



**GUIDE FOR THE PREPARATION OF APPLICATIONS FOR
RADIOACTIVE MATERIALS LICENSES FOR MEDICAL PROGRAMS**

Kansas Department of Health and Environment
Bureau of Community Health Systems
Radiation Control Program
1000 SW Jackson, Suite 330
Topeka, Kansas 66612-1365

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1.0 Introduction

1.1 Purpose of Guide

This guide describes the type and extent of information needed by the department licensing staff to evaluate an application for a specific license to possess and use radioactive material in or on human beings.

The department will usually issue a single radioactive material license to cover the applicant's entire radioisotope program. Separate licenses are not normally issued to different departments of a medical institution, nor are they issued to individuals associated with the facility.

The applicant should carefully study the regulations and this guide and submit all information requested. Department staff will request additional information, when necessary, to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

1.2 Applicable Regulations

- a. Part 3, "Licensing of Sources of Radiation" K.A.R. 28-35-175a
- b. Part 4, "Standards for Protection Against Radiation" K.A.R. 28-35-211a
- c. Part 6, "Use of Sealed Radioactive Sources in the Healing Arts" K.A.R. 28-35-264
- d. Part 10, "Notices, Instructions and Reports to Workers; Inspections" K.A.R. 28-35-331
- e. Title 10 Code of Federal Regulations (CFR) Part 35 "Medical Use of Byproduct Material"

1.3 As Low As Reasonably Achievable (ALARA)

K.A.R. 28-35-211d(b) states "Each licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are As Low As Reasonably Achievable (ALARA)."

This section also requires that licensees review the content of the Radiation Protection Program and its implementation at least annually. The Radiation Safety Officer (RSO) is responsible for the day-to-day operation of the Radiation Protection Program.

1.4 Types of Materials Licenses

- a. General In-Vitro license - a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for in-vitro clinical or laboratory tests not involving the internal or external administration of radioactive material or the radiation therefrom to human beings or animals. General license requirements are described in K.A.R. 28-35-178(h) and the applicant is required to register with the department and receive a registration number prior to receiving or using the radioactive material for in-vitro testing.
- b. Specific licenses of limited scope are issued to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one medical

discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license. Since a physicians' group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are specifically listed in the license. A medical institution may be required to have a Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee) to evaluate all proposals for clinical research, diagnostic, and therapeutic uses of radioisotopes. Specific requirements for this type of license are described in K.A.R. 28-35-181a and 10 CFR 35.24.

Licenses issued for private or group medical practices specify the radioisotopes and the clinical uses that may be performed by the authorized users are specifically listed in the license. A Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee) is not required for private or group medical practices. Specific requirements for this type of license are described in K.A.R. 28-35-181b and 10 CFR 35.24.

- c. Specific licenses of broad scope - licenses authorizing multiple quantities and types of radioactive material for unspecified users, are issued to medical institutions that (1) have had previous experience operating under a specific license of limited scope and (2) are engaged in medical research as well as routine diagnosis and therapy using radioisotopes. Such programs operate under the supervision of a Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee). Authorized users are not named on the license nor are radioisotopes limited to specified uses. Authorized users and procedures are approved by the Radiation Safety Committee (Radioisotope, or Medical Isotopes Committee). A specific license of broad scope is not appropriate for most medical institutions using radioactive material. Specific requirements for this type of license are described in K.A.R. 28-35-182a.

2.0 Filing An Application

A license application for specific licenses for human use should be submitted on Form RH-10 "Application For Radioactive Materials License - Medical". All items on the application form should be completed in sufficient detail for the bureau licensing staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form RH-10 is limited, the applicant should append additional sheets for Items 7-23 listed in the Form. Each separate sheet should contain the item number and the application date at the bottom right-hand corner of each page.

The application should be completed in duplicate. The signed original copy should be mailed to:

Kansas Department of Health and Environment
Radiation Control Program
1000 SW Jackson, Suite 330
Topeka, KS 66612-1365

One copy of the application with all attachments should be retained by the applicant since the license will require that the licensee follow the statements and representations set forth in the application and any supplement to it.

3.0 Contents Of An Application

Item 1.a. APPLICANT'S NAME AND MAILING ADDRESS

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment by a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address. Provide an individuals' name and contact information for the facility.

Item 1.b. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1.a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use. If a private practice, also provide office phone number for each address.

Item 2 PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual who can answer questions about the application and include his or her telephone number and e-mail. This is typically the proposed RSO, unless the applicant has named a different person as the contact. The department will contact this individual if there are questions about the application.

