IOWA DEPARTMENT OF PUBLIC HEALTH

MOBILE NUCLEAR MEDICAL SERVICE REGULATORY GUIDE

IDPH
IOWA Department of PUBLIC HEALTH

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IDPH REGULATORY GUIDE FOR MOBILE NUCLEAR MEDICAL SERVICE

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1. INTRODUCTION

1.1 GENERAL

The Iowa Department of Public Health (IDPH) regulates the intentional internal or external administration of by-product material to human beings and to individuals exposed to patients that have received radiopharmaceutical doses. 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

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.

1.1.1 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 mobile nuclear medicine service license. It also summarizes the by-product material regulations for medical use in a mobile environment.

This regulatory guide is intended for use by mobile nuclear medicine services regardless of the type of service provided. As such, not all sections are applicable. The licensee should review the information and respond as appropriate.

1.2 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 https://idph.iowa.gov/radioactivematerials/rules.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) of IDPH Radiation Machines and Radioactive Materials Rules states that "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), and management are required to audit the by-product material program to ensure the continued safe use of by-product material. The RSO serves as a technical consultant to the management and 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.

1.4 ADDITION CONSIDERATIONS

Nuclear medicine technologist is an individual, other than a licensed physician, who performs nuclear medicine procedures utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures. These duties and include but are not limited to:

1. Administration of any radiopharmaceutical to human beings for diagnostic purposes;
2. Administration of radioactive material to human beings for therapeutic purposes;
3. Use of radioactive material for diagnostic purposes involving transmission or excitation; or
4. Quality control and quality assurance.

Because mobile nuclear imaging systems employ radioactive material for transmission or excitation, a nuclear medicine technologist is the only qualified individual other than a physician who can operate the imaging equipment.

2. FILING AN APPLICATION

You should apply for a license by completing an "Application for Radioactive Materials License" 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 possible. If larger drawings are necessary, fold them to 8 1/2 x 11 inches.

You should complete all items in the application. There should be 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 Form 229-0514. 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/contacts.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license.

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.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of use by the street address, city, and state or other descriptive address (such as five (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. In items 6 through 12 of the application, describe the intended use and the facilities and equipment at each location.

ITEM 2. -- PERSON TO BE CONTACTED 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 the CEO or President with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee if the CEO or President provides that authorization in writing 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. -- 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 for amendments or renewals.

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

Responsible individuals 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) provide specific criteria for acceptable training and experience for authorized users and the RSO. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

4.1. -- AUTHORIZED USERS FOR NUCLEAR VAN LICENSES

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

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

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 and each individual user and note, by reference to Item 6, which proposed uses are requested for the individual.

B. If a physician has been previously authorized for medical use and wishes to use material permitted by the previous Iowa Department of Public Health 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 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 "*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).

4.2 -- PERMIT TO PRACTICE

A Nuclear medicine procedure is defined in 641-42.1 as any procedure utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures and include, but is not limited to:

1. Administration of any radiopharmaceutical to human beings for diagnostic purposes.
2. Administration of radioactive material to human beings for therapeutic purposes.
3. Use of radioactive material for diagnostic purposes involving transmission or excitation.
4. Quality control and quality assurance.

Nuclear Medicine Technologists working in Iowa must have an Iowa Department of Public Health permit to practice in accordance with Chapter 42.

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

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 Supplement A. 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 ITEM 7. -- PURPOSE

641-41.2(31), 41.2(33), 41.2(37), and 41.2(41) divide by-product material for medical use into types of use. Using the table format of Table I 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 I

RADIOACTIVE MATERIAL	AMOUNT	PURPOSE
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
6.c Material in 641-41.2(37)	As needed	7.c. Medical Use
6.d Material in 641-41.2(41)	As needed	7.d Medical use

If you need other items, make a separate line entry for each item. 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. You do not have to list certain calibration and references sources if they meet the criteria in 41.2(20). For sealed sources used in 41.2(41), list manufacturer, serial number, and activity.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

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.

NOTE: Items 9. - Through - 12.

Your response to these items should consist of one sentence that says that you will follow the model procedure in Appendix __ in IDPH Mobile Nuclear Medical Service 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

Describe your training program for individuals who work with or near radioactive material described in Item 6.a. for mobile nuclear medicine service. 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

10.1. -- ANNOTATED DRAWING

Submit an annotated drawing of the areas where by-product material will be used. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The principal use of each area (for example, hot lab, examining, imaging, reading, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet).
3. Any shielding available.
4. 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

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

For dose calibrator testing, review Appendix C carefully. Commit to following the model procedure or submit your own procedures using the appendix as a guide. Indicate "NA" if not applicable. (Special requirements for remote afterloading devices are included in a separate regulatory guide.)

