. Records maintained?

Radiation Survey Instruments

1. Survey instruments used to show compliance with LAC 33:XV

a. Appropriate operable survey instruments possessed or available?
b. Calibrations:
   i. Before first use, annually, and after repairs?
   ii. Within 20 percent on each scale or decade of interest, as applicable?
   iii. Instrument sent to a licensed instrument service provider?
   iv. Copy of instrument service provider license on file?

c. Records maintained?

2. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements?

   a. Daily in all areas where radiopharmaceuticals requiring a WD are prepared or administered (except patient rooms)?
   b. Weekly in all areas where radiopharmaceuticals or wastes are stored?
   c. Weekly for wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
   d. Trigger levels for surveys established?
   e. Corrective action taken and documented if trigger level exceeded?
   f. Techniques can detect 0.1 milliroentgen/hour, 2,000 disintegrations per minute?
   g. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry and records maintained?
      i. After new source installation?
      ii. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

1. Is licensed material used in a manner to keep doses below 1 mSv [100 mrem] in a year [LAC 33:XV.421]?

2. Has a survey or evaluation been performed, per LAC 33:XV.430?

3. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

4. Do unrestricted area radiation levels exceed 0.02 mSv [2 mrem] in any 1 hour?

5. Is licensed material used or stored in a manner that would prevent unauthorized access or removal?

6. Are records maintained?

Patient Release

1. Individuals released when total effective dose equivalent (TEDE) is less than 5 mSv [0.5 rem] [LAC 33:XV.725.A]?

2. Instructions to the released individual, including breastfeeding women, include required information [LAC 33:XV.725.B]?

3. Release records maintained [LAC 33:XV.725.C]?

4. Records of instructions given to breastfeeding women maintained, if required?

Unsealed Byproduct Material for Which a Written Directive Is Required [LAC 33:XV.737]

1. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls?

2. RSO and AU promptly notified if patient had a medical emergency or died?

Brachytherapy or Brachytherapy Source Use [LAC 33:XV.745]

1. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment?

2. Survey immediately after implant?

3. Patients surveyed immediately after removing the last temporary implant source?

4. RSO and AU promptly notified if patient had a medical emergency or died?

5. Records maintained?

Radioactive Waste

1. Disposal:

   a. Decay-in-storage [LAC 33:XV.728]?
   b. Procedures followed?
   c. Labels removed or defaced?

2. Special procedures performed as required?

3. Authorized disposals?

4. Records maintained?

5. Effluents:

a. Release to sanitary sewer [LAC 33:XV.462]?
   i. Material is readily soluble or readily dispersible?
   ii. Monthly average release concentrations do not exceed LAC 33:XV.499. Appendix B, Table 2 values?
   iii. No more than 5 curies (Ci) (185 GBq) of tritium (H-3), 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radionuclides combined, released in a year?
   iv. Procedures to ensure representative sampling and analysis implemented?

b. Release to septic tanks ? Within unrestricted limits [LAC 33:XV.499. Appendix B, Table 2]?

c. Waste incinerated?
   i. License authorizes [LAC 33:XV.463]?
   ii. Exhaust directly monitored?
   iii. Airborne releases evaluated and controlled [LAC 33:XV.422 & 430]?

d. Air effluents and ashes controlled?
   i. Air effluent less than 0.10 mSv [10 mrem] constraint limit?
      1. If no, reported appropriate information to the Department?
      2. If no, corrective actions implemented and on schedule?
   ii. Description of effluent program:

e. Monitoring system hardware adequate?

f. Equipment calibrated, as appropriate?

g. Air samples/sampling technique (e.g., charcoal, high-efficiency particulate air) analyzed with appropriate instrumentation?

6. Waste storage:

a. Protection from elements and fire?
b. Control of waste maintained including constant surveillance of waste not in storage and secure from unauthorized removal or access for waste in storage?
c. Containers properly labeled and area properly posted?
d. Package integrity adequately maintained?

