IOWA DEPARTMENT OF PUBLIC HEALTH

MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE

~~DATE~~

Iowa Department of Public Health
Bureau of Radiological Health
Radioactive Materials Section
Lucas State Office Building, 5th Floor
321 East 12th Street, Des Moines, Iowa 50319-0075
http://www.idph.iowa.gov/radiological-health
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IDPH REGULATORY GUIDE FOR MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES

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IDPH REGULATORY GUIDE FOR

MEDICAL USE OF RADIOACTIVE MATERIALS FOR DIAGNOSTIC PROCEDURES

1. INTRODUCTION

1.1 GENERAL

The Iowa Department of Public Health (IDPH) regulates the intentional internal or external administration of by-product material or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained ~~in Iowa Radiation Machines and Radioactive Materials Rules,~~ Chapter 641-41.2, Use of radionuclides in the healing arts.

You should carefully study this guide and all the regulations identified in Chapter 641-41.2 before completing the application form~~, IDPH Form 299-0514~~. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program

1.2 PURPOSE OF GUIDE

This guide is designed to describe the type and extent of information needed by the IDPH to evaluate an application for a medical use of radioactive materials in diagnostic procedures. The uses of radioactive material for a therapeutic administration or any administration of quantities greater than 30 microcuries of either sodium iodide (Iodine-125 or Iodine-131), which require a written directive, are not authorized in diagnostic procedures. A Radiation Safety Committee is not required for this type of license.

1.3 APPLICABLE REGULATIONS

In addition to 641-41.2, other regulations pertaining to the medical use of by-product material are found in Chapters 38, 39, 40, and 42 of the Radiation Machines and Radioactive Materials Rules. To view these rules you may go to http://idph.iowa.gov/radioactivematerials/rules.

1.4 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states: "...In addition to complying with the requirements set forth in this Chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. The Radiation Safety Officer (RSO) ~~or an individual who has special expertise in the safe use of by-product material~~ is required to review uses for safety and ALARA considerations.

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The Radiation Safety Officer and management are required to audit the ~~by-product~~ALARA ~~material~~ program to ensure the continued safe use of by-product material. The RSO is responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing an "Application for Radioactive Materials License." (Form 229-0514)." found on the IDPH website at https://idph.iowa.gov/radioactivematerials/forms. You should complete Items 1 through 5, and 14/15 on the form itself. For Items 6 through 12, submit the required information on supplementary pages. Identify each sheet or document with the item number on the application. All typed papers, sketches, and drawings should be on 8 1/2 x 11-inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8 1/2 x 11 inches, if possible.

You should complete all items in the application in enough detail for the IDPH to determine that your equipment, facilities, training, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the IDPH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of propriety information to the public or substantial delays in processing your application.

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

Retain a copy of your application because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations. The statements and representations become enforceable as if they were regulations.

3. CONTENT OF APPLICATION

This portion of the guide explains, item-by-item, the information requested on IDPH radioactive materials license application. The appendices to this guide serve to provide additional information on certain subject areas. Model procedures that the applicant may adopt in response to an item on the application form are provided. As an alternative, the applicant may use the procedures as an outline to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, email iowaram@idph.iowa.gov or call program staff listed on the website at https://idph.iowa.gov/radioactivematerials/contacts515-281-3478.

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ITEM 1.a. ~~—~~ ~~APPLICANT'S NAME AND MAILING ADDRESS~~NAME AND ADDRESS OF APPLICANT

The applicant should be the corporation or other legal entity applying for the license and with direct control over use of the radioactive material.~~.~~

The address specified here should be the mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 1.b.

The IDPH must be notified and the transfer approved before control of the license is transferred. For more information see IDPH Information Notice 12-01, Unauthorized Transfer of Ownership or Control of Licensed Activities found at https://idph.iowa.gov/radioactivematerials/notices.

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ITEM 1.b. ~~--~~ ~~LOCATIONS OF USE~~STREET ADDRESS AT WHICH RADIOACTIVE MATERIAL WILL BE USED

Any locations of use/storage beyond the address of Item 1.a need to be specified~~You should specify each location of use~~ by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. ~~If by-product material is to be used at more than one location, you must give the specific address of each location.~~ An attachment may be appropriate if numerous locations. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at each location.

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

ITEM 2. ~~--~~ PERSON TO BE CONTACTED REGARDING THIS~~ABOUT~~ APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the Radiation Safety Officer (RSO) or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only and it would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to a member of management with a copy to the RSO. Management can designate a different person if the authorization to make commitments on behalf of the licensee if authorization in writing is provided to IDPH.

The IDPH recognizes that licensees may use a consulting service to help prepare the license application and provide support to the radiation safety program. However, if you choose to have the consultant the point of contact for any IDPH questions, we remind you that the licensee management is ultimately responsible for all aspects of the program. This includes any services performed by the consulting service.

ITEM 3. ~~--~~ THIS APPLICATION IS FOR (TYEP OF LICENSE) ~~INFORMATION~~

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated if applying for an ~~for~~ amendment~~s~~ or renewal~~s~~.

ITEM 4. ~~--~~ INDIVIDUAL USERS ~~-- TRAINING AND EXPERIENCE~~

~~Responsible individuals~~Individuals who are responsible for the supervision of radioactive materials use are the authorized users and the RSO. 641-39.4(25) requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. 41.2(65) through 41.2(82) provides specific criteria for acceptable training and experience for the ~~RSO and~~ authorized users, RSO, and associate radiation safety officer (ARSO). Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

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~~4.1. -- AUTHORIZED USERS FOR MEDICAL USE~~

Authorized users involved in medical use have the following special responsibilities:

1. ~~1.~~ Examination of patients and medical records to determine if a radiation procedure is appropriate,
2. ~~2.~~ Prescription of the radiation dosage or dose and how it is to be administered,
3. ~~3.~~ Actual use or direct the technologists or other paramedical personnel in the use of by-product material, ~~and~~

There is no IDPH requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. The IDPH recognizes that the AU may or may not be the physician who interprets such studies.

~~4. Interpretation of diagnostic procedures.~~

The above responsibilities~~Numbers 1 through 4~~ may be delegated to a physician who is under the direct supervision of an authorized user. Technologists or other personnel may use by-product material under an authorized user's supervision when permitted under Chapter 42. Supervision is defined in 641-41.2(11).

A. Provide the full name of the RSO, ARSO (if proposed) and each individual user and note, by reference to Item 6, which proposed uses are requested for the individual.

B. If an authorized user ~~physician~~ has been previously authorized for medical use and wishes to use material permitted by the previous Iowa Department of Public Health radioactive materials license, you only need to submit the previous license number. You should submit a copy of the license on which the physician was specifically named as an authorized user if the license was issued by any other Agreement State or the US NRC.

C. If a physician is certified by an organization listed in the appropriate section of 641-41.2(65-82), submit a copy of the specialty board certificate indicating that the physician is "AU Eligible". Medical specialty board(s) certification recognized by IDPH are posted on the Nuclear Regulatory Commission's website at https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html. An individual that is board-eligible will not be considered for this pathway until the individual is actually board certified. Further, individuals holding other board certifications, but not certified by a board recognized by IDPH, will not be considered for this pathway.

~~If a physician is certified by an organization listed in the appropriate section of 641-41.2(65-82), submit the "*Medical Use Training and Experience and Preceptor Attestation*" along with a copy of the specialty board certificate indicating that the physician is "AU Eligible".~~

D. Physicians not previously authorized by NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using the "*Authorized User (Diagnostic/Therapeutic/Brachytherapy) Training and Experience and Preceptor Attestation*" found on the IDPH website at https://idph.iowa.gov/radioactivematerials/forms. This documentation will be reviewed on a case-by-case basis. ~~Physicians not previously authorized by NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using the "*Medical Use Training and Experience and Preceptor Attestation*". This documentation will be reviewed on a case-by-case basis.~~

E. All training and experience shall have been obtained within the seven years preceding the date of application or the individual must submit verification of continuing applicable experience since the required training and experience was completed. See 41.2(77).

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Vs Physican,dentist,podiatrist
Vs AU, AMP, ANP

ITEM 5. ~~--~~ RADIATION SAFETY OFFICER (RSO)

Licensee's management must appoint an RSO who has adequate training and experience and agrees in writing to be responsible for implementing the Radiation Protection Program. State the name and title of the person designated by, and responsible to, the applicant's management as RSO. Submit a complete description of the individual's training and experience using "*RSO or ARSO Training, Experience and Preceptor Attestation"* as required by 41.2(65) & (75) found on the IDPH website at https://idph.iowa.gov/radioactivematerials/forms, or provide the previous license number (issued by IDPH), or a copy of the specific license issued by the NRC or another agreement state on which the individual was named as the RSO or ARSO. Even if the licensee employs a consultant as RSO, the licensee is still responsible for the radiation safety program as required by the license.

