

**UNIVERSITY OF LOUISVILLE
BROAD SCOPE MEDICAL LICENSE**

RADIATION SAFETY MANUAL

UPDATED SEPTEMBER 2016

Contents

<u>RADIATION SAFETY COMMITTEE</u>	3
<u>ANNUAL MEDICAL LICENSEE PROGRAM AUDIT</u>	5
<u>PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM</u>	15
<u>PERSONNEL TRAINING PROGRAM</u>	18
<u>AREA SURVEY PROCEDURE</u>	19
<u>PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL</u>	21
<u>PROCEDURE FOR SAFELY OPENING PACKAGES OF RADIOACTIVE MATERIAL</u>	22
<u>RECORDS OF RADIOACTIVE MATERIAL USE</u>	24
<u>RELEASE OF PATIENTS</u>	25
<u>SEALED SOURCES</u>	26
<u>PROCEDURES FOR USE OF A THERAPEUTIC DOSE OF RADIOACTIVE MATERIAL</u>	27
<u>PROCEDURES FOR THERAPIES REQUIRING A WRITTEN DIRECTIVE</u>	28
<u>FOR RADIOPHARMACEUTICAL THERAPY</u>	28
<u>PROCEDURE FOR THE SAFE USE OF RADIOACTIVE MATERIAL IN AN INPATIENT</u>	30
<u>PROCEDURES FOR THERAPIES REQUIRING A WRITTEN DIRECTIVE FROM SEALED SOURCES</u>	32
<u>EMERGENCY PROCEDURES</u>	35
<u>Notification Requirements</u>	36
<u>RADIOACTIVE WASTE DISPOSAL</u>	40
<u>APPENDIX A – August 19, 2016</u>	41
<u>PROCEDURE FOR SEALED SOURCE LEAK TESTING AND INVENTORY</u>	41
<u>Appendix B</u>	43
<u>Calibration Procedures for Radiation Detection Equipment</u>	43
<u>Appendix C</u>	48
<u>Criteria for Evaluating Users Qualifications for the Use of Radioactive Materials</u>	48
<u>Appendix D</u>	55
<u>BIOASSAY PROGRAM</u>	55

RADIATION SAFETY COMMITTEE

902 KAR 100:072, section 10

ROLE:

The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;
2. Ensure that licensed material is used in compliance with Cabinet regulations and the institutional license;
3. Establish a table of investigational levels for individual occupational radiation exposures;
4. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;
5. Identify program problems and solutions.

MEMBERSHIP:

Membership of the Committee will consist of persons that understand and represent responsibilities of maintaining an ongoing radiation safety program. The Radiation Safety Office will act as the chair of the committee. The membership must include but is not limited to the following:

- Radiation Safety Officer
- A representative of management who is not an authorized user or the RSO
- A representative of the nursing service
- An authorized user for each type of use authorized by the license
- Other members as deemed appropriate.

RESPONSIBILITIES:

The Committee shall:

1. Be familiar with all pertinent Cabinet regulations, the license application, the license and amendments;
2. Review the training and experience of the proposed authorized users and the Radiation Safety Officer (RSO) to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license; training and experience must be indicated as in Appendix C of the Radiation Safety Manual.
3. Review on the basis of safety and approve or deny, consistent with the limitation of the regulations, the license and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;
5. Review the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;
6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing security, housekeeping, physical plant) are appropriately instructed as required in 902 KAR 100:165;
7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with Cabinet regulations, and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of Cabinet inspections, written safety procedures, and the adequacy of the management control system;
8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and result of all votes taken;
10. Ensure that the byproduct material license is amended, if required, prior to any changes in facilities, equipment, policies, procedures, and personnel.