7. Waste disposal:

a. Sources transferred to authorized individuals?
b. Name of organization: _____ .

c. Copy of waste disposal recipient's license on file?

8. Records of surveys and material accountability maintained?

Receipt and Transfer of Radioactive Material

1. Description of how packages are received and by whom?

2. Written package-opening procedures established and followed?

3. All incoming packages with a U.S. Department of Transportation (DOT) label monitored for radioactive contamination, unless exempted (gases and special form)?

4. Incoming packages surveyed?

5. Monitoring in (3) and (4) performed within time specified?

6. Transfer(s) performed per [LAC 33:XV.340]?

7. All sources surveyed before shipment and transfer?

8. Records of surveys and receipt/transfer maintained?

9. Package receipt/distribution activities evaluated for compliance with LAC 33:XV.421?

Transportation (LAC 33:XV.1504.B and 49 CFR 171-178)

1. Shipments are:
   a. Delivered to common carriers?
   b. Transported in own private vehicle?
   c. Both?
   d. No shipments since last audit?

2. Return radiopharmacy doses to drug manufacture or commercial nuclear pharmacy or sealed sources to source or device manufacturer?
   a. Licensee assumes shipping responsibility?
   b. If "NO," describe arrangements made between licensee and radiopharmacy for shipping responsibilities.

3. Packages:
   a. Authorized packages used [49 CFR 173.415, 49 CFR 416]?
   b. Performance test records on file?
      i. DOT-7A packages
      ii. Special form sources

c. Two labels (White-I, Yellow-II, Yellow-III), on opposite sides not to include the bottom, with Transport Index (TI), Nuclide, Activity, and Hazard Class? [49 CFR 173.403, 49 CFR 415, 49 CFR 416]
d. Properly marked [Shipping Name, United Nations (UN) Number, Weight, Package Type, Reportable Quantity, "This End Up" (liquids), Name and Address of consignee] [49 CFR 172.403, 49 CFR 172.441, 49 CFR 173.471]?
e. Closed and sealed during transport [49 CFR 173.475(f)]?

4. Shipping Papers:
a. Prepared and used [49 CFR 172.200(a)]?
b. Contain proper entries (Shipping Name; Hazard Class; Identification Number (UN Number); Total Quantity; Package Type; Nuclide; Reportable Quantity; Physical and Chemical Form; Activity; Category of Label; TI; Shipper's Name, Certification and Signature; Emergency Response Telephone Number; "Limited Quantity" {if applicable); "Cargo Aircraft Only" (if applicable)} [49 CFR 172.200-204]?
c. Readily accessible during transport [49 CFR 177.817(e)]?

5. Any incidents reported to DOT [49 CFR 171.15, 171.16]?

Teletherapy and Gamma Stereotactic Radiosurgery (as permitted under LAC 33:XV.747**)**

1. Full-inspection servicing performed following source replacement or at intervals not to exceed 5 years for each teletherapy unit and gamma stereotactic radiosurgery unit [LAC 33:XV.762]?

2. Needed service arranged for as identified during the inspection?

3. Service performed by persons specifically authorized to do so [LAC 33:XV.762]?

4. Were security requirements implemented, if applicable? [LAC 33:XV.Chapter 16]

Full Calibration-Therapeutic Medical Devices [LAC 33:XV.756]

1. Proper protocol(s) used (e.g., AAPM Task Group (TG)–21 (TG-21), AAPM 54, AAPM TG-56, AAPM TG-40)?

2. Performed prior to first patient use [LAC 33:XV.756]?

3. At intervals not to exceed 1 year for teletherapy, gamma stereotactic radiosurgery (GSR), and low dose-rate (LDR) remote afterloader; at intervals not exceeding 1 quarter for high dose-rate, medium dose-rate (MDR), and pulsed dose-rate (PDR) remote afterloaders [LAC 33:XV.756]?