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
Lite Scientific, Inc.	DKM-007	1 - 100000 cpm

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 charges are not considered "servicing."

10.3 -- INFORMATION REQUIRED FOR LICENSING MOBILE NUCLEAR MEDICINE SERVICES

I. LOCATION OF USE

The locations of use for mobile nuclear medicine service licensees, which provide diagnostic imaging and bone mineral analysis services, are of two basic types. One type of location is the base hot lab where licensed material shall be received, stored and used. The other type of location is the temporary job site at medical care (client) facilities.

A. Base Hot Lab

Depending upon the scope of services, the licensee may request multiple base hot lab locations. Multiple base hot labs are strategically situated to enable the licensee to comply with 41.2(28) without compromising the geographical area of service.

The base hot lab may be located in a medical institution or a non-medical facility. The application should specify whether the proposed facility is a medical institution. The following information should be requested from the applicant:

1. Medical Institutions

If the applicant is part of a medical institution, there must be a clear link to the medical facility and its management. The mobile nuclear medicine license must be issued to one management entity, which presides over all base hot lab locations and has full responsibility for assuring compliance with all applicable regulatory requirements.

If the base hot lab is in a medical institution ***that is not a licensee***, the mobile nuclear medicine licensee must assume full responsibility for the used space(s). The license must provide IDPH with a statement verifying that arrangement.

2. Non-Medical Facilities

Base hot labs are typically authorized at commercial facilities. However, applicants have also requested base hot labs at residential locations.

a. Requests for base hot labs that appear to be located at a residence require the following additional information:

(1) Justification for a private residence location rather than a commercial location. This justification should be based on patient need, public health and safety, and adequate radiological protection.
(2) Documentation of a clear contractual agreement concerning access to the residence for purposes of decontamination or removal of licensed material from the residence in case of disharmony between these two entities. Signed documentation from both parties must be provided to illustrate the agreement between the residence owner and the licensee.
(3) Confirmation in the form of letters from local agencies, that operation of the base hot lab does not conflict with local codes and zoning laws.
(4) Confirmation in the form of signed statements by the licensee that police and fire departments with jurisdiction in the area shall be notified of by-product material content initially and at six-month intervals.
(5) Detailed descriptions and diagrams of the facility should include information regarding construction of the building and adjacent areas.

(6) A description of the scope of activities conducted at each location. Locations may range from being a hot lab up to a full-service imaging center from which the mobile nuclear medicine service is based.
(7) Demonstration that restricted areas shall not include areas adjacent to restricted areas, including above and below. The applicant should discuss how radiation levels in unrestricted adjacent areas will remain in compliance with 641-40.26.
(8) A description of the security provisions used to restrict facility access from unauthorized persons. The facility should be of adequate construction and design to ensure security of licensed material and prevent unauthorized access. Security should consider residents and the general public.

b. Documentation must be submitted for all commercial facilities to indicate the management body that presides over all proposed locations. This documentation should show clear delineation of authority and responsibility. The mobile nuclear medicine service license should be issued to one management entity that presides over all base hot lab locations. If business arrangements exist which would negate the issuance to one entity, documentation describing the business arrangement and the base hot lab management must be included in the application.

B. Temporary Job Site

The temporary job site at medical care facilities (client's address) is where a mobile nuclear medicine service uses by-product material in accordance with 641-41.2. The mobile nuclear medicine service may transport licensed material and equipment from the van into a client's building, or bring patients into the van located on the client's property. The application should clearly describe whether "scan-in-van" services will be provided. If an applicant requests scan-in-van service, the following information should be submitted:

1. Procedures for positioning the mobile van at temporary job sites. Mobile vans should be sited on the client's property, preferably adjacent to the building.
2. A detailed diagram of the mobile van including all the information requested in Item 10.1 of the IDPH Mobile Nuclear Medical Service Regulatory Guide.
3. How the scan-in-van operation shall remain in compliance with 641-40.26 and 40.27 for unrestricted areas (e.g., outside of van).
4. Procedures for compliance with 641-41.2(13)"c" during times when patients are being injected and/or scanned in the mobile van. The procedures should describe how the client will assure that services are conducted in accordance with the regulations while the mobile nuclear medicine service is under the client's direction.
5. Survey procedures to check for contamination before leaving each location of use according to 641-41.2(28).