Notify the department of changes of contact name or telephone number so the department can contact the applicant or licensee in the future with questions, concerns, or information.

The individual named in Item 2 may or may not be the same individual who signs the application as the "certifying officer" on behalf of the licensee with the authority to make commitments to the department.

Provide a current organization chart relevant to the Radiation Protection Program.

The department recognizes that licensees may use a consultant or consultant group to help prepare the license application and provide support to the Radiation Protection Program. However, the department reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

Item 3 TYPE OF APPLICATION

Indicate whether the application is for a new license, amendment or renewal and provide the license number if the application is for a renewal or amendment.

Item 4 AUTHORIZED USERS (AU)

List the full name of all physicians who will use or directly supervise the use of radioactive material. These are the physicians who use the radioactive material directly or who are direct supervisors of physicians, technicians, technologists, or other paramedical personnel to whom specific activities are delegated.

The responsibilities of Authorized User's involved in medical use of radioactive material include the following:

- a. Prescription of the radioactive material including radiation safety commensurate with use;
- b. Prescription of the route of administration of radioactive material;
- c. Prescription of the dose or dosage of radioactive material;
- d. Preparation of written directives (WD), if required;
- e. Direction of individuals under the AU's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material;

Applicants must meet recentness of training requirements described in 10 CFR 35.59. Applicants must have successfully completed the training and experience criteria within 7 years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways under the following conditions:

The training and experience was received beyond the 7-year time frame allowed in 10 CFR 35.59; and

The individual is not currently identified on a medical-use license nor permit as an AU, AMP, or ANP, as appropriate in 10 CFR 35.13(b)(4).

On a case-by-case basis, evaluating the adequacy of "related continuing training and experience" to determine compliance with 10 CFR 35.59, department staff considers the training and experience criteria specified in the applicable regulations, and whether the continuing training and experience would further competency in those areas. The number of hours required of continuing education and clinical experience depends on the period of time the individual has not been involved in licensed activities and how closely the individual's recent educational and work experience are related to the proposed area of medical use.

To facilitate department's review, the licensee may also elect to provide a preceptor statement attesting to current competency in the identified radiation safety areas.

Technologists, therapists, or other personnel may use radioactive material for medical use under an AU's supervision in accordance with 10 CFR 35.27, "Supervision," and in compliance with applicable FDA, other Federal and State requirements (10 CFR 35.7). The responsibility for a medical procedure may not be delegated to technicians, technologists or other paramedical personnel, however, properly trained technicians, technologists, or other paramedical personnel under a user's supervision may perform the following activities:

- a. Preparation and quality control testing of radiopharmaceuticals and sources of radiation.
- b. Measurement of radiopharmaceutical doses prior to administration.
- c. Use of appropriate instrumentation for the collection of data to be used by the AU.

- d. Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable federal, state or local laws.

There is no requirement that an AU must render an interpretation of a diagnostic procedure or results of a therapeutic procedure. The AU may or may not be the physician who interprets such studies. Additionally, regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

AU for Nonmedical Uses: For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include the individuals who will actually be responsible for the safe use of the radioactive material for the requested use.

Training and Experience

- a. Authorized User (AU)

New AU, initial training and experience within seven years and never been named on a radioactive material license. Complete the Training and Experience and Preceptor Attestation form for each type of authorization being requested. (Diagnostic (35.100, 35.200, 35.500), Unsealed Written Directive required (35.392, 35.394, 35.396), Sealed Source Written Directive required (35.400, 35.600)).

Current Authorized User to be added to a license or increase the authorized use. Submit a copy of a current radioactive material license issued by the NRC or an agreement state that names the AU for the requested authorized use or complete the Training and Experience and Preceptor Attestation form for the type of increased authorization being requested. Provide documentation of relevant continuing education and documentation of relevant work experience received within seven years preceding the date of application.

Current authorized user with no change in authorized use. State the authorized user name. Provide documentation of relevant continuing education and documentation of relevant work experience received within seven years preceding the date of application.

Documentation containing equivalent information to the Training and Experience and Preceptor Attestation forms may be used for the description of the physician's training and experience.

- b. Authorized Medical Physicist (AMP)

New AMP, initial training and experience within seven years and never been named on a radioactive material license. Complete the Training and Experience and Preceptor Attestation form to include hands on device operation, emergency procedures, clinical use and operation of a treatment planning system for each device to be used.