4. Whenever spot-checks indicate output differs from expected by ±5% [LAC 33:XV.756]?

5. After source exchange, relocation, and major repair or modification?

6. Performed with properly calibrated instrument?

7. Includes:
   a. For teletherapy: [LAC 33:XV.756.A]
      i. Output measured within ±3% of expected for the range of field sizes, range of distances?
      ii. Coincidence of radiation field and field light localizer?
      iii. Uniformity of radiation field and beam angle dependence?
      iv. Timer accuracy and linearity over the range of use?
      v. On-off error?
      vi. Accuracy of all measuring and localization devices?

   b. For remote afterloaders: [LAC 33:XV.756.B]
      i. Output measured within ±5% of expected?
      ii. Source positioning accuracy within ±1 millimeter?
      iii. Source retraction with backup battery upon power failure?
      iv. Length of source transfer tubes?
      v. Timer accuracy and linearity over the typical range of use?
      vi. Length of the applicators?
      vii. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces?
      viii. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory?

   c. For gamma stereotactic radiosurgery: [LAC 33:XV.756.C]
      i. Output measured within ±3% of expected?
      ii. Helmet factors?
      iii. Isocenter coincidence?
      iv. Timer accuracy and linearity over the range of use?
      v. On-off error?
      vi. Trunnion centricity?
      vii. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off?
      viii. Helmet microswitches?
      ix. Emergency timing circuit?
      x. Stereotactic frames and localizing devices (trunnions)?

8. Output corrected mathematically for decay?

9. Records maintained?

Periodic Spot-Checks for Therapeutic Devices [LAC 33:XV.757]

1. Performed at required frequency?

2. Procedures established by AMP?

3. Procedures followed?

4. Medical physicist reviews results within 15 days?

5. Performed with properly calibrated instrument?

6. Output and safety spot-checks include:
   a. For teletherapy: [LAC 33:XV.757.A]
      i. Timer accuracy and linearity over the range of use?
      ii. On-off error?
      iii. Coincidence of radiation field and field light localizer?
      iv. Accuracy of all measuring and localization devices?
      v. The output for one typical set of operating conditions?
      vi. Difference between measured and expected output?
      vii. Interlock systems?
      viii. Beam stops?
      ix. Source exposure indicator lights?
      x. Viewing and intercom systems?
      xi. Treatment room doors, inside and out?
      xii. Electrical treatment doors with power shut off?

   b. For remote afterloaders: [LAC 33:XV.757.B]
      i. Interlock systems?
      ii. Source exposure indicator lights?
      iii. Viewing and intercom systems, except for LDR?
      iv. Emergency response equipment?
      v. Radiation monitors used to indicate source position?
      vi. Timer accuracy?
      vii. Clock (date and time) in the unit's computer?
      viii. Decayed source(s) activity in the unit's computer?

   c. For gamma stereotactic radiosurgery: [LAC 33:XV.757.C]
      i. Treatment table retraction mechanism?
      ii. Helmet microswitches?

iii. Emergency timing?
iv. Stereotactic frames and localizing devices?
v. The output for one typical set of operating conditions?
vi. Difference between measured and expected output?
vii. Source output compared against computer calculation of output?
viii. Timer accuracy and linearity over the range of use?
ix. On-off error?
x. Trunnion centricity?
xi. Automatic positioning system?
xii. Interlock systems?
xiii. Source exposure indicator lights?
xiv. Viewing and intercom systems?
xv. Timer termination?
xvi. Radiation monitors used to indicate room exposures?
xvii. Emergency off buttons?

7. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required?

8. Records maintained?

Installation, Maintenance, and Repair of Therapy Devices

1. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [LAC 33:XV.748, LAC 33:XV.762]? Name of organization/individual.

2. License verification?

3. Records maintained?

Emergency Procedures for Therapy Devices

1. Instructions on location of emergency procedures and emergency response telephone numbers posted at the device console [LAC 33:XV.750]?