ADMINISTRATIVE INFORMATION:

- The Committee shall meet as often as necessary to conduct its business but no less than once in each calendar quarter;
- Membership of the Committee must include the RSO, a representative of management who is not an authorized user or the RSO, a representative of the nursing service, and an authorized user for each type of use authorized by the license.
- To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

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

ANNUAL MEDICAL LICENSEE PROGRAM AUDIT

Note: An audit of the radiation protection program shall be performed at least annually; the audit must be presented to the radiation safety committee for review. This audit may be revised as necessary based on use of radioactive material in the facility.

Date of This Audit: _____

Date of Last Audit: _____

Auditor: _____

(Signature)

Date: _____

Management Review: _____

(Signature)

Date: _____

Audit History

- A. Were previous audits conducted annually (**902 KAR 100:019**)?
- B. Are records of previous audits being maintained for three years after they were made (**902 KAR 100:019**)?
- C. Were any deficiencies identified during previous audit?
- D. Were corrective actions taken? (**Note:** Look for repeated deficiencies.)

Organization and Scope of Program (**902 KAR 100:072**)

A. Radiation Safety Officer:

- 1. If the RSO position has changed, was license amended?
- 2. Does the new RSO meet the agency's training requirements?
- 3. Is the RSO fulfilling all of his/her duties?
- 4. Is the written agreement in place for new RSO?

B. Are all locations of use listed on the license?

C. Were annual audits performed at each location (**902 KAR 100:019**)? If no, explain.

D. Licensed Material:

- 1. The isotope, the chemical forms, the quantity and authorized use is listed (**L/C**).
- 2. Calibration, transmission, and reference sources?
 - a. Sealed sources manufactured and distributed by a person licensed pursuant to RHB (**902 KAR 100:058**), NRC, or another equivalent Agreement State regulations who is authorized to redistribute sealed sources that do not exceed 1.11GBq (30 mCi) each.
 - b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceeding 0.555 GBq (15 mCi)?
 - c. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200uCi) or 10^3 times the quantities in **902 KAR 100:080**?
 - d. Technetium-99m in amounts as needed?
- 3. Unsealed materials used under **902 KAR 100:072** are:
 - a. Obtained from a manufacturer or preparer licensed under **902 KAR100:040**?

OR

 - b. Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of an authorized nuclear pharmacist or physician authorized user?

E. If places of use changed, was the license amended (**902 KAR 100:072**)?

- F. If control of the license was transferred or bankruptcy filed, was the agency's prior consent obtained or notification made, respectively (**902 KAR 100:040**)?

Radiation Safety Program

- A. Minor changes or revision to radiation safety program (**902 KAR 100:072**)?
B. Records of changes maintained for five (5) years (**902 KAR 100:072**)?
C. Content and implementation reviewed annually by the licensee (**902 KAR 100:019**)?
D. Records of annual reviews maintained 3 years after the date on which they were made (**902 KAR 100:019**)?

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

Authorized User (**902 KAR 100:072**)

- _____ 1. Certified by specialty board
_____ 2. Identified on RHB, NRC or another Agreement State license
_____ 3. Identified on permit issued by a broad scope or master materials licensee
_____ 4. Listed on current facility license

Authorized Medical Physicist [**902 KAR 100:072**]:

- _____ 1. Certified by specialty board
_____ 2. Identified on RHB, NRC or another Agreement State license
_____ 3. Identified on permit issued by broad scope or master materials licensee
_____ 4. Listed on current facility license

Amendments Since Last Audit:

- A. Any amendments since last inspection (**902 KAR 100:072**)?
B. Notifications Since Last Audit: (**902 KAR 100:072**)
C. Appropriate documentation provided to the department for Authorized Nuclear Pharmacist (ANP), Authorized Medical Physicists (AMP), or Authorized User (AU) no later than 30 days after the individual starts work?
D. RHB notified within thirty (30) days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use?