Current AMP to be added to a license. Provide a copy of a current radioactive material license issued by the NRC or an agreement state that names the individual as AMP for each device to be used and documentation of relevant continuing education.

Current AMP with no change in authorized use. State the AMP name. Provide documentation of relevant continuing education received within seven years preceding the date of application.

Documentation containing equivalent information to the Training and Experience and Preceptor

Attestation forms may be used for the description of the proposed AMP training and experience.

c. Authorized Nuclear Pharmacist (ANP)

New ANP, initial training and experience within seven years and never been named on a radioactive material license. Complete the Training and Experience and Preceptor Attestation form.

Current ANP to be added to a license. Provide a copy of a current radioactive material license issued by the NRC or an agreement state that names the individual as ANP and documentation of relevant continuing education.

Current ANP with no change in authorized use. State the ANP name. Provide documentation of relevant continuing education received within seven years preceding the date of application.

Documentation containing equivalent information to the Training and Experience and Preceptor Attestation forms may be used for the description of the proposed ANP training and experience.

Item 5 RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the institutions management for the coordination of the institution's radiation protection program (sometimes designated the "Radiation Safety Officer").

Provide a statement with the application outlining the named individual's duties and responsibilities. The radiation protection officer is expected to coordinate the safe use of the radioactive material and ensure compliance with the requirements of the Kansas Radiation Protection Regulations.

Provide a Delegation of Authority signed by a member of management and the proposed radiation safety officer accepting the responsibility for implementing the radiation safety program.

New RSO, initial training and experience within seven years and never been named on a radioactive material license. Complete the Training and Experience and Preceptor Attestation form.

Current RSO to be added to a license. Provide a copy of a current radioactive material license issued by the NRC or an agreement state that names the individual as RSO for equivalent radioactive material and uses (a diagnostic RSO should **NOT** be named as RSO for a license authorized for sealed source therapy, HDR, gamma knife etc) and documentation of relevant continuing education received within seven years preceding the date of application.

Current RSO named on the license with no change. State the RSO name. Provide documentation of relevant continuing education received within seven years preceding the date of application.

Documentation containing equivalent information to the Training and Experience and Preceptor Attestation forms may be used for the description of the proposed RSO training and experience.

Item 6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

35.100 Use: - Any radioactive material permitted by 10 CFR 35.100

The chemical/physical form – Unsealed; Any radiopharmaceutical permitted by 10 CFR 35.100 for uptake, dilution and excretion studies that do not require a written directive;

Possession limit - As Needed

35.200 Use: Any radioactive material permitted by 10 CFR 35.200

The chemical/physical form – Unsealed; Any radiopharmaceutical permitted by 10 CFR 35.200 for imaging and tumor localizations that do not require a written directive;

Possession limit – As Needed

Iodine-131 Use: The chemical/physical form – Unsealed; Sodium iodide referenced by 10 CFR 35.392 for oral administration requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

Possession limit - Enter the amount required

Iodine-131 Use: The chemical/physical form – Unsealed; Sodium iodide referenced by 10 CFR 35.394 for oral administration requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

Possession limit - Enter the amount required

35.396 Use: Any radioactive material referenced by 10 CFR 35.396

The chemical/physical form – Unsealed; Any radiopharmaceutical referenced by 10 CFR 35.396 for parenteral administration requiring a written directive

Possession limit - Enter the amount required

35.400 Use: Any radioactive material permitted by 10 CFR 35.400

The chemical/physical form - Any source permitted by 10 CFR 35.400 for manual brachytherapy therapeutic medical use requiring a written directive.

Possession limit - Enter the amount required

Item 6.b.

For human use not described above and for non-human use, list each radionuclide to be used, the chemical or physical form, and the maximum quantity (in millicuries) required.

Any sealed source authorized by 10 CFR 35.65 not to exceed 30 millicuries each source for quality control, calibration, transmission and reference use.

List the manufacturer's name, model number, and activity (in millicuries) for each sealed source and device containing radioactive material. Include remote afterloader units (HDR), teletherapy units and gamma stereotactic radiosurgery units (gamma knife).

A specific authorization must be obtained from the department to perform studies involving the use of radioactive material in animals.

Describe the intended use for each radioactive material listed in Item 6.b. If the radioactive material is for human use and has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence that procurement, preparation and use of the material will be in accordance with the Federal Food, Drug and Cosmetic Act and the Public Health Service Act. If the study is conducted under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) sponsored by the physician or institution, state the radionuclide, chemical form, possession limit, use and submit a copy of the IND acceptance letter from the Food and Drug Administration.