The RSO is responsible for the day to day oversight of the Radiation Protection Program. In accordance with 41.2(10), the licensee must provide the RSO sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals, in a safe manner, and have independent authority to stop operations that are considered unsafe. IDPH requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that named individual knows of their designation and assumes the responsibilities of RSO. The RSO's duties and responsibilities should include those areas listed in Appendix B or its equivalent. A model RSO delegation of authority is also included in Appendix B.

A licensee may choose to identify one or more individuals as ARSOs to support the RSO in accordance with 41.2(10)"b". The ARSO can be delegated radiation safety duties and tasks by the RSO for the types of uses for which he or she is listed on the license. The ARSOs are required to complete the same training and experience requirements as the named RSO for their assigned sections of the radiation safety program. If proposing an ARSO, state the name of the individual(s), identify the sections(s) of the licensee's program for which the individual will be given duties and tasked in the oversight of radiation safety operations (e.g., 41.2(33) authorized uses or 41.2(33) uses at an alternate location), and provide documentation of completion of the training and experience requirements described in 41.2(65).~~State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using "*Medical Use Training and Experience and Preceptor Attestation."* Even if the licensee employs a consultant as RSO, the licensee is still responsible for the radiation safety program as required by the license.~~

~~The RSO needs independent authority to stop operations that are considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner. The RSO's duties and responsibilities should include those areas listed in Appendix B or its equivalent.~~

ITEM 6. ~~--~~ RADIOACTIVE MATERIAL and~~AND~~ ITEM 7. -- PURPOSE

For diagnostic purposes, 641-41.2(31), 41.2(33), and 41.2(41) separate radioactive material for medical use into types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may state, "As needed" in the "Amount" column as shown.

TABLE 1

RADIOACTIVE MATERIAL	AMOUNT	PURPOSE

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6.a Material in 641-41.2(31)	As needed	7.a. Medical use
6.b Material in 641-41.2(33)	As needed	7.b. Medical use

If you need other items, make a separate line entry for each isotope. Number each line entry consecutively following the 641-41.2 material. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in mCi, and the purpose for which the material will be used. Examples:

1. Survey meter or calibration source not exempted under 41.2(20)
2. Material for *in-vitro* human studies (example: 39.4(20)"i")
3. ~~Gases or aerosols as specified in 41.2(33)"c."~~

For all calibration, transmission, and reference sources covered under 41.2(20), the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 41.2(3) for the medical use of byproduct material.

~~You do not have to list certain calibration and references sources if they meet the criteria in 41.2(20). Any reference sources used for quality control using Technetium99m more than 50 millicuries must be listed on the license. An example is a 150 millicuries of Technetium-99m used for linearity testing of dose calibrators.~~

ITEM 8. ~~—~~ INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Licensees are responsible for their Radiation Protection Programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program.

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~~Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program.~~

ITEM 9. through ITEM 12.

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Your response to these items should consist of a statement, which states that you will follow the model procedure in Appendix ___ of IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE~~Medical Use of Radioactive Materials for diagnostic Procedures Regulatory Guide~~; that you have enclosed your procedure for review; or "NA" for "not applicable." Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your short sentence or "NA" response to Items 9 through 12 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to name specific individuals, equipment by serial number, room numbers, or other site-specific information, there is no need to submit that procedure for review. Other than hot labs, procedures should allow for replacement of identical equipment, personnel, and administration rooms.

~~NOTE: Items 9. - Through - 12.~~

~~Your response to these items should consist of a statement, which states that you will follow the model procedure in Appendix __ of IDPH Medical Use of Radioactive Materials for diagnostic Procedures Regulatory Guide; that you have enclosed your procedure for review; or "NA" for "not applicable." Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your short sentence or "NA" response to Items 9 through 12 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.~~

~~If you edit a model procedure solely to name specific individuals, equipment by serial number, room numbers, or other site-specific information, there is no need to submit that procedure for review. Other than hot labs, procedures should allow for replacement of identical equipment, personnel, and administration rooms.~~

ITEM 9. ~~--~~ TRAINING FOR INDIVIDUALS 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 100 mrem in a year, they must receive instructions, as specified by 40.111. Describe your training program for individuals who work with or near radioactive material described in Item 6.a. for medical use. Include the training for individuals who handle non-medical radioactive materials listed in Item 6.a. Appendix E of this guide provides a model training program that is one way to satisfy the requirements referenced above.
~~Describe your training program for individuals who work with or near radioactive material described in Item 6.a. for medical use. Include the training for individuals who handle non-medical radioactive materials listed in Item 6.a. See Appendix E of this guide.~~

ITEM 10. ~~--~~ FACILITIES AND EQUIPMENT

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Facilities and Equipment will contain at a minimum (as described below): An annotated drawing, description of other equipment/facilities, and Survey instruments.

~~10.1. -- ANNOTATED DRAWING~~Annotated Drawing

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Submit an annotated drawing of the room or rooms and adjacent areas where by-product material will be used. Append it as ATT 10.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The direction of north.
3. 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).
4. Any shielding available.
5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors) including manufacturer and model or serial numbers where appropriate.

10.2. -- Other Equipment and Facilities~~OTHER EQUIPMENT AND FACILITIES~~

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Describe any other equipment and facilities available for the use and/or storage that is listed in Item 6 of this application.

10.3. Survey InstrumentsSURVEY INSTRUMENTS

All licensees shall possess calibrated radiation detection instruments that will be used for radiation protection, including survey and monitoring instruments, and be sufficiently sensitive to measure the type and energy of radiation used. Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:
Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
Short Scientific, Inc.	LGD-310	1 - 100000 cpm

Radiation survey meter calibrations must be performed by people who are qualified to perform calibrations. If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide on survey instrument calibration from the IDPH.

Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing." Records of the calibration of instruments and equipment used for quantitative radiation measurements must be retained for 3 years in accordance with 40.82

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. Instruments must be calibrated annually and after servicing or repair. Battery changes are not considered "servicing."

ITEM 11. RADIATION SAFETY PROGRAM

The elements of a radiation safety program are contained in Appendices A through R. Review each appendix carefully. (Some of these appendices have been addressed in the proceeding text and need not be re-addressed.) Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate "not applicable."

Appendix A	Program for maintaining occupational radiation exposure at medical facilities ALARA
Appendix B	Duties of the RSO
Appendix C	Procedure for calibrating dose calibrators
Appendix D	Personnel exposure monitoring program
Appendix E	Training program
Appendix F	Reserved
Appendix G	Reserved
Appendix F~~H~~	Leak-testing sealed sources
Appendix G~~I~~	Safe use of radiopharmaceuticals
Appendix H~~J~~	Spill procedures and action limits
Appendix I~~K~~	Guidance for ordering and receiving radioactive material
Appendix J~~L~~	Procedure for safely opening packages containing radioactive material
Appendix K~~M~~	Records of Byproduct material use

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ITEM 11.1. -- SEALED SOURCE INVENTORIES

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Accountability of licensed material may be ensured by conducting physical inventories and maintaining records. State that you will conduct inventories, at ~~intervals not to exceed~~ six (6) months intervals, to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least five (5) years from the date of the inventory. The record should include:

- model number of each source,
- serial number if one has been assigned,
- identity of each source radionuclide,
- estimated activity,
- location of each source,
- date of inventory,
- initials or name of individual performing the inventory, and
- signature of the Radiation Safety Officer.

Licensed material must be tracked from "cradle to grave," from receipt to its eventual transfer/disposal, to ensure accountability at all times.

ITEM 11.2. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

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40.10(3) requires an annual audit. Currently the IDPH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems be corrected promptly and comprehensibly. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The IDPH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The IDPH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with IDPH rules.

A model audit program is included in Appendix U of this Regulatory Guide.