Training, Retraining, And Instructions to Workers

- A. Have workers been provided with all required instructions (**902 KAR 100:072, 902 KAR 100:165**)?
B. Is the individual worker understanding of current procedures and RHB regulations adequate?
C. Training program implemented?
1. Emergency procedures (**902 KAR 100:072**)?
2. Were all workers who are likely to exceed 1.0 mSv (100 mrem) in a year instructed, and was refresher training provided (**902 KAR 100:165**)?
3. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate (**902 KAR 100:072**)?
4. Are initial and periodic training records maintained for each individual for three years (**902 KAR 100:072**)?

Note: NRC RIS 8.13 'Instructions Concerning Prenatal Radiation Exposure' is a useful reference.

- D. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with **902 KAR 100:072**?

Manual Brachytherapy and Unsealed Therapy Training

- A. Safety instruction to personnel provided include (**902 KAR 100:072**):
1. Control of patient and visitors?
 2. Routine visitation to patients in accordance with **902 KAR 100:019**?
 3. Contamination control and size/appearance of sources?
 4. Safe handling and shielding instructions?
 5. Waste control?
 6. Records of training retained for three years?

Facilities

- A. Facilities as described in license application (L/C)?
- B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights (**902 KAR 100:019, 902 KAR 100:072**)?
- C. Emergency source recovery equipment available (**902 KAR 100:072**)?
- D. Storage areas: (**902 KAR 100:019**)
1. Materials secured from unauthorized removal or access?
 2. Licensee controls and maintains constant surveillance of licensed material not in-storage?

Dose or Dosage Measuring Equipment

- A. Possession, use, calibration, and check of instruments to measure activities of unsealed radionuclides (**902 KAR 100:072**):
1. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
 2. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., $\pm 10\%$)?
 3. Records maintained and include required information?
- B. Determination of dosages of unsealed radioactive material (**902 KAR 100:072**)?
1. Each dosage determined and recorded prior to medical use?
 2. Measurement of unit dosages made either by direct measurement or by decay correction?
 3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation?

Radiation Protection and Control of Radioactive Material

- A. Use of radiopharmaceuticals:
1. Protective clothing worn?
 2. Personnel routinely monitor their hands?
 3. No eating/drinking in use/storage areas?
 4. No food, drink, or personal effects kept in use/storage areas?
 5. Proper dosimetry worn?
 6. Radioactive waste disposed of in proper receptacles?
 7. Syringe shields and vial shields used?
 8. Leak tests and Inventories of sealed sources performed semiannually: (**902 KAR 100:072**)

9. Records maintained for three years?

Radiation Survey Instruments

A. Survey instruments used to show compliance with **902 KAR 100:040**?

1. Appropriate operable survey instruments possessed or available (**902 KAR 100:072**)
2. Calibrations (**902 KAR 100:072**):
 - a. Before first use, annually and after repairs?
 - b. Within 20% on each scale or decade of interest?
3. Records maintained for three years (**902 KAR 100:072**)?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements (**902 KAR 100:019, 902 KAR 100:072**)?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms)?
2. Trigger/action levels established?
3. Corrective action taken and documented if trigger/action level exceeded?
4. Techniques can detect 0.1 mR/hr, 2000dpm?
5. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry and records maintained?
 - a. After new source installation?
 - b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic and mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose (902 KAR 100:019)

- A. Is licensed material used in a manner to keep doses below 1 mSv (100 mrem) in a year?
- B. Has a survey or evaluation been performed?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?
- E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal?
- F. Records maintained?

Patient Release (902 KAR 100:072)

- A. Individuals released when TEDE less than 5 mSv (500 mrem)?
- B. Instructions to the released individual, including breast-feeding women, include required information?
- C. Release records maintained for three (3) years?
- D. Records of instructions given to breast-feeding women maintained, if required, for three (3) years?

Radiopharmaceutical Therapy (902 KAR 100:072)

- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls?
- B. RSO and AU promptly notified if patient died or had a medical emergency?

Brachytherapy (902 KAR 100:072)

- A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment?
- B. Survey immediately after implant?
- C. Patients surveyed immediately after removing the last temporary implant source?
- D. RSO and AU promptly notified if patient died or had a medical emergency?
- E. Records maintained for three years?