Item 7 - Radiation Safety Committee (Radioisotopes, or Medical Isotopes Committee)

In accordance with 10 CFR 35.24, a licensee authorized for two or more different types of use under 35.300, 35.400, 35.600 or two or more different types of units under 35.600 shall establish a Radiation Safety Committee (Radioisotopes, or Medical Isotopes Committee) to oversee all uses of radioactive material permitted by the license. This committee shall include an authorized user for each type of use permitted by the license, the radiation safety officer, a representative of nursing, and a representative of executive management who is neither an authorized user nor a radiation safety officer. The committee may include other members the licensee considers appropriate.

Provide the following information:

- a. The duty and responsibility of the committee,
- b. The meeting frequency of the committee (at least quarterly), and
- c. The name and specialty or title of each member on the committee.

Item 8 – Radiation Monitoring Instruments

Radiation monitoring instruments are any device used to measure radiological conditions. Radiation monitoring instruments are used to measure radiation levels, radioactive contamination, and radioactivity, as applicable are sufficiently sensitive to measure the type and energy of radiation used and be available for use at all times when radioactive material is in use.

Radiation monitoring instruments that may be used to perform these functions include:

- a. Portable or stationary count rate meters,
- b. Portable or stationary dose rate or exposure rate meters,
- c. Dose calibrators and other instruments to assay radiopharmaceuticals.
- d. Diagnostic instruments for all procedures (gamma camera, thyroid probe).
- e. Other pertinent instrumentation (liquid scintillation counter, area monitor, well counter).

Item 9 - Calibration of Instruments

- a. Radiation Monitoring Instruments

Radiation monitoring instruments used for quantitative radiation measurements must be calibrated for the radiation measured and in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions.

An adequate calibration of radiation monitoring instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Constancy checks of radiation monitoring instruments performed each day of use are used to monitor the instruments condition to perform its intended function and are not to replace the calibration performed every 12 months.

Calibration of radiation monitoring instruments must be performed every 12 months by persons who are qualified to perform calibrations and after repairs that affect the calibration.

b. Dose Calibrator

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions.

All radiopharmaceuticals should be assayed for activity to an accuracy of 10 percent prior to being administered to patients. The usual method for performing assays is with a dose calibrator. Upon installation and periodically thereafter dose calibrators should be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for day-to-day constancy of operation.

Submit a description of the procedures. These should include as a minimum:

- (1) The radioactive material of sealed sources to be used,
- (2) The activity (in millicuries) of radioactive material in the standards,
- (3) The accuracy of each standard. Traceability of the source to a primary standard (NIST) should be provided, and
- (4) Step-by-step procedure used each calibration (accuracy, linearity (sleeve or decay method), geometry and constancy).

c. Diagnostic Instruments

Manufacturer's directions should be followed for calibration and maintenance of diagnostic instrumentation.

Item 10 - Facilities and Equipment

Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods, security and fire protection) at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation, and measurement of radioactive material.

Describe the storage of radioactive material, including security of the radioactive material to prevent unauthorized use and access, include any administrative measures (log in/out sheets, key controls, authorized personnel, security personnel) and physical devices (locked rooms, locked storage safes).

Submit diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Any wall shielding, special storage area shielding, or movable shielding around storage areas, generators, kit preparation areas, etc. should be indicated. Diagrams should be drawn to a specified scale, North and dimensions should be indicated.

For facilities in which radioactive material may become airborne, the diagrams should also include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments.

Item 11 - Personnel Training Program

Describe training required for all personnel who work with or in the vicinity of radioactive materials. The description should include the form of training (e.g., formal course work, lectures), the duration of training, the subject matter included, evaluation criteria and instructor qualifications. The training program should be of sufficient scope to ensure that ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 1 mSv (100 mrem) will include instruction commensurate with potential radiological health protection problems present in the work place receive proper instruction in the items specified in K.A.R. 28-35-333, appropriate to their job duties. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel.

Item 12 - Ordering and Receipt of Radioactive Material

Describe the procedure for ordering radioactive materials, for receipt of materials during off-duty hours and for notification of responsible persons upon receipt of radioactive material. The procedure should be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured at all times against unauthorized removal and that radiation levels in uncontrolled areas do not exceed the limits specified in K.A.R. 28-35-214a.