2. Copy of the entire procedures physically located at the device console?

3. Procedures include:
   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions?
   b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure?
   c. The names and telephone numbers of the AUs, the AMP, and the RSO to be

contacted if the unit or console operates abnormally?

4. AMP and AU:
   a. Physically present during initiation of patient treatment with remote afterloaders? (Note: for MDR and PDR, an appropriately trained physician under the supervision of the AU may be physically present instead of the AU) [LAC 33:XV.751].
   b. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device?

Patient Surveys and Therapy Devices

1. Radiation survey of patient is performed to ensure source is returned to shielded position?

2. RSO and AU promptly notified if patient had a medical emergency or died?

3. Records of radiation surveys maintained for 3 years?

Personnel Radiation Protection

1. Exposure evaluation performed [LAC 33:XV.430]?

2. As low as is reasonably achievable (ALARA) program implemented [LAC 33:XV.406]?

3. External Dosimetry:
   a. Monitors workers per [LAC 33:XV.431]?
   b. External exposures account for contributions from airborne activity [LAC 33:XV.412]?
   c. Supplier Frequency
   d. Supplier is National Voluntary Laboratory Accreditation Program-approved [LAC 33:XV.430]?
   e. Dosimeters exchanged at required frequency?

4. Internal Dosimetry:
   a. Monitors workers per LAC 33:XV.431?
   b. Program for monitoring and controlling internal exposures [LAC 33:XV.430 & 431] briefly described?
   c. Monitoring/controlling program implemented (includes bioassays)?
   d. Respiratory protection equipment [LAC 33:XV.442]?

5. Review of Records and Reports:
   a. Reviewed by _____ Frequency_____
   b. Auditor reviewed personnel monitoring records for period _____ to _____

c. Prior dose determined for individuals likely to receive doses [LAC 33:XV.414]?
d. Maximum exposures TEDE _____ Other _____
e. Maximum committed dose equivalents (CDEs) _____ Organs
f. Maximum CEDE _____
g. Internal and external summed [LAC 33:XV.412]?
h. Occupational limits met for adults [LAC 33:XV.410]?
i. If applicable, occupational limits met for minors [LAC 33:XV.411]?
j. NRC forms or equivalent?
   i. NRC-4 Complete:
   ii. NRC-5 Complete:
k. If a worker declared her pregnancy during the audit period, was the dose in compliance [LAC 33:XV.417] and were the records maintained?

6. Any planned special exposures (number of people involved and doses received)?

7. Records of exposures, surveys, monitoring, and evaluations maintained?

Other Medical Uses of Byproduct Material or Radiation from Byproduct Material [10 CFR 35.1000]

Use specific 10 CFR 35.1000 licensing guidance and the above components, as applicable, to develop an audit of other medical uses licensed under 10 CFR 35.1000.

Security Program for Category 1 and Category 2 Materials [LAC 33:XV.Chapter 16]

1. Is access to the material controlled so that only authorized individuals can gain access to the material? Are personnel who have not been authorized escorted?

2. Have all personnel who have unescorted access to the material been deemed trustworthy and reliable, been fingerprinted, and been authorized in writing for access to the material? Is the list of authorized personnel up to date?

3. Is a system in place so that any unauthorized access to the material will be detected immediately? Are weekly verification checks conducted for Category 2 quantities of radioactive material?

4. Are procedures in place to ensure that any unauthorized access will be assessed to determine whether further response is required? If there have been any such accesses, was the procedure followed?

5. Is the security plan current? Is contact information for the local law enforcement agency current?

6. Is the security system operable?

7. Does the security system have a dependable means of communication to notify assessment personnel? Do personnel have a dependable means of communication to notify response staff or local law enforcement?

8. Are all documents being retained as required?

9. Is all sensitive information secured and protected in accordance with the procedure? Does the procedure address all required information?

10. Have personnel with access to the material been trained on security procedures, including emergency response, notifications, and surveillance?