ITEM 12. ~~---~~ WASTE MANAGEMENT

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Generally, medical licensees dispose of radioactive waste by decay in storage and/or transfer to an authorized recipient. Submit your procedures for waste disposal. See Appendix R. Be sure to include a procedure for all material listed in Item 6.
~~Submit your procedures for waste disposal. See Appendix R. Be sure to include a procedure for all material listed in Item 6.~~

ITEM 13. ~~---~~ LICENSINGE FEES

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~~1.~~ An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at https://idph.iowa.gov/radioactivematerials/forms~~www.idph.state.ia.us~~. An application received without a

fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

1.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH emails a billing invoice in July and August of each year for the annual fee. Make check or money order payable to the IDPH. You may also contact program staff at https://idph.iowa.gov/radioactivematerials/contacts to receive instruction on how to pay the annual fee via credit card. ~~An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.~~

3. Review 39.4(26) "Financial Assurance and Recordkeeping for Decommissioning." Submit financial assurance as described or provide information that exempts the facility.

ITEMS 14, 15 -- CERTIFICATION

A senior partner, the president, director or chief executive officer must sign the application. Identify the title of the office held by the individual who signs the application. If the application is for an institution, hospital, or medical center, the director or chief executive officer must sign it.

If the senior partner, president, director, or chief executive officer wishes another person to sign the application, a delegation of authority must be enclosed. The delegation of authority signed by the senior partner, president, director, or chief executive officer should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later. ~~A senior partner, the president, director or chief executive officer must sign the application. Identify the title of the office held by the individual who signs the application. If the senior partner, president, director, or chief executive officer wishes another person to sign the application, a delegation of authority must be enclosed. The delegation of authority signed by the senior partner, president, director, or chief executive officer should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.~~

4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer, adding to the staff of authorized users, or location of use. See 641-41.2(4) for the specific requirements. An application for an amendment must be filed on "Application for Radioactive Materials License" found on the IDPH website at https://idph.iowa.gov/radioactivematerials/forms, ~~IDPH Form 299-0514~~ or as a letter and must be signed by the person delegated in Item 14/15. The appropriate fee must be included.

The licensee may not place into effect any amendment until receiving written verification from the IDPH that the amendment has been approved.

5. RENEWAL OF LICENSE

Licenses are issued for a period of five (5) years. An application for the renewal should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on

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the application has been taken by the IDPH as provided for in paragraph 641-39.4(34). The application for renewal should not reference material that was previously submitted. Each application is a stand-alone document.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

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Except where specifically referenced, the information in this regulatory guide is guidance, not requirement. The IDPH reviews each application to ensure that users of by-product material are capable of complying with IDPH's regulations. This guide provides one set of methods approved by the IDPH for meeting the regulations and represents the minimum acceptable standards.

7. INSPECTIONS

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IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses occur at the normal schedule after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

~~Appendices~~

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APPENDIX A

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MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION

EXPOSURE AT MEDICAL FACILITIES ALARA

In addition to 641-41.2(7)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to IDPH MEDICAL USE OF RADIOACITCVIE MATERIAL IN DIAGNOSTIC PROCEDURES REGULATORY GUIDE." Submit the signed commitment in section six (6) of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of 641-41.2(7). Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in section six (6) of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

   a. We, the management of this facility, are committed to the program described herein 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 the 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 unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing the changes.

   d. In addition to maintaining doses to individuals as far as 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. REVIEW OF PROPOSED USERS AND USES

   a. Review of proposed users and uses:

      (1) The RSO will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials and methods of use.

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(2) When considering the use of by-product material, the RSO will review efforts of the applicant to maintain exposure ALARA.
(3) The RSO will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of authority:

Management will delegate authority for enforcement of an ALARA program to the RSO.

c. Review of the ALARA Program:

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

(2) The RSO, ARSO, or designee will perform a quarterly review of occupation radiation exposure with particular attention to instances in which the investigational levels in Table I 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.

TABLE 1 - INVESTIGATIONAL LEVELS

	Investigational Levels (mrem per calendar quarter~~month~~)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

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

3. RADIATION SAFETY OFFICER COMMITMENT

a. Education Responsibilities for ALARA Program:

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

b. 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.

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

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 COMMITMENT

a. New methods of Use Involving Potential Radiation Doses:

(1) The authorized user will consult the RSO 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 As Low As Reasonably Achievable (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 health physics practices and in maintaining exposures ALARA.

5. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES[1]

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by 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, ARSO, or designee will review and record ~~ord on IDPH Form, "~~cCurrent oO~~ccupational~~ eExternal rRadiation eExposures~~," or an equivalent form (e.g., dosimeter processor's report)~~ results of personnel monitoring not less than once in any calendar quarter ~~as required by 641-40.100~~. 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 doses equal to or greater than Investigation Level I but less than Investigational Level II:

[1] IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

APPENDIX A

The RSO, ARSO, or designee will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. However, the RSO will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

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 and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's ~~Form IDPH 588-2834 "oO~~Occupational eExposure rRecord for the m~~M~~onitoring p~~P~~eriod" and their ~~588-2833 "cC~~umulative o~~O~~ccupational e~~E~~xposure h~~H~~istory~~" or its equivalent~~.

d. Re-establishment of investigational levels to levels above those listed in Table I:

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSO will review the justification for and must approve all investigational level revisions.

6. SIGNATURE OF CERTIFYING OFFICIAL[1]: Sign and submit as part of Appendix A.

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

_____
Signature

_____
Name (Print or type)

_____
Title

[1] The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

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APPENDIX B

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APPENDIX B

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DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

In aAddition to 41.2(8)

You may use the following model guidelines to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for RSO that was published in Appendix B to the IDPH MEDICAL USE OF RADIOACTIVE MATERIALS IN DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

You may develop your own guidelines for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of the Iowa Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or IDPH inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
   a. The licensee is abiding by IDPH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
   b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
   c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with IDPH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least 3 years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation more than ALARA levels or Chapter 40 limits are investigated and reported to IDPH within the required time limits.
10. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
11. Ensure that licensed material is disposed of properly.

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12. Ensure that the facility has up-to-date copies of IDPH's regulations, completing a review of new or amended IDPH regulations, and revising licensee procedures, as needed, to comply with IDPH regulations.
13. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to IDPH in the licensing process.

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. 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 rules. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to request amendment changes and raise issues with the Iowa Department of Public Health, Bureau of Radiological Health at any time.

_____
Signature of Management Representative

_____
Date

I accept the above responsibilities,

_____
Signature of Radiation Safety Officer

_____
Date

cc: Affected Department Heads

APPENDIX C

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APPENDIX C

~~APPENDIX C~~

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

In addition to 641-41.2(17)

It is recommended that you use the manufacturer's calibration process. ~~You or your contractor may use the following model procedure for checking and testing the dose calibrator.~~ If you~~, or the contractor,~~ follow the manufacturer's calibration procedure, ensure to meet the requirements of the Iowa Rules (i.e. testing periodicity will be the shorter of the manufacturer's recommendation and the periodicity required by Iowa Rules). T~~he t~~able C.1~~below~~ summarizes but does not supersede Iowa Rules requirements. If you use the process of the manufacturer's calibration process combined with the requirements of the Iowa Rules, ~~model procedure,~~ you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If you develop your own dose calibrator calibration procedure for review, you should carefully review 641-41.2(17) and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as Appendix C," and submit your dose calibrator calibration procedure for approval.~~.~~

MODEL PROCEDURE

Test at the indicated frequency in 41.2(17). Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of ±5 are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

1. Constancy

   Constancy means reproducibility in measuring a source over a long period. In addition to the requirements of 41.2(17)"b"(1), 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. Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
   d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
   e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels shall be written in the logbook, posted on the calibrator, or maintained in a database. The regulation requires repair or replacement if the error exceeds ±10 percent.

2. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

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3. Linearity

Linearity means that the calibrator is able to indicate the correct activity over the range of use between the maximum activity administered and 30 µCi according to the requirements of 41.2(17)"b"(3). This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed for administration. The vial or syringe may be in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

a. DECAY METHOD

(1) 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. This first assay should be done in the morning at a regular time, for example, 8 a.m.
(2) Repeat the assay at approximately 4-hour intervals (i.e.noon and 4 p.m.). Continue on subsequent days until the assayed activity is less than 30 µCi. For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
(3) Convert the recorded time and date to hours elapsed.
(4) On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.
(5) Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

b. SHIELD METHOD

If you decide to use a set of "sleeves" to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the “sleeves” must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer’s instructions when performing the linearity test.

4. Geometry independence

Geometry means that the indicated activity does not change with volume or configuration and is conducted in accordance with 41.2(17)"b"(4). This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2.0 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 non-radioactive saline. You may also use tap water.
b. Draw 0.5 cc of the Tc-99m solution into the syringes and assay. Record the column and millicuries.
c. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries 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 millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal ten (10) percent error lines above and below the chosen "Standard volume."