All personnel who receive packages containing radioactive material during off-duty hours, should be issued written instructions as to procedure to be followed for receiving, examining and securing the package and for notification procedures if the package is found or suspected to be leaking and immediate steps to be taken to prevent spread of contamination.

Item 13 - Safely Opening Packages Containing Radioactive Material

Describe the procedure for monitoring incoming packages for leakage, contamination or damage, and for safely opening packages in accordance with K.A.R.28-35-221a. Monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedure may vary depending on the quantity of radioactive material received, but should, at a minimum include instructions for surveying package, wearing gloves while opening packages and checking packing material for contamination after opening. Even though K.A.R.28-35-221a exempts certain packages from immediate monitoring, procedures must be established for safely opening all packages containing radioactive material.

Item 14 - General Rules for the Safe Use of Radioactive Material

Describe the general instructions to be followed while working with radioactive material. The instruction should include:

- a. Contamination control,
- b. use of safety equipment,
- c. preparation and assay of patient doses,
- d. personal monitoring,

- e. waste disposal,

Item 15 - Emergency Response

Describe the emergency procedure to follow in areas where radioactive material is used. These instructions should (1) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off ventilation, evacuation of the area, containment of the spill), (2) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (3) instruct personnel on appropriate methods of reentering, decontamination, and recovering facilities that may have been accidentally contaminated.

Item 16 - Radiation Safety Procedure

Submit a description of the Radiation Safety Procedures.

- a. Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125 or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled or absorbed into the body. The applicant should show in his application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for his intended use of radioactive material, (i.e., hydrogen-3 (urinalysis), iodine-125 or 131 (thyroid counting determinations etc.).

Bioassay sampling procedures should include trigger level and frequency for performing bioassay sampling, type of sample to be collected, method of analysis, levels at which increased oversight or investigations will be performed to ensure personnel exposures are ALARA and include the considerations or actions to be taken when the levels are exceeded to prevent reoccurrence.

- b. Describe the procedures for testing for leakage and/or contamination of sealed sources (i.e., cobalt-57 flood sources, simulated liquid (epoxy resin) etc). Each sealed source containing more than 100 microcuries of a beta or photon emitting material must be leak tested at six-month intervals. Each sealed source containing more than 10 microcuries of an alpha emitting material must be leak tested at three-month intervals.

If a commercial firm is to perform the leak tests, the name, address, and license number of the firm should be submitted. If the tests are to be performed using a commercial "kit" the name of the kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform leak tests without the use of a commercial kit, the following information should be submitted:

- (1) Qualification of personnel who will perform the leak test,
- (2) Procedure and material to be used in taking test samples,
- (3) The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples,
- (4) Instrument calibration procedures, including calibration source characteristics, make, and model number, and

- (5) The method, including a sample calculation, to be used to convert instrument readings to units of activity, e.g., microcuries.
- c. Describe the ALARA Program and how the facility will maintain exposure to radiation and radioactive material as low as reasonably achievable.
- d. Describe breakthrough determination when using generators such as technetium-99m or rubidium-82.
- e. Describe the procedures to be followed on the mobile nuclear medicine coach, the following information should be submitted:
 - (1) Equipment checks,
 - (2) Base location, radioactive material receipt only when occupied by licensee personnel, security while parked, exposure to members of the general public, shielding, surveys,
 - (3) Procedures for patient voiding prior to imaging, patient instructions, and
 - (4) Provide copies of contract or agreement between the mobile service and each client authorizing the use of radioactive material at the client facility.

Item 17 - Area Radiation and Contamination Survey

Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable and provisions for maintaining records of surveys.

If the application is to cover multiple users and areas of use, the individual user should supplement the surveys performed by the radiation safety staff.

Item 18 – Disposal of Radioactive Waste

Describe specific methods used for disposal of waste radioactive material. A licensee may dispose of waste by:

- a. Transfer to a person properly licensed to receive such waste, e.g., commercial waste disposal firms. (See K.A.R.28-35-223a.) Submit the name and NRC or Agreement State license number of the commercial firm selected,
- b. Release into a sanitary sewer in conformance with K.A.R.28-35-224a. Describe the method for controlling sewage disposal of radioactive wastes in order to ensure that disposals do not exceed the limits specified in Appendix B, Appendices to Part 4, Standards for Protection Against Radiation,
- c. Burial in soil in conformance with K.A.R.28-35-225a,
- d. Release into the air in conformance with K.A.R.28-35-214b, and
- e. Other methods specifically approved by the department pursuant to K.A.R.28-35-223(b).