II. TRANSPORTATION

All licensees are required to comply with 641-39.5 regarding transportation of licensed material. The mobile nuclear medicine service acts as a shipper and carrier of radioactive material. Review of mobile van licensee inspection reports indicates a relatively high incidence of violations pertaining to transportation, even when the license was conditioned to alert the licensee of the requirements in 641-39.5. Therefore, the applicant should provide a description of the mechanisms or procedures used to assure the following:

A. Transportation of radioactive material is in accordance with 641-39.5. Procedures should include:
   1. Approved packages
   2. Appropriate labeling

3. Proper surveys
4. Complete and accurate shipping papers
5. Bracing of packages
6. Security provisions
7. Emergency procedures

B. Training for drivers and technologists, which include transportation regulations and emergency procedures. Documentation of this training should minimally include dates, topics discussed, attendees and instructor's name.

C. Emergency procedures that van drivers shall follow in case of an accident involving licensed material in transport shall be maintained in the vehicle during transport. Emergency procedures should minimally include posting the area, maintaining surveillance, and notifying the RSO. A copy of these procedures must be included in the application.

D. Procedures for handling radioactive waste during transport. Describe the method of storage and final disposal.

III. SUPERVISION

Due to the potential for using licensed material at locations distant from the authorized user(s), it is necessary to request information from the applicant regarding compliance with 641-41.2(11). The applicant should discuss how the authorized user(s) periodically review the supervised individual's use of by-product material and the records kept reflecting this pursuant to 41.2(11). Records should be maintained for IDPH review.

Procedures should be submitted to indicate that the RSO and authorized user can be physically present at the temporary job site in response to incidents (e.g., accidents, spills, and misadministrations) that occur at temporary job sites. Response times of less than one hour may be considered acceptable and should be evaluated on a case-by-case basis. Additional training for technologists involved may be warranted.

ITEM 11. -- RADIATION SAFETY PROGRAM

The elements of a radiation safety program are contained in Appendices A through R. The following table is provided as a reference and indicates the applicability to the two types of mobile nuclear medicine services. 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	TITLE	APPLICABILITY	
		NV	NV2
Appendix A	Model program for maintaining occupational radiation exposure in mobile nuclear medicine services As Low As Reasonably Achievable (ALARA)	Yes	Yes
Appendix B	Duties of the RSO	Yes	Yes
Appendix C	Model procedure for calibrating dose calibrators	Yes	No
Appendix D	Personnel exposure monitoring program	Yes	Yes
Appendix E	Training program	Yes	Yes
Appendix F	Leak-testing sealed sources	Yes	Yes

Appendix G	Safe use of radiopharmaceuticals	Yes	Partial
Appendix H	Spill procedures and action limits	Yes	No
Appendix I	Guidance for ordering and receiving radioactive material	Yes	Partial
Appendix J	Safely opening packages containing radioactive material	Yes	Partial
Appendix K.1	Records for unit dosage use	Yes	No
Appendix K.2	Records for multi-dose vial use	Yes	No
Appendix K.3	Measuring and recording molybdenum concentration	Yes	No
Appendix L	Area survey procedures	Yes	Partial
Appendix M.1	Estimating worker dose from submersion in noble gases	Yes	No
Appendix M.2	Estimating worker dose from aerosol concentrations	Yes	No
Appendix M.3	Estimating aerosol and gas concentration in effluents	Yes	No
Appendix M.4	Calculating spilled gas clearance times	Yes	No
Appendix N	Waste Disposal	Yes	Partial

11.1. -- SEALED SOURCE INVENTORIES

State that you will conduct inventories, at intervals not to exceed three (3) months 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
- the signature of the Radiation Safety Officer.

11.2. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

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 once problems are identified they are promptly and comprehensibly corrected. 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 through, 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.

Supplement D contains a suggested audit program that is acceptable to the IDPH.

ITEM 12. -- WASTE MANAGEMENT

Submit your procedures for waste disposal. See Appendix N. Be sure to include a procedure for all material listed in Item 6.

ITEM 13. -- LICENSE FEES

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 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.

2. 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.