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f. If any correction factors are greater than 1.1 or less than 0.9, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." This will also be necessary if any data points lie outside the ten (10) percent error lines. Be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
g. To test the geometry dependence of 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 millicuries indicated.
h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries 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 radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal ten (10) percent error lines above and below the chosen "standard volume."
k. If any correction factors are greater than 1.1 or less than 0.9, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." This will also be necessary if any data points lie outside the ten (10) percent error lines. Be sure to label the table or graph "vial" geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
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.

5. Accuracy

Accuracy means that for a calibrated reference source, the indicated activity (e.g. mCi) value is equal to the activity value determined by the National Institutes of Standards and Technoloty (NIST) or by the supplier. The supplier must compare that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radioisotope suppliers. In addition to the requirements of 41.2(17)"b"(2), consider using at least one reference source whose activity is within the range of activities normally assayed.

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 three determinations.
b. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.
c. Repeat the procedure for other calibrated reference sources.
d. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent and the RSO must be notified.
e. 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 radioisotope settings. Record the settings and indicated millicurie values.

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

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Derek to pretty up.

APPENDIX C

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Table C.1 41.2(17) Reference Table

		Constancy	Accuracy	Linearity	Geometry
Calibration Requirement	Install		x	x	x
	Adjustment/Repair	x	x	x	x
	Periodicity	Each Use	12 month	3 month	N/A
Process	Sealed sources	≥ 1	≥ 2		
	Activity Level	≥ 50µCi y *	≥ 50µCi y *		
	Other Notes		1 with Primary between 100-500keV	Range: 30µCi to highest dosage used	
Recorded Data	Model # of DC	x	x	x	x
	Serial # of DC	x	x	x	x
	Check Source/Source				
	Serial #		x		
	Model #		x		
	Isotope Identity	x	x		
	Activity	Calibrated	x	Calculated	x
	Measured Activity	x		x	x
	Test Result		x		
	Volume Configuration				x
	Date	x	x	x	x
	Instrument Settings	x	x		for each volume
	Initials of Checker	x			
	Identity of Checker		x	x	x
	RSO Signature		x	x	x
	Retention Period	3 yrs			Life of DC
Error	Limits	>10%			
	Actions	Replace/Repair		Correct Mathematically	
	Recommended Investigation	>5%			

* If using Radium 226, at least 10 microcuries are required to perform test

This table does not supercede 41.2(17). While this table has been developed as a tool, Licensees will be held to the requirements in the Rule.

APPENDIX C

MODEL PROCEDURE

Test at the indicated frequency in 41.2(17). Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of ±5 are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

		Constancy	Accuracy	Linearity	Geometry
Calibration Requirement	Install		x	x	x
	Adjustment/Repair	x	x	x	x
	Periodicity	Each Use	12 month	3 month	N/A
Process	Sealed sources	≥ 1	≥ 2		
	Activity Level	≥ 50µCi γ	≥ 50µCi γ *	Range: 30µCi	
	Other Notes		1 with Primary Dosage Used	to highest	
			500kev		
Recorded Data	Model # of DC	x	x	x	x
	Check Source/Source				
	Activity Calculated				x
	Test Result				
	Initials of Checker				
	Identity of Checker		x	x	x
Error	Limits	>10%			
	Actions	Replace/Repair		Correct Mathematically	
	Recommended Investigation	>5%			

* If using Radium 226, at least 10 microcuries are required to perform test

1. Constancy

Constancy means reproducibility in measuring a source over a long period. In addition to the requirements of 41.2(17)"b"(1), 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. Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

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

e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds ±10 percent.

2. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

3. Linearity

Linearity is necessary to be able to indicate the correct activity over the range of use of that calibrator according to the requirements of 41.2(17)"b"(3). This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed. The vial or syringe may be in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

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Commented [ED9]: Both this and accuracy test state in addition to requirements….
Rules for constancy say one source
Rules for Accuracy say at least two.

Our guide (which suggests that you can do these procedures without looking at the rules (as they appear overly thorough), don't highlight the source requirement per the Rules. I have added the word "additional" to clue the licensee to read the rule a bit more closely than they might normally… but would suggest a re-write of this section of the guide.

Commented [ED10]: Add bit about >50uCi

Commented [ED11]: How much of this is of value? Do most NMT have this training already? Is it part of mfr guidance?

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APPENDIX C

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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. This first assay should be done in the morning at a regular time, for example, 8 a.m.

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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 the amount specified in 41.2(17)"b"(30). For dose calibrators with a range selection switch, select the range you would normally use for the measurement.

c. Convert the recorded time and date to hours elapsed.

d. On a sheet of semi-log graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-line) = deviation.

SHIELD METHOD

If you decide to use a set of "sleeves" to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the "sleeves" must be performed each time the dose calibrator is returned from repair.

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Follow the manufacturer's instructions when performing the linearity test.

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4. Geometry independence

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Geometry means that the indicated activity does not change with volume or configuration and is conducted in accordance with 41.2(17)"b"(4). This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2.0 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 non-radioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringes and assay. Record the column and millicuries.

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries 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 millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen "Standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." This will also be necessary if any data points lie outside the five (5) percent error lines.

APPENDIX C

Be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence of 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 millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries 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 radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph "vial" geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

5. Accuracy

Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. In addition to the requirements of 41.2(17)"b"(2), consider using at least one reference source whose activity is within the range of activities normally assayed.

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 three determinations.

b. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

e. 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 radioisotope settings. Record the settings and indicated millicurie values.

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

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APPENDIX DD

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APPENDIX D

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MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

In addition to 641-40.36 and 40.37

"Dosimetry" is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 40.37 and shall maintain records of doses received in accordance with 40.86.

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials is a management responsibility. It is important that management recognize the importance of radiation monitoring as part of the overall requirements for radiation protection.

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application. "We will establish and implement the model personnel exposure monitoring program published in Appendix D to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES."

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If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.36 and 40.37. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

~~You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application. "We will establish and implement the model personnel exposure monitoring program published in Appendix D.1 and/or D.2 to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."~~

~~If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.36 and 40.37. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.~~

D.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO, ARSO, or designee will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).

2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor. The device will be processed by a contract service on a monthly basis if they exceed 500 millirem per quarter. Those licensees whose employees receive exposures of less than 500 millirem a quarter may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:

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- Supporting documentation that confirms that no employee will exceed 500 millirem/ quarter; and
- Proposed frequency of exchange.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor. The device will be processed by a contract service on a monthly basis if they exceed 500 millirem per quarter. Those licensees whose employees receive exposures of less than 500 millirem a quarter may request to extend the exchange frequency upon agency approval. To receive approval provide the following information:

   - Supporting documentation that confirms that no employee will exceed 500 millirem/ quarter; and
   - Proposed frequency of exchange.

4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages.

5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.

6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

7. In accordance with 40.15(6), 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.

8. If an individual's monitor 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. Some methods for estimating an individual's dose, depending on the types of work, include:
   - Use his or her recent dose history.
   - Use doses of coworkers as the basis for the dose estimate (nonroutine types of work).
   - Use modeling and calculation (i.e. reconstruction) of scenarios leading to dose.

9. In accordance with 40.112, the licensee shall provide an annual radiation exposure report to monitored individuals under 40.37 if the individual's occupational dose exceeds 100 mrem TEDE, 100 mrem to any individual organ or tissue, or the individual requests the individual's annual dose report. This report shall contain all of the information described in 40.112.

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APPENDIX EE

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MODEL TRAINING PROGRAM

In addition to 641-40.111 and 641-41.2(8)"b"(2)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix E to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE." You may use lectures, videos-taped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 641-40.111. Say on your application, "We have developed a training program for your review that is appended as Appendix E." Be sure to include the groups of workers, the method of their training, and the frequency of training.

It may not be assumed that prior occupational training, board certification, etc have adequately covered safety instructions. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work near radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel to be instructed:

1. All workers that might receive an occupational dose.
2. Ancillary personnel (e.g. nursing, clerical, housekeeping, security) whose duties may require them to work near radioactive material.

Frequency of instruction:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects in addition to 40.111:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. Locations where the licensees have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 641-40.110.
4. Question and answer period.
5. Record of date of program, subject and attendees.

APPENDIX FE

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APPENDIX G~~F~~

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APPENDIX ~~H~~HF

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APPENDIX HF

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MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

In addition to 641-41.2(21)

As a licensee, you must perform leak testing of sealed sources according to 641-40.32(2). The IDPH requires tests to determine whether or not there is any leakage from the radioactive source. The leak test should be performed at 6-month intervals unless otherwise authorized by your license.