Radioactive Waste

- A. Disposal:
 - 1. Decay-in-storage (902 KAR 100:072)?
 - 2. Procedures followed (902 KAR 100:072)?
 - 3. Labels removed or defaced (902 KAR 100:019, 902 KAR 100:072)?
- B. Special procedures performed as required (L/C)?
- C. Improper/unauthorized disposals (902 KAR 100:019)?
- D. Records maintained (902 KAR 100:015, 902 KAR 100:040, 902 KAR 100:019, 902 KAR 100:072)?

Note: Useful references are NRC Inspection Procedure 87102 and NRC Regulatory Guide 8.37. They are available at www.nrc.gov.

- E. Waste storage: (902 KAR 100:019)
 - 1. Protection from elements and fire?
 - 2. Control of waste maintained?
 - 3. Containers properly labeled and area properly posted?
 - 4. Package integrity adequately maintained?
- F. Waste disposal:
 - 1. Sources transferred to authorized individuals (902 KAR 100:040, 902 KAR 100:019)?
 - 2. Name of organization: _____.
 - 1. Release to sanitary sewer?
 - a. Material is readily soluble or readily dispersible?
 - b. Monthly average release concentrations do not exceed 902 KAR 100:019 values?
 - c. No more than 185 GBq (5.0 Ci) of H-3, 37GBq (1.0 Ci) of C-14 and 37 GBq (1.0 Ci) of all other radionuclides combined released in a year?
 - d. Procedures to ensure representative sampling and analysis implemented?
- G. Records of surveys and material accountability are maintained (902 KAR 100:019, 902 KAR 100:072)?

Receipt and Transfer of Radioactive Material

- A. Written package opening procedures established and followed (902 KAR 100:019, 902 KAR 100:070)?
- B. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [902 KAR 100:019)?
- C. Incoming packages surveyed as required (902 KAR 100:019)?
- D. Monitoring in (C) and (D) performed within time specified (902 KAR 100:019)?

- E. Transfer(s) performed per **902 KAR 100:040**?
- F. All sources surveyed before shipment and transfer (**902 KAR 100:019, 49 CFR 173.475(i)**)?
- G. Records of surveys and receipt/transfer maintained (**902 KAR100:015, 902 KAR 100:040, 902 KAR 100:019**)?
- H. Package receipt/distribution activities evaluated for compliance with **902 KAR 100:019**?

Transportation [902 KAR 100:070 and 49 CFR 171-189]

A. Shipments are:

- 1. Delivered to common carriers;
- 2. Transported in own private vehicle;
- 3. Both;
- 4. No shipments since last audit.

B. Return radiopharmacy doses or sealed sources?

- 1. Licensee assumes shipping responsibility?
- 2. Current radiopharmacy RML kept in file?
- 3. If no, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages:

- 1. Authorized packages used?
- 2. Performance test records on file?
 - a. DOT-7A packages
 - b. Special form sources
- 3. Two labels (White-I, Yellow-II, or Yellow-III) with TI, Nuclide, Activity, and Hazard Class?
- 4. Properly marked (Shipping Name, UN Number, Package Type, RQ, *"This End Up"* (liquids), Name and Address of consignee)?
- 5. Closed and sealed during transport?

D. Shipping Papers:

- 1. Prepared and used?
- 2. Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, *"Limited Quantity"* (if applicable), *"Cargo Aircraft Only"* (if applicable)?
- 3. Readily accessible during transport?

C. US Dept. of Transportation 49 CFR 172 Subpart H Hazmat Training

- 1. All persons involved in the receipt or shipping of hazardous materials, including Class 7 radioactive materials, have current US Dept. of Transportation, 49 CFR 172 subpart H hazmat training.
- 2. DOT hazmat training includes general awareness/familiarization, safety and security training and function specific training tailored to each individuals job function(s) as it relates to shipping.
- 3. DOT hazmat training provided within ninety (90) days of initial employment or within 90 days of a change in job function as it relates to shipping.
- 4. Each hazmat employee has been trained, tested and certified by the employer.
- 5. Recurrent training has occurred every three (3) years.
- 6. Training records include hazmat employee's name; completion date of most recent training; training materials (copy, description, or location); name and address of hazmat trainer; and certification that the hazmat employee has been trained and tested.