ITEM 14, 15 -- CERTIFICATION

The application must be signed by a senior partner, the president, director or chief executive officer. 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.

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 changing locations of use. See 641-41.2(4) for the specific requirements. An application for an amendment must be filed on 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 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 should be 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

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

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 are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE IN MOBILE NUCLEAR MEDICINE SERVICES AS LOW AS REASONABLY ACHIEVABLE (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 Mobile Nuclear Medical Service Regulatory Guide." Submit the signed commitment in section number 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 number 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.

   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 them.

   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 licensee 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.

      (2) When considering the use of by-product material, the licensee will review efforts of the applicant to maintain exposure ALARA.

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

b. 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 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)	
	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 efforts to maintain doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. RADIATION SAFETY OFFICER COMMITMENT

a. Annual and Quarterly Review

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

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section five (5) of this appendix.

b. 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.

c. Cooperative Efforts for Development of ALARA Procedures

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

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those 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 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 will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter 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.

[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.

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.

The RSO 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 unless deemed appropriate by the Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

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

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation 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 “Occupational Exposure Record for Monitoring Period” and 588-2833 “Cumulative Occupational Exposure History” 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.

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).

APPENDIX B

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

In Addition to 41.2(8)

You may use the following model procedure 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 Mobile Nuclear Medical Service 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 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 fume hood flow rates are tested at appropriate intervals and that employees utilize hoods in accordance with the safe use of radiopharmaceuticals.
11. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
12. Ensure that licensed material is disposed of properly.
13. 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.
14. 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.

Model Delegation of Authority

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

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

In addition to 641-41.2(17)

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the 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 the IDPH Mobile Nuclear Medical Service 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.

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 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 means that the calibrator is 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.

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.
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" of various thicknesses 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 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. 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.

APPENDIX D

MODEL PERSONNEL EXPOSURE MONITORING PROGRAM

In addition to 641-40.36 and 40.37

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 the IDPH Mobile Nuclear Medical Service 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 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:

    - 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.

D.2. MODEL PROGRAM FOR INTERNAL EXPOSURE

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Historically, bioassays for medical personnel have been required only in cases of administration to hospitalized patients because these are the patients receiving substantial doses of radiopharmaceuticals. This in turn meant that the medical personnel who prepared or administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials. The preparation or administration of these smaller dosages posed a relatively lower risk to the medical personnel involved.

The change in the criteria for release of patients who have been administered radiopharmaceuticals may involve the administration of relatively large dosages of radioactive materials without requiring patient confinement. Bioassays are only applicable to the administration of radiopharmaceuticals at levels that require hospitalization. It may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without coming under the bioassay requirements in 641-41.2(39)"a"(8).

Although licensees may no longer be tied to a bioassay program because of the new patient release criteria, they remain subject to the requirements of 40.37(136C) "Conditions requiring individual monitoring of external and internal occupational dose." This requires the licensee to monitor all occupationally exposed personnel who may receive, in one (1) year, an intake in excess of the applicable ALI in Table I, Columns 1 and 2, of Appendix B to Chapter 40.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed 10 percent of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For medical licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay. Baseline surveys should be completed for all individuals likely to require future monitoring.

APPENDIX E

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 the IDPH Mobile Nuclear Medical Service Regulatory Guide." You may use lectures, videos-taped presentations, or demonstrations 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) 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) whose duties may require them to work in the vicinity of 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 F

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 F.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 (H.1 and/or H.2) to the IDPH Mobile Nuclear Medical Service 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 F," and submit your leak-test procedure.

H.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. Prepare 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:

    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. 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.

H.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

(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 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 microcuries 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 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 the IDPH Mobile Nuclear Medical Service 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 G," 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).

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 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.

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 and therapy 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 10 percent of the prescribed dosage with approval of an authorized user (except for prescribed dosages of less than 10 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.

APPENDIX H

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 H to the IDPH Mobile Nuclear Medical Service 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 H" and submit your spill procedures.

MODEL PROCEDURES

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.
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.

MAJOR SPILLS OF LIQUIDS AND SOLIDS

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing. Flush the contaminated skin with lukewarm water. Wash the affected area with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

MAJOR SPILLS AND MINOR SPILLS

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables 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.

TABLE H-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major. Spills of the amounts shown below are considered minor.