The options for leak testing are:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
2. Take the sample using a commercial leak-test kit and send the sample to the kit supplier who reports the results to you.
3. Perform the test and analysis yourself.

For Option 1, specify the name, address, and license number of the consultant or commercial organization.

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix HF.1 or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Identify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include the minimum sensitivity for the instrument used for analysis and a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application.

You may use the following model procedure to leak-test sealed sources. If you follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix (HF.1 and/or HF.2) to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of 641-41.2(21). Say on your application, "We have developed a leak-test procedure for your review that is appended as Appendix HF," and submit your leak-test procedure.

HF.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES (IN ADDITION TO 41.2(21))
(Option 2)

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Wear gloves and pPrepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

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a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism

~~c. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.~~

~~d~~c. If you are testing radium sources, you should also check for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak-test period.

~~HF~~.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

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(Option 3)

1. Select an instrument that is sufficiently sensitive to detect the levels in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source (standard) that is the same isotope and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum.
3. Calculate the counting efficiency of the detector.

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

Where cpm = counts per minute
std = standard
bkg = background
Bq = Becquerel (1 dps = 1 Bq = 2.7E-8 millicuries)
1 min. = 60 seconds

4. If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula (assuming the sample and background counting times are the same):

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

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

If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used. Note: 1 Bq = 1 dps = 2.7E-8 millicuries. or 0.005 microcuries = 185 Bq.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample:

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

5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with IDPH rules.

APPENDIX HF

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7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain records for five (5) years.

~~Select an instrument that is sufficiently sensitive to detect the levels in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.~~

~~2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that is the same isotope and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.~~

~~3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.~~

~~4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.~~

~~5. Continue the same analysis procedure for all wipe samples.~~

~~6. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with IDPH rules.~~

~~7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain records for five (5) years.~~

APPENDIX IG

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APPENDIX IG

~~APPENDIX G~~

MODEL RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

In addition to 641-41.2 and 40.61

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix G to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of 641-41.2. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix IG," and submit your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Protective clothing is to be worn at all times during the preparation, assay, and injection of radiopharmaceuticals. Wear long-sleeved laboratory coats, long pants, and closed toe and heel shoes in all areas where radioactive materials are being used. The protective clothing concept is for at least one protective layer over your skin in the event of a spill.

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

3. Before leaving the restricted area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.

4. Use syringe shields in accordance with to 41.2(22) and (23) 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 or 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 so syringe shields could still be used).

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 a finger exposure monitor while handling radioactive material including during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and while in contact with patients that have been administered radiopharmaceuticals.

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

10. Never pipette by mouth.

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11. Wipe-test by-product material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.

12. With a radiation survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation.

14. A log should be used to record additional information such as:
    - the total prepared activity,
    - specific activity (in mCi/cc) at a specified time,
    - total volume prepared,
    - the measured activity of each patient dosage, and
    - any other appropriate information.

15. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

16. Assay each patient dosage in the dose calibrator before administration. Only use a dosage that differs by more than 20 percent of the prescribed dosage with approval of an authorized user (except for prescribed dosages of less than 30 microcuries). When measuring the dosage, the radioactivity that adheres to the syringe wall or remains in the needle does not need to be considered.

17. Check the patient's name, the prescribed radionuclide, and the dosage before administering.

18. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

19. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

20. Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the Iowa specific license (or such individual's designee).

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APPENDIX JH

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MODEL SPILL PROCEDURES

In addition to 641-41.2 and 40.61(4)

You may use the following model procedures as they appear here, saying on your application, "We will establish and implement the model spill procedure published in Appendix JH to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as Appendix JH" and submit your spill procedures.

The variables that affect the spill procedure include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

MODEL PROCEDURE FOR MINOR SPILLS OF LIQUIDS AND SOLIDS

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent material.
3. Clean up the spill by wiping from the perimeter of the spill to the center of the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag labeled “Caution, Radioactive Material” for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill.
5. Survey for removable contamination to ensure contamination levels are below trigger levels.
6. Continue to clean up the spill and resurvey until radiation levels and removable contamination are below trigger levels.
7. Survey hands, clothing, and shoes for contamination prior to leaving the area.
8. Report the incident to the RSO promptly and follow any additional instruction.
9. The RSO will review the Radioactive Spill Contamination Survey records for trends, and as appropriate, determine cause and corrective actions needed; consider bioassay if licensed material may have been ingested, inhaled, or absorbed through the skin.

~~1. Notify persons in the area that a spill has occurred.~~
~~2. Prevent the spread of contamination by covering the spill with absorbent.~~
~~3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.~~
~~4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also, check your hands, clothing, and shoes for contamination.~~
~~5. The RSO will review the Radioactive Spill Contamination Survey records for trends.~~

APPENDIX K~~I~~

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APPENDIX K~~I~~

~~APPENDIX I~~

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

In addition to 641-40.65 and 641-41.2(11)"b"

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K~~I~~ to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 641-40.65 and 641-41.2(11)"b". Say on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix K~~I~~," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee shall ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting authorized user. Checks should be made to ensure 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 identifying the authorized user or department, isotope, chemical form, activity, and supplier
      (2) Verification that material received was ordered by an authorized user.

   b. For occasionally used materials:

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

3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.

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

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APPENDIX KL

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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 arrives 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 on top of the counter, and re-lock the door.

If the package appears damaged or leaking, you should immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that the driver and the delivery vehicle are not contaminated.

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

Radiation Safety Officer:
_____

Chief of Nuclear Medicine:
_____

Chief of 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~~J~~

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APPENDIX L~~J~~

~~**APPENDIX J**~~

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

In addition to 641-40.65 and 39.5

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L~~J~~ to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 641-40.65 and 39.5. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix L~~J~~," and submit your procedure.

MODEL PROCEDURE

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination as soon as practicable after receipt of the package, but no more than 3 hours after receipt during normal business hours, or no later than 3 hours from the beginning of the next working day if received after working hours according to 40.65.

~~1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination according to 40.65.~~

2. 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).
   c. Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (3) feet (1 meter), stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or a "Yellow III" label is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
   d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour on the external surface of the package.

Table L-1: Radioactive Materials Package Labels as Described in 49 CFR 172.403(c)

Transport index (TI)	Max. radiation level at any point on the external surface (mrem/hr)	Label category	Example
0*	Less than or equal to 0.5.	White I	
More than 0 but less than 1	Greater than 0.5 but less than or equal to 50.	Yellow II	

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More than 1 but less than 10	Greater than 50 but less than or equal to 200.	Yellow III	

* If the measured TI is not greater than 0.05, the value may be considered to be zero (0)

e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

Table L-2: Non-Fixed External Radioactive Contamination Limits for Packages	
Containment:	**Maximum Permissible Limit:**
Beta & gamma emitters and low toxicity alpha emitters	240 dpm/cm^2
All other alpha emitting radionuclides	24 dpm/cm^2

f. Immediately notify the final delivery carrier and IDPH when the limits of Table L-2, or 10 CFR 71.47 are exceeded.

g. Open the package with the following precautionary steps:

(1) Remove packing slip.
(2) Open outer package following the supplier's instructions, if provided.
(3) Verify that the contents agree with the packing slip.
(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
(5) If anything is other than expected, stop and notify the RSO.

h. 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(TI) 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 samples 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.

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

j. Monitor the packing material and the empty packages for contamination with a 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 it.

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

3. For packages received under the general license in 641-39.4(22)"i", the following procedure for opening each package will be followed.

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

b. Check to ensure that the material received is the material that was ordered.

~~Put on gloves to prevent hand contamination.~~

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APPENDIX L J

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).
c. Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirems per hour at three (3) feet (1 meter), stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or a "Yellow III" label is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour on the external surface of the package.
e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

βBeta-γgamma-emitting radionuclides; αall radionuclidesemitters with half-lives less than ten d days..... 24 dpm/cm^2

All other αalpha-emitting radionuclides..... 2.4 dpm/cm^2

f. Open the package with the following precautionary steps:
(1) Remove packing slip.
(2) Open outer package following the supplier's instructions, if provided.
(3) Verify that the contents agree with the packing slip.
(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
(5) If anything is other than expected, stop and notify the RSO.
g. 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 samples 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.
h. Check the user request to ensure that the material received is the material that was ordered.
i. Monitor the packing material and the empty packages for contamination with a 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 it.
j. Make a record of the receipt.