Full Calibration-Therapeutic Medical Devices (902 KAR 100:072)

- A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.)?
- B. Performed prior to first patient use?
- C. At intervals not to exceed one year for teletherapy, and LDR remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and PDR remote afterloaders?
- D. Whenever spot-checks indicate output differs from expected by $\pm 5\%$?
- E. After source exchange, relocation, major repair or modification?
- F. Performed with properly calibrated instrument?

Periodic Spot Checks For Therapeutic Devices (902 KAR 100:072)

- A. Performed at required frequency?
- B. Procedures established by authorized medical physics?
- C. Procedures are being followed?
- D. Authorized medical physicist reviews results within 15 days?
- E. Performed with properly calibrated instrument?
- F. Output and safety spot checks include:
 - 1. For remote afterloaders: **(902 KAR 100:072)**
 - a. Interlock systems?
 - b. Source exposure indicator lights?
 - c. Viewing and intercom systems, except for LDR?
 - d. Emergency response equipment?
 - e. Radiation monitors used to indicate source position?
 - f. Timer accuracy?
 - g. Clock (date and time) in the unit's computer accurate?
 - h. Decayed source(s) activity in the unit's computer **(902 KAR 100:072)**?
- G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required **(902 KAR 100:072)**?
- H. Records maintained for three years **(902 KAR 100:072)**?

Installation, Maintenance, and Repair of Therapy Devices

- A. Only authorized individuals perform installations, maintenance, adjustment, repair, and inspections?
Name of organization/individual: _____
- B. Records maintained for three years (902 KAR 100:072)?

Operating Procedures For Therapy Devices (902 KAR 100:072)

- A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console?
- B. Procedures include: **(902 KAR 100:072)**
 - 1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions?
 - 2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure?
 - 3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally?

- C. Radiation survey of patient is performed to ensure source is returned to shielded position **(902 KAR 100:072)**?
- D. Records of radiation surveys maintained for 3 years **(902 KAR 100:072)**?
- E. Authorized medical physicist and authorized user: **(902 KAR 100:072)**
 - 1. Physically present during initiation of patient treatment with remote afterloaders for MDR and PDR, an appropriately trained physician under the supervision of the authorized user may be physically present instead of the AU?

Personnel Radiation Protection

- A. Exposure evaluation performed **(902 KAR 100:019)**?
- B. External Dosimetry **(902 KAR 100:019)**
 - 1. Monitor workers per
 - 2. External exposures account for contributions from airborne activity ?
 - 3. Dosimetry supplier _____ Exchange frequency _____
 - 4. Supplier is NVLAP-approved?
- C. Internal Dosimetry: **(902 KAR 100:019)**
 - 1. Monitor workers?
 - 2. Briefly describe program for monitoring and controlling internal exposures?
 - 3. Monitoring/control program implemented (includes bioassays)?
 - 4. Respiratory protection equipment?
- D. Review of Records and Reports: **(902 KAR 100:019)**
 - 1. Reviewed by _____ Frequency _____
 - 2. Auditor reviewed personnel monitoring records for period _____ to _____
 - 3. Prior dose determined for individuals likely to receive doses?
 - 4. Any exposure exceed annual limits as listed in 902 KAR 100:019?
 - 5. Internal and external summed?
 - 6. Were occupational limits met?
 - 7. RHB forms or equivalent used?
 - a. RHB Form, 'Occupational Exposure Record Per Monitoring Period'
 - 8. If a worker declared her pregnancy in writing during audit period, then was the dose in compliance and were the records maintained?
 - 9. Were annual occupational exposure reports provided to workers **(902 KAR 100:165)**?
- E. Who performed any planned special exposures at this facility (number of people involved and doses received)? **(902 KAR 100:019)**
- F. Records of exposures, surveys, monitoring, and evaluations maintained? **(902 KAR 100:019)**

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events (902 KAR 100:072)

If medical events have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

- A. Event date _____ Information Source _____

B. Notifications

1. Kentucky Department for Public Health, Radiation Health Branch
2. The referring physician
3. Patient in writing/by telephone
4. If notifications did not occur, why not?