RELATIVE HAZARDS OF COMMON RADIONUCLIDES ESTIMATE THE AMOUNT OF RADIOACTIVITY SPILLED. INITIATE A MAJOR SPILL PROCEDURE BASED ON THE FOLLOWING DIVIDING LINE. SPILLS ABOVE THESE MILLICURIE AMOUNTS ARE CONSIDERED MAJOR, BELOW ARE CONSIDERED MINOR.	
RADIONUCLIDE	MILLICURIES
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99m, Tl-201	100

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 I to the IDPH Mobile Nuclear Medical Service 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 I," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee ensures 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, isotope, chemical form, activity, and supplier
        (2) Verification that material received was ordered by an authorized user.

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

        (1) The authorized user who will perform the procedure will make a written request to 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.

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 J to the IDPH Mobile Nuclear Medical Service 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 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.

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	
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.

APPENDIX K

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. If you take thirty Ir-192 seeds that are 0.5 millicuries each, you do not have to list each seed individually.

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 K.1 to the IDPH Mobile Nuclear Medical Service 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 K.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 the IDPH Mobile Nuclear Medical Service Regulatory Guide."

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.”

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

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix K.3 to the IDPH Mobile Nuclear Medical Service Regulatory Guide."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider the inclusion of all the features in the model procedure and carefully review the requirements of 641-41.2(34). Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as Appendix K.3" and submit your procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, make records of the items required by 41.2(34)"c":

In addition to 41.2(34)"c", record:

1. Date the generator was received.
2. Product of the measured Mo-99 activity and the correction factor. This is noted by the manufacturer.
3. Maintain record of three (3) years.

RECOMMENDED ACTION LEVEL -- An action level of 0.07 allows for the decay of the Tc-99m throughout the day of use. It is assumed that the material will be used within six (6) hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.

In conformance with 641-41.2(32)"d", the licensee must notify the IDPH if a leaking generator is detected.

APPENDIX L

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 L to the IDPH Mobile Nuclear Medical Service 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 L" and submit your survey procedures.

MODEL PROCEDURE

AMBIENT DOSE RATE SURVEYS in addition to 41.2(26)

1. Surveys -- Restricted Areas:

   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.
   c. 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.		

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.

    1. 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.

2. Maintain record of three (3) years.

APPENDIX M

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)

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 you exhaust spent gas to the atmosphere, you must also estimate worker dose by calculation. It is not necessary to submit the calculations, but you should keep them for IDPH review during inspections. If you will follow the model procedure for calculating worker dose from noble gases, you may respond by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix M of the IDPH Mobile Nuclear Medical Service Regulatory Guide."

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.

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.) If you follow the model procedure below for calculating worker dose from aerosols, you may respond by saying "We will follow the model procedure for calculating worker dose from aerosol concentrations that is appended as Appendix M.2." Submit your procedure for monitoring worker dose from aerosols.

M.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Determine the highest dose to an individual from all external radiation for the previous 12 month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.

2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rems (50 mSv) and divide this number by five (5) rems.

    a. This yields the fraction of the dose limit of five (5) rems that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in Appendix B to Chapter 40 in Table 1, column 3.

b. If the highest annual external dose is 2 rems, and the listed DAC value for xenon-133 is 1E-4 mCi/ml, then the modified DAC value should be based on 3 rems that could still be incurred from internal exposure.

3. The following calculations must be made:

a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
b. The estimated activity released to the restricted areas.

(1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.
(2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

M.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

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

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

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 radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

3. The RSO will establish an action level based on cpm or a multiple of background cpm. If there is a significant increase in the activity measured on the bag, the trap must be replaced.

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

PUBLIC DOSE FROM AIRBORNE EFFLUENT (ITEM 11.13.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Table II of Appendix B to Chapter 641-40.

If you are not directly venting aerosols and gases to the atmosphere, you may respond by saying "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary.

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for IDPH review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond by saying "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix M.3 to the IDPH Mobile Nuclear Medical Service Regulatory Guide."

If neither 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 airborne effluent concentration that is appended as Appendix M.3" and append your procedure for monitoring airborne effluent concentration.

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.

M.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

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

    b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser 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 $t = -V/Q \times \ln (C \times V/A)$.

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 N

MODEL PROCEDURE FOR WASTE DISPOSAL

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 N to the IDPH Mobile Nuclear Medical Service 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 N" and attach your procedure.