For

2. 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).
c. Measure the exposure rate from the package at one (1) meter and at the package surface. If it is more than 10 millirems per hour at three (3) feet (1 meter), stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or a "Yellow III" label is the approximate dose rate, in millirem per hour, at one (1) meter from the package surface).
d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate

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from packages with "White I" labels should be less than 0.5 millirem per hour on the external surface of the package.

e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days..... 24 dpm/cm^2

All other alpha-emitting radionuclides..... 2.4 dpm/cm^2

f. Open the package with the following precautionary steps:

(1) Remove packing slip.

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

(3) Verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

g. 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 samples 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.

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

i. Monitor the packing material and the empty packages for contamination with a 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 it.

j. Make a record of the receipt.

3. For packages received under the general license in 641-39.4(22)"i", the following procedure for opening each package will be followed.

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

b. Check to ensure that the material received is the material that was ordered.

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RECORDS OF BY-PRODUCT 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 replicate entries. For example, if you prepare a multi-dose vial for use one day, you do not have to record the date each time you draw a dose from it.

K.1. RECORDS OF UNIT DOSAGE USE in addition to 641-40.90 and 41.2(19)

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix MK.1 to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedures in the model procedure and carefully review the requirements of 641-40.90 and 41.2(19). Indicate on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as Appendix MK.1" and submit your unit dosage record procedure.

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, and expiration date;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. If administered,
   a. Prescribed dosage (unless already recorded in clinical procedure manual),
   b. Measured activity in millicuries or microcuries and date and time of assay and administration,
   c. Patient name and identification number if one has been assigned;
8. If discarded, the date and method of disposal; and
9. Initials of the individual who performed the assay.
10. Maintain record of three (3) years.

K.2 RECORDS OF MULTI-DOSE VIAL USE in addition to 641-40.90 and 41.2(19)

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a multi-dose vial record system that was published in Appendix K.2 to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

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If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of 641-40.90 and 41.2(19). Say on your application, "We have developed a procedure for a multi-dose vial record system for your review that is submitted as Appendix K.2" and submit your multi-dose vial record procedure.

MODEL PROCEDURE

For each multi-dose 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 performed the assay.
9. Maintain record of three (3) years.

K.3. MEASURING AND RECORDING MOLYBDENUM CONCENTRATION (641-41.2(34))

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (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. If so, it should be reported according to 641-41.2(34)"d."

Verify that you will not be using a technetium generator or submit your procedure used to measure the molybdenum concentration in Mo-99/Tc-99m generator elutions.

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MODEL PROCEDURE FOR AREA SURVEYS

In addition to 641-40.27 and 41.2(26)

You may use the following procedure to perform area surveys. If you follow this procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix NL to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of 641-40.27 and 41.2(26). Say on your application, "We have developed survey procedures for your review that are appended as Appendix NL" and submit your survey procedures.

MODEL PROCEDURE

AMBIENT DOSE RATE SURVEYS in addition to 41.2(26)

1. Surveys -- Restricted Areas:

a. Survey at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. If diagnostic administrations are occasionally made in patients' rooms (e.g. Tc-99m labeled bone scan, or heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
b. Survey at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.
c. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation survey meter.
d. Survey quarterly in sealed source storage areas with a radiation survey meter.
e. The wearer should survey protective clothing after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.

~~a. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation survey meter.~~
~~b. The wearer should survey protective clothing after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.~~

2. Surveys -- Unrestricted Areas:

Quarterly surveys should be accomplished in areas
- adjacent to restricted areas
- through which radioactive materials are transferred
- where radioactive material is temporarily stored before shipment.

More frequent surveys will be necessary if radiation levels are suspect.

3. Trigger levels for ambient radiation level surveys:

Trigger levels for ambient radiation level shall be established. If exceeded, would require the individual performing the survey to immediately notify the radiation safety officer, and follow instruction to responding and investigating the cause of the increase radiation level.
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	0.04 mR/hr
Ambient Dose Rate	Restricted	1.0 mR/hr

REMOVABLE CONTAMINATION SURVEYS in addition to 41.2(26)
Removable contamination is the amount of removable radioactive material per 100 cm^2 of surface area 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 know efficiency.

1. Survey Areas:

Survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored. If diagnostic administrations are occasionally made in patients' rooms (e.g. Tc-99m labeled bone scans, heart agents), with special care taken to remove all paraphernalia, those rooms need not to be surveyed.

Survey quarterly any area where the potential for spreading contamination is likely to occur, (cafeterias, snack bars, furniture and equipment). Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate decontamination of the area and corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200-dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm to disintegrations per minute or dpm).

3. Immediately notify the RSO if you find levels that exceed the established action levels. Recommended removable surface contamination action levels are listed in Table N-2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels. When it is not possible to decontaminate to background levels, the licensee must shield, post, and restrict from use.

Table N-2: Removable Contamination Levels (dpm/100cm^2)		
Area, clothing	**Restricted areas, protective clothing used only in restricted area**	***Unrestricted area**
Alpha emitters	200	20
Beta/Gamma emitters	2,000	200
*Licensee shall make a reasonable effort to decontaminate to background levels.		

~~1. Survey Areas:~~

~~Survey at least quarterly in any area where the potential for spreading contamination is likely to occur, (cafeterias, snack bars, furniture and equipment). Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred~~

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Review NRC Reg Guide 8.23 for trigger levels.
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Commented [SJ17]: These values come from NUREG. Our 41.2(26)"f" has an MDA of 2000 dpm, not sure if we want to put 2,000 for Alpha as well or leave according to NUREG. Unrestricted should be decontaminated to background. NUREG has a table that state 1,000 dpm/100cm2 value I can add too. Or, we could go more restrictive to 10% of the restricted area values like before? Thoughts?

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~~out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.~~

~~2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200-dpm/100 cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm to disintegrations per minute or dpm).~~

~~3. Immediately notify the RSO if you find levels that exceed the established action levels. Recommended removable surface contamination action levels are published in NRC Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions" or see Table L-1 below for guidance in establishing your action levels.~~

RECORDS

1. Records must contain the information required by 41.2(26)"h", which includes the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

3. ~~2.~~ In those cases in which radiation or contamination action levels were exceeded, a follow-up survey should be completed and recorded. The RSO should promptly review and sign survey records that document the results of any actions implemented to corrective the excessive radiation or contamination levels.

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3. Maintain record of three (3) years.

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MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS

In addition to 641-40.15, 16, 17, and 18; 41.2(29) and 41.2(35)

O.1 WORKER DOSE FROM NOBLE GASES (ITEM 11.13.1)

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.

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 are not monitoring trap effluent, you must estimate worker dose by calculation.

If none of the above applies, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 641-40.15, 16, 17, and 18, 41.2(29) and 41.2(35). Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as Appendix O," and append your procedure for monitoring worker dose from noble gases.

O.2 WORKER DOSE FROM AEROSOLS (ITEM 11.13.2)

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. (You do not have to submit the calculations, but you should keep them for IDPH review during inspections.)

O.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 continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.

2. If you do not continuously monitor the trap effluent, check it on receipt and once each month. During one patient study, collect the effluent from the trap 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, 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. **If there is a significant increase in the activity measured on the bag, the trap must be replaced.**

3. The charcoal Xenon trap should be replaced at time intervals recommended by the manufacturer.

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O.4 PUBLIC DOSE FROM AIRBORNE EFFLUENT (ITEM 11.13.3)

Verify that you are not directly venting aerosols and gases to the atmosphere. Respond by saying, "We will not directly vent spent aerosols and gases to the atmosphere."

O.5 SPILLED GAS CLEARANCE TIME (ITEM 11.13.4)

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, the calculations described in Appendix O .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.

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 values), 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 re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system

   d. C -- the modified derived air concentrations (DAC) in restricted areas. These should be figured according to M.1. Numbers 1 and 2.

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

2. Make the following calculations for each room:

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

   b. The evacuation time t= -V/Q X ln (C x V/A).

3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted
   * 2.0 mrem in any one (1) hour from external sources, and
   * 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

APPENDIX PL

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TABLE L-1 RECOMMENDED ACTION LEVELS IN DPM/100 CM2 FOR SURFACE CONTAMINATION		
	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

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APPENDIX QL

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APPENDIX QL

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MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS

In addition to 641-40.15, 16, 17, and 18; 41.2(29) and 41.2(35)

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M.1 WORKER DOSE FROM NOBLE GASES (ITEM 11.13.1)

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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 are not monitoring trap effluent, you must estimate worker dose by calculation.

If none of the above applies, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of 641-40.15, 16, 17, and 18, 41.2(29) and 41.2(35). Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as Appendix M," and append your procedure for monitoring worker dose from noble gases.