11. Are procedures in place to ensure the safe and secure transport of Category 1 and Category 2 radioactive sources or material? Were the procedures followed for preplanning, license verification, coordination, advance notification, physical protection, and reporting, as applicable?

12. Is the security program content and implementation reviewed annually with records maintained for 3 years?

Confirmatory Measurements

1. Detail location and results of confirmatory measurements.

Written Directive Review and Identification of Medical Events

1. Review a sampling of records for administrations requiring a WD. The number of patient cases to be sampled should be representative of each treatment modality performed in the institution.

2. Conduct a review of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work.

3. Review the procedures developed in accordance with LAC 33:XV.777 to ensure that the procedures for administrations requiring a WD are effective.

4. Determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. Determine if a medical event, as defined in LAC 33:XV.712, has occurred, and for permanent implant

brachytherapy, that within 60 calendar days from the date the implant was performed the total source strength administered outside of the treatment site was compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented in accordance with LAC 33:XV.777. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

If medical events meeting the criteria in LAC 33:XV.712 have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering WDs using the existing guidance.

1. Event date _____ Information Source _____

2. Notifications:
   ☐ LDEQ ☐ Referring Physician
   ☐ Patient ☐ In writing
   ☐ By telephone

   If notification did not occur, why not?

3. Written Reports [LAC 33:XV.712]: Submitted to Region within 15 days?

4. Patient intervention that resulted in the total dose or dosage not being administered? Describe each intervention.

Notification and Reports

1. In compliance with LAC 33:XV.1013 (reports to individuals, public and occupational, monitored to show compliance with LAC 33:XV.chapter 3)?

2. In compliance with LAC 33:XV.485 (theft or loss)?

3. In compliance with LAC 33:XV.486 and LAC 33:XV.341 (incidents)?

4. In compliance with LAC 33:XV.487 and LAC 33:XV.341 (overexposure and high radiation levels)?

5. Aware of LDEQ 24 hour telephone number [225-765-0160]?

6. In compliance with LAC 33:XV.487 (constraint on air emissions)?

Posting and Labeling

1. NRC Form 3, “Notice to Workers” is posted [LAC 33:XV.1011]?

2. LAC 33:XV.Chapter 10, LAC 33:XV.Chapter 4, procedures adopted pursuant to LAC 33:XV, and license documents are posted, or a notice indicating where documents can be examined is posted?

3. Other posting and labeling per LAC 33:XV.451, LAC 33:XV.453, and not exempted by LAC 33:XV.452, LAC 33:XV.454?

Recordkeeping for Decommissioning

1. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [LAC 33:XV.325.D]?

2. Records include all information outlined in LAC 33:XV.325?

Special License Conditions or Issues (L/C)

Special license condition or issues to be reviewed:

1. If authorized for other medical uses, review the program for conformance with license application commitments, license conditions, and regulations.

2. Other special license conditions.

Performance-Based Review

1. Conduct performance-based reviews of radiation workers performing licensed activities:
   a. to assess the capability of the radiation workers to maintain exposures ALARA;
   b. to assess that radiation workers follow the operating procedures;
   c. to assess the effectiveness of the operating procedures and compliance with the regulations, license conditions and the licensee commitments submitted in support of a license (and incorporated by “tie-down” conditions);
   d. to ensure the safe and secure use of radioactive material;
   e. to verify that radiation workers are cognizant of the emergency procedures and, if necessary, would be able to implement them and maintain exposures ALARA; and
   f. to ensure that emergency procedures have been developed for all likely scenarios.

2. Take the necessary actions to address programmatic and performance deficiencies with radiation workers and facilitate immediate corrective actions.

Evaluation of Other Factors

1. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight?

2. RSO has sufficient time to perform radiation safety duties and is not too busy with other assignments?

3. Licensee has sufficient staff?

Audits and Findings

1. Summary of findings.
2. Corrective and preventive actions.
3. Amendment required