Note: No licensee may dispose of radioactive material waste by incineration unless specifically

authorized by the department. (See K.A.R.28-35-226a.)

Item 19 – Administration when a Written Directive is Required

Describe the procedure(s) to provide high confidence that radioactive material will be administered as directed by authorized users.

The administration of radioactive material can involve a number of treatment modalities (e.g., diagnostic imaging, radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each modality which a written directive is required, develop, implement, and maintain written procedure(s) to meet the requirements and/or objectives outlined below:

Prior to each administration when a written directive is required:

- a. Have an AU date and sign a WD that includes the information in 10 CFR 35.40(b);
- b. Verify the identity of the patient or human research subject;
- c. Verify that the administration is in accordance with the treatment plan, if applicable, and the WD;
- d. Check both manual and computer-generated dose calculations;
- e. Verify that any computer-generated dose calculations are correctly transferred into the console of therapeutic medical devices; and
- f. Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

Conduct periodic reviews of each applicable program area (e.g., diagnostic imaging, radiopharmaceutical therapy, high-dose-rate brachytherapy, manual brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery).

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by 10 CFR 35.41, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Notify the department no later than the next calendar day after discovery of a medical event and submit a written report to the department within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. Also notify the referring physician and the patient as required by 10 CFR 35.3045.

Item 20 – Release of Patients Administered Radioactive Material

Describe the radiation safety instructions (including written instructions) provided to patients administered radioactive material when the exposure to other individuals is not likely to exceed 0.5 rem. If the dose to a breast-feeding infant or a child could exceed 0.1 rem, assuming there was no interruption of breast-feeding, the instructions also shall include:

- Guidance on the interruption or discontinuation of breast-feeding, and
- Information on the potential consequences of failure to follow the guidance.

Item 21 - Use of Radioactive Gases and Aerosols

The use of radioactive gases (xenon-133) or aerosols (technetium-99m DTPA) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas or aerosol in controlled and uncontrolled areas. The department requires that each applicant make such determinations for its own unique situation and submit sufficient evidence to support the request.

Describe the gas delivery system including the manufacturer make and model, number of patients, activity per patient and estimate of effluent concentration. When evaluating an external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within Appendix B to Part 4: Standards for Protection Against Radiation Effective April 1994 limits.

Describe the aerosol delivery system including the manufacturer make and model, number of patients, activity per patient and estimate of effluent concentration. When evaluating doses from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within Appendix B to Part 4: Standards for Protection Against Radiation Effective April 1994 limits.

Item 22 - Personnel Monitoring Devices

State the name of the organization providing the personnel monitoring service. Specify the frequency with which the badges are changed and evaluated, and give a description of the type, e.g., whole body, wrist, or finger badge. The vendor providing the personnel monitoring service must be accredited by the national voluntary laboratory accreditation program (NVLAP) for the device, energy, radiation and exposure level being monitored. Where wrist badges are worn to monitor extremity exposures and exposures to fingertips are likely to be greater than the wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of fingertip monitors, and provide any backup data used to perform or verify these estimates.

Item 23 - Certificate

Items 23 a. and b. provide the signature of an individual authorized by management to represent an applicant institution or the signature of an individual physician, in the case of private practice, with the date of signature.

Procedures and Precautions For Use Of Radioactive Material In Animals

Describe procedures to be followed if radioisotopes will be used in animals including (1) a description of the animal housing facilities, (2) a copy of instructions provided to animal caretakers for the handling of animals, animal waste and carcasses, (3) instructions for cleaning and decontaminating animal cages, and (4) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

4.0 Amendments to a License

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including type of monitoring and survey instruments), procedures, personnel, or radioactive material to be used.

Applications for license amendments may be filed either on the application Form RH-10 or in a letter. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page and paragraph.

5.0 Renewal of a License

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the department as provided for in K.A.R. 28-35-186a.

Renewal applications should be filed on Form RH-10 appropriately supplemented if there are major program changes, and should contain complete and up-to-date information about the applicant's current program.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

- a. The reference is made in response to a particular item of required information (e.g., bioassay procedures).
- b. The reference is clear and specific (e.g., title of document, date of submission, page, and paragraph).
- c. The referenced document contains all information required for a particular item at the time of renewal.

The application should be completed in duplicate. The original copy should be mailed to the department and one duplicate copy of the application, with all attachments, should be retained by the applicant. The license will require the licensee follow the statements and representations set forth in the application and any supplement to it.