M.2 WORKER DOSE FROM AEROSOLS (ITEM 11.13.2)

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. (You do not have to submit the calculations, but you should keep them for IDPH review during inspections.)

M.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 continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.

2. If you do not continuously monitor the trap effluent, check it on receipt and once each month. During one patient study, collect the effluent from the trap 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, compare its counts per minute (cpm) to background cpm with no other

APPENDIX QL

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~~3.~~ **The charcoal Xenon trap should be replaced at time intervals recommended by the manufacturer.**

~~M.4 PUBLIC DOSE FROM AIRBORNE EFFLUENT (ITEM 11.13.3)~~

~~Verify that you are not directly venting aerosols and gases to the atmosphere. Respond by saying, "We will not directly vent spent aerosols and gases to the atmosphere."~~

~~M.5 SPILLED GAS CLEARANCE TIME (ITEM 11.13.4)~~

~~Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, the calculations described in Appendix M.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.~~

~~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 values), 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 re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas exhaust system~~

~~d. C -- the modified derived air concentrations (DAC) in restricted areas. These should be figured according to M.1. Numbers 1 and 2.~~

~~e. V -- the volume of the room in milliliters.~~

~~2. Make the following calculations for each room:~~

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

~~b. The evacuation time t= -V/Q X ln (C x V/A).~~

~~3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted~~

- ~~2.0 mrem in any one (1) hour from external sources, and~~
- ~~100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.~~

~~Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.~~

APPENDIX RN

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MODEL PROCEDURE FOR WASTE DISPOSAL

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In addition to 641-40.70, 40.88 and 41.2(30))

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that was published in Appendix RN to IDPH MEDICAL USE OF RADIOACTIVE MATERIAL FOR DIAGNOSTIC PROCEDURES REGULATORY GUIDE."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of 641-40.70 and 41.2(30). Say on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix RN" and attach your procedure as Appendix RN.

Note 1: Nnothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 641-38.4(1) and 40.88.)

Note 2: In your waste disposal, be sure to include all radioactive materials, not just your day-to-day diagnostic materials (i.e. sealed sources for camera calibration, material for QA/QC of dose calibrator)

OVERVIEW

40.70 describesThe commonly used methods of waste disposal:

* Ddecay-lin-Sstorage (DIS);
* Ttransfer to the an authorized recipientmanufacturer; and
* Rrelease to in-house wasteeffluents within the limits in 40.72(1)"d."

[illegible] pursuant to 641-39.4(22)"i"), are exempt waste disposal regulations and can be disposed along with in-house waste. Radioactive labels should still be defaced or removed. There is no need to keep any record of release or make any measurement.

GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed form containers and packages before disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that no unnecessary radioactive waste is created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, and pathogenicity), and expense.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

APPENDIX RN

41.2(30) describes the requirements for disposal by "decay-in-storage." Short-lived material (physical half-life less than or equal to 12065 days) may be disposed of by DIS. Facilities should ensure that adequate space are available and containers should have shielded covers to maintain occupational exposure ALARA. Storage areas must be in a secure location. If you use this procedure, keep material separated according to half-life, and consider short-term and long-term storage.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.

1. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
2. Consider using separate containers for different types of waste (e.g., capped 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 waste will be disposed of must not provide any radiation shielding for material.
3. 2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed the longest-lived radioisotope in the container, and the initials of the person sealing the container.
4. The container should be labeled in accordance with 641-40.63 and 641-40.64. The container may then be transferred to the DIS area. The container may then be transferred to the DIS area.
5. 3. Decay the material for at least 10 half-lives. The expected radiation levels in most cases should not be distinguishable from background, but this depends of the radionuclides and original activity present.
6. 4. Before disposal as in-house waste, monitor each container as follows:
   a. a. Check your radiation detection survey meter for proper operation.
   b. Plan to monitor in a low-level background radiation area away from all sources of radioactive material. (less than 0.05 millirem per hour) area.
   b. c. Remove any shielding from around the container.
   d. Monitor, at contact, all surfaces of each individual container, with the survey meter on its most sensitive setting. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages).
   c. Surveys of all surfacese. Discard as in-house waste only those containers that cannot be distinguished from background to be disposed in-house.
   d. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
7. Prior to disposing in-house, deface/remove Check to be sure that no all visible radiation labels are visible.
8. Make a record of each disposal as described in 41.2(30)"b":
   - Date of disposal
   - Date on which the radioactive material was placed in storage
   - Radionuclides disposed
   - Model and serial number of the survey instrument used
   - The background dose rate
   - The radiation dose rate measured at the surface of each waste container
   - [illegible]
8. Retain records for three (3) years.

Note: Any calibration sources with half-lives greater than 120 days (e.g. cobalt-57, germanium-68, gadolinium-153) may not be held for decay-in-storage and must be disposed of in accordance with 641-39 and 641-40.

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APPENDIX RN

~~4. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.~~

~~5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, and then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.~~

MODEL PROCEDURE FOR ~~RETURNING~~ TRANSFERRING ~~GENERATORS~~ MATERIAL TO THE AUTHORIZED RECIPIENT~~MANUFACTURER~~

Frequently, longer-lived sources~~Used Mo-99/Tc-99m generators~~ may be returned to the manufacturer or sent to a licensed waste disposal user. This process~~permission~~ does not relieve licensees from the requirement to comply with 641-39.5 and Department of Transportation (DOT) regulations.

1. ~~1.~~ Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, ~~paragraph 173.415(a) of~~ 49 CFR Part 173.415(a)).
2. ~~2.~~ Assemble the package in accordance with the manufacturer's instructions.
3. ~~3.~~ Perform the dose rate and removable contamination surveys required by DOT regulations 49 CFR via 39.5~~(15)~~.
4. ~~4.~~ Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
5. Retain records of receipts and transfers in accordance with 641-39.4(52).

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APPENDIX SN

RESERVEDMODEL PROCEDURE FOR EFFLUENT DISPOSAL RELEASE TO IN-HOUSE WASTE

DO WE WANT THIS SECTION??

Waste from *in-vitro* kits that are generally licensed pursuant to 641-39.4(22)"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.

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~~**APPENDIX O**~~

MODEL ANNUAL AUDIT CHECKLIST

Auditor: _____
Date of Audit: _____
Management review: _____

ORGANIZATIONAL STRUCTURE

a.	Radiation Safety Officer (RSO) same as listed on the license	☐ N/A	☐ Yes	☐ No
b.	Visiting Authorized User(s)			
(1)	Has written permission. [41.2(12)"a"(1)]	☐ N/A	☐ Yes	☐ No
(2)	Visitor authorized user's license on file. [41.2(12)"a"(2)]	☐ N/A	☐ Yes	☐ No
(3)	Performs only those procedures authorized on visitor's license. [41.2(12)"a"(3)]	☐ N/A	☐ Yes	☐ No
(4)	Uses materials under licensee's license or 60 days per year or less. [41.2(12)"a"]	☐ N/A	☐ Yes	☐ No
(5)	Records maintained five (5) years after the visiting authorized user's last visit. [41.2(12)"c"]	☐ N/A	☐ Yes	☐ No

AUDIT HISTORY

a.	Last audit conducted on: _____			
b.	Deficiencies identified.	☐ N/A	☐ Yes	☐ No
c.	Were they corrected?	☐ N/A	☐ Yes	☐ No

SCOPE OF PROGRAM

a.	Are there multiple authorized locations of use?	☐ N/A	☐ Yes	☐ No
	If multiple locations authorized, list locations audited.	☐ N/A	☐ Yes	☐ No
b.	Have there been radiation safety program changes? [41.2(4)"f"] If yes, list changes.	☐ N/A	☐ Yes	☐ No

TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a.	Instructions to workers provided. [40.111]	☐ N/A	☐ Yes	☐ No
b.	Training program conducted according to license commitments.	☐ N/A	☐ Yes	☐ No

FACILITIES, MATERIALS, AND EQUIPMENT

a.	Facilities are as described in the license application.	☐ N/A	☐ Yes	☐ No
b.	Storage and use of radioactive material			
(1)	Adequate method to prevent unauthorized individuals from entering restricted area.	☐ N/A	☐ Yes	☐ No
(2)	Radioactive material secured to prevent unauthorized removal or access. [40.55"a"]	☐ N/A	☐ Yes	☐ No
c.	Dose Calibrator			
(1)	Constancy checked. [41.2(17)"b"(1)]	☐ N/A	☐ Yes	☐ No