OVERVIEW

There are four commonly used methods of waste disposal:

- release to the environment through the sanitary sewer or by evaporative release;
- decay-in-storage (DIS);
- transfer to a burial site or back to the manufacturer; and
- release to in-house waste.

With the exception of the patient excreta (see 641-40.72) and generally licensed *in-vitro* kit exemptions (see 641-39.4(22)"i"), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 641-38.4(1) and 40.88.)

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)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

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.
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. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives.

4. Before disposal as in-house waste, monitor each container as follows:
    a. Check your radiation detection survey meter for proper operation.
    b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
    c. Remove any shielding from around the container.
    d. Monitor all surfaces of each individual container. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages).
    e. Discard as in-house waste only those containers that cannot be distinguished from background. Check to be sure that no radiation labels are visible.
    f. 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 GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 641-39.5 and Department of Transportation (DOT) regulations.

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).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination surveys required by 39.5(15).
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

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.

ANNUAL AUDIT CHECKLIST

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
c.	Mobile Nuclear Medicine Service meets technical requirements. [41.2(28)]	☐ 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.			
b.	Have there been radiation safety program changes? [41.2(4)"f"]	☐ N/A	☐ Yes	☐ No
	If yes, list changes			

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
(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

RADIOLOGICAL PROTECTION PROCEDURES

a.	Individual has understanding of procedures.	☐ N/A	☐ Yes	☐ No
(1)	In general, rules for safe use of RAM.	☐ N/A	☐ Yes	☐ No
(2)	In emergency procedures	☐ 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)	Quarterly inventory of sealed sources. [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

RADIOPHARMACEUTICAL THERAPY

a.	Oral and written safety instructions provided to personnel caring for patients. [41.2(38)"a"]	☐ N/A	☐ Yes	☐ No
b.	Record of training maintained. [41.2(38)"c"]	☐ N/A	☐ Yes	☐ No
c.	Performed according to license commitments.	☐ N/A	☐ Yes	☐ No
d.	Release of patients containing radiopharmaceuticals meets [41.2(27)"a"].	☐ N/A	☐ Yes	☐ No
e.	Thyroid burden measurements on all individuals involved in dose administration. [41.2(39)"a"(8)]	☐ N/A	☐ Yes	☐ No
f.	Record of thyroid measurements. [41.2(39)"a"(8)]	☐ 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
c.	ALARA program implemented. [41.2(7)"a"]	☐ N/A	☐ Yes	☐ No
d.	Written description of ALARA program available. [41.2(7)"d"]	☐ N/A	☐ Yes	☐ No

PERSONNEL RADIATION MONITORING – INTERNAL

a.	Bioassay program implemented and performed at proper intervals	☐ N/A	☐ Yes	☐ No
b.	Radioactive gases			
	(1) Clearance time and safety procedures are posted. [41.2(35)"e"]	☐ N/A	☐ Yes	☐ No
	(2) Reusable collection system checked monthly. [41.2(35)"f"]	☐ N/A	☐ Yes	☐ No
	(3) Ventilation rates checked for negative pressure at six-month intervals. [41.2(35)"f"]	☐ 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

MISADMINISTRATIONS

a.	Misadministrations occurred	☐ N/A	☐ Yes	☐ No
b.	Compliant with reporting requirements for misadministration. [41.2(14)"a" or "c"]	☐ N/A	☐ Yes	☐ No
c.	Appropriate action taken to prevent recurrence.	☐ N/A	☐ Yes	☐ No
d.	Records maintained. [41.2(14)"d"]	☐ 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

REVISION	SECTION	DESCRIPTION
03/13/01	10.3.1.A.1.	Revised wording to clarify requirements.
	10.3III	Changed review of employees from a minimum of 30 days to quarterly.
	All	Changed NV 1-01 to IDPH Mobile Nuclear Medical Service Regulatory Guide to avoid any confusion regarding NV1 and NV2 type licenses.
12/17/01	4.3	Added discussion concerning permits to practice.
06/19/02	Appendix G	Added additional isotopes in spill procedures.
03/13/03	Section 1.2	Replace the website address of the IDPH rules and publications.
12/07/04	Appendix G	Added requirement for long-sleeve laboratory coats.
07/01/05	All	Changed address for the Bureau of Radiological Health
07/17/07	Appendix B	Added new Model Delegation of Authority
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.
10/7/20	Item 1, Appendix A	Updated IDPH website and contact information. Changed ALARA note from per “month” to per “calendar quarter.”