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(2) Linearity tested. [41.2(17)"b"(3)]	☐ N/A	☐ Yes	☐ No
(3) Accuracy tested. [41.2(17)"b"(2)]	☐ N/A	☐ Yes	☐ No
(4) Geometry dependence test. [41.2(17)"b"(4)]	☐ N/A	☐ Yes	☐ No
(5) Readings mathematically corrected if linearity error is greater than 10%. [41.2(17)"c"]	☐ N/A	☐ Yes	☐ No
(6) Records maintained. [41.2(17)"e"]	☐ N/A	☐ Yes	☐ No
(7) RSO signs linearity, accuracy, and geometry dependence tests. [41.2(17)"e"]	☐ N/A	☐ Yes	☐ No
d. Survey instruments.			
(1) Appropriate operable survey instruments. [41.2(32); 41.2(36); and 41.2(40); 41.2(42)]	☐ N/A	☐ Yes	☐ No
(2) Calibration, as required. [41.2(18)"a"]	☐ N/A	☐ Yes	☐ No
(3) Records maintained. [41.2(18)"e"]	☐ N/A	☐ Yes	☐ No
e. Syringes containing RAM properly labeled and shielded, unless contraindicated. [41.2(22)"b"]	☐ N/A	☐ Yes	☐ No
f. Syringes properly labeled. [41.2(23)]	☐ N/A	☐ Yes	☐ No
g. Vials containing RAM properly shielded. [41.2(24)]	☐ N/A	☐ Yes	☐ No
h. Vials properly labeled. [41.2(25)]	☐ N/A	☐ Yes	☐ No

MATERIALS

a. Molybdenum-99 breakthrough tests performed.	☐ N/A	☐ Yes	☐ No
b. Records Molybdenum-99 breakthrough tests maintained.	☐ N/A	☐ Yes	☐ No
c. Leak tests of sealed sources performed at appropriate intervals. [41.2(21)"b"]	☐ N/A	☐ Yes	☐ No
(1) Leak test records in units of microcuries. [41.2(21)"d"]	☐ N/A	☐ Yes	☐ No
(2) Leak test records signed by RSO. [41.2(21)"d"]	☐ N/A	☐ Yes	☐ No
(3) Records of leak tests kept for five (5) years. [41.2(21)"d"]	☐ N/A	☐ Yes	☐ No
d. Inventories	☐ N/A	☐ Yes	☐ No
(1) Inventory of sealed sources at six month intervals. [41.2(21)"g"]	☐ N/A	☐ Yes	☐ No
(2) Inventory records signed by RSO. [41.2(21)"g"]	☐ N/A	☐ Yes	☐ No
(3) Records of leak tests and inventories kept for five years. [41.2(21)"g"]	☐ N/A	☐ Yes	☐ No

RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Procedure for opening packages adequate. [40.65(5)]	☐ N/A	☐ Yes	☐ No
b. Incoming packages monitored for radioactive contamination. [40.65(2)"a" or "c" and 40.65(3)]	☐ N/A	☐ Yes	☐ No
c. Incoming packages monitored for external radiation levels. [40.65(2)"b" and 40.65(3)]	☐ N/A	☐ Yes	☐ No
d. Transfers performed, as required. [39.4(41)]	☐ N/A	☐ Yes	☐ No
e. Records of receipt surveys. [40.82(1)]	☐ N/A	☐ Yes	☐ No
f. Records of receipt, transfer, & disposal of radioactive material. [38.4(1)]	☐ N/A	☐ Yes	☐ No

AREA SURVEYS

a. Ambient dose rate surveys performed. [41.2(26)"a" and "b"]	☐ N/A	☐ Yes	☐ No
b. Contamination surveys conducted. [41.2(26)"e"]	☐ N/A	☐ Yes	☐ No
c. Trigger levels established. [41.2(26)"d" and "g"]	☐ N/A	☐ Yes	☐ No
d. Dose rate survey records in mR/hr. [41.2(26)"h"]	☐ N/A	☐ Yes	☐ No
e. Contamination survey records maintained in dpm/100 cm^2. [41.2(26)"h"]	☐ N/A	☐ Yes	☐ No

PERSONNEL RADIATION MONITORING – EXTERNAL

a. Supplier NVLAP approved. [40.36(3)"a" and "b"]	☐ N/A	☐ Yes	☐ No
b. Dose(s) exceeded regulatory limits. [40.15]	☐ N/A	☐ Yes	☐ No

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c. ALARA program implemented. [41.2(7)"a"]	☐ N/A	☐ Yes	☐ No
(1) Annual review by Radiation Safety Officer completed. [41.2(7)"c"]	☐ N/A	☐ Yes	☐ No
(2) Written description of ALARA program available. [41.2(7)"d"]	☐ N/A	☐ Yes	☐ No

WASTE DISPOSAL

a. Radioactive material disposed of as authorized. [40.70(1)]	☐ N/A	☐ Yes	☐ No
b. Record of disposal by decay in storage maintained. [41.2(30)"b"]	☐ N/A	☐ Yes	☐ No
c. Survey of waste before disposal. [40.36]	☐ N/A	☐ Yes	☐ No
d. Records of waste surveys. [40.82(2)"d"]	☐ N/A	☐ Yes	☐ No

NOTIFICATION AND REPORTS

a. Notifications and reports provided to individuals. [40.112]	☐ N/A	☐ Yes	☐ No
b. Reporting theft or loss compliant with rules. [40.95]	☐ N/A	☐ Yes	☐ No
c. Compliant regarding overexposures notification of incidents. [40.96]	☐ N/A	☐ Yes	☐ No
d. Compliant regarding reporting of excessive levels and concentrations. [40.97]	☐ N/A	☐ Yes	☐ No
e. Termination reports furnished, if requested by workers. [40.112(5)]	☐ N/A	☐ Yes	☐ No

POSTING AND LABELING

a. Radiation Areas posted. [40.61(1)]	☐ N/A	☐ Yes	☐ No
b. High Radiation Areas posted. [40.61(2)]	☐ N/A	☐ Yes	☐ No
c. Use or storage areas posted "Caution Radioactive Material." [40.61(5)]	☐ N/A	☐ Yes	☐ No
d. Containers or devices labeled. [40.63]	☐ N/A	☐ Yes	☐ No
e. Notice to Workers posted. [40.110(1) and (2)]	☐ N/A	☐ Yes	☐ No
f. Notice to Employees posted. [40.110(3)]	☐ N/A	☐ Yes	☐ No

TRANSPORTATION (641-39.5) AND 49 CFR 171-178

a. Authorized packages used.	☐ N/A	☐ Yes	☐ No
b. DOT-7A performance test records on file. [173.415(a)]	☐ N/A	☐ Yes	☐ No
c. For special form sources, performance test records on file. [173.476(a)]	☐ N/A	☐ Yes	☐ No
d. Packages properly labeled. [172.403(b)]	☐ N/A	☐ Yes	☐ No
e. Packages properly marked. [172.301(a)]	☐ N/A	☐ Yes	☐ No
f. Proper shipping papers prepared. [172.200]	☐ N/A	☐ Yes	☐ No
g. Shipping paper contains emergency response telephone number. [172.201(d)]	☐ N/A	☐ Yes	☐ No

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SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
11/02/01	Appendix L	Edited portion pertaining to records to clarify when the RSO should sign survey documents.
01/18/02	Appendix G	Revised guidelines to reflect actual practices.
01/08/02	Section 7	Added information concerning inspections.
06/19/02	Appendix H	Added additional isotopes in spill procedures.
01/24/03	ALL	Name changed. All references to therapy and RSC removed.
03/12/03	Appendix G	Revised the requirement for use of extremity monitors (Paragraph 8).
03/13/03	Section 1.3	Replace the website address of the IDPH rules and publications.
07/01/05	ALL	Changed address for the Bureau of Radiological Health
07/17/07	Appendix B	Added new Model Delegation of Authority/Removed old Model Delegation of Authority from Appendix A
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.
08/08/12	Item 4.1	Updated the requirements for physician authorized user approval.
2/28/17	Section 1.3 Item 11.1 Appendix G Appendix J	Replace the website address of the IDPH rules. Revised frequency of sealed source inventory to align with IAC 641-41.2(21). Revised model rule number 16 to align with IAC 641-41.2(19). Revised non-fixed external radioactive contamination limits for packages to align with 49 CFR 173.433.
07/22/20	ALL	Entire guide reviewed & updated to reflect rule changes for 641-41.2
10/7/20	Appendix A	Changed ALARA note from per “month” to per “calendar quarter.”