C. Written Reports (**902 KAR 100:072**):

1. Submitted to the agency within fifteen (15) days?

Notification and Reports (902 KAR 100:019 and 902 KAR 100:165)

- A. In compliance with reports to individuals; public and occupational doses monitored?
- B. In compliance with theft or loss?
- C. In compliance with incidents?
- D. In compliance with overexposures and high radiation levels?
- E. Aware of the Radioactive Materials Branch phone numbers [Office: (502) 564-3700 8:00 AM – 4:30 PM, Emergency (800) 255-2587]
- F. In compliance with constraint on air emissions?

Posting and Labeling

- A. RHB Form KR-441, 'Notice to Employees' is posted (**902 KAR 100:165**)?
- B. '**Kentucky Radiation Protection Regulations**', **902 KAR 100:019** '**Standards For Protection Against Radiation**' and **902 KAR 100:165** '**Notices, Reports and Instructions to Workers**', license documents, operating procedures applicable to activities under the license or registration are posted or post a notice indicating where documents may be examined?
- C. Other posting and labeling per **902 KAR 100:019**?

Recordkeeping for Decommissioning (902 KAR 100:040)

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination?
- B. Records include all information outlined in **902 KAR 100:040**?

Information Notices and Regulatory Issue Summaries

- A. **RHB Information Notices, etc., received?**
- B. Appropriate action in response to RHB Information Notices, etc.?

Special License Conditions or Issues

- A. Special license conditions or issues to be reviewed:
- B. Evaluation:

Audits and Findings

- A. Summary of findings:

B. Corrective and preventive actions:

PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

902 KAR 100:019

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. All individuals requiring monitoring will be provided with a NVLAP accredited film, OSL, and/or TLD as required by 902 KAR 100:019. The device utilized shall be placed near the location expected to receive the highest dose during the year.

ADULT ANNUAL OCCUPATIONAL DOSE LIMITS

LOCATION	LIMIT
Whole Body (Total effective dose equivalent)	0.05 Sv (5 rem)
Eyes	0.15 Sv (15 rem)
Skin	0.5 Sv (50 rem)
Elbows to hands	0.5 Sv (50 rem)
Knees to feet	0.5 Sv (50 rem)
Internal Organs	0.5 Sv (50 rem)

Individual monitoring devices are required for personnel whose annual exposure may exceed 10% of the limits listed above.

Individuals entering a high or very high radiation area shall be provided individual monitoring devices.

MINORS ANNUAL OCCUPATIONAL DOSE LIMITS

The annual occupational dose limits for minors shall be 10% of the dose limits listed above for adults.

Individual monitoring will be required for minors who exposure may exceed the following:

LOCATION	LIMIT
Whole Body (Total effective dose equivalent)	1.0 mSv (0.1 rem)
Eyes	1.5 mSv (0.15 rem)
Skin	5 mSv (0.5 rem)
Extremity	5 mSv (0.5 rem)

DOSE TO EMBRYO OR FETUS

The dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, shall not exceed:

5 mSv (0.5 rem)

Declared pregnant personnel shall require individual monitoring for the embryo/fetus if they are likely to exceed 1.0 mSv (0.1 rem)

We shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. The pregnancy will be declared in writing and, includes the worker’s estimated date of conception, the dose to an embryo/fetus shall be taken as the sum of:

- The deep-dose equivalent to the declared pregnant woman; and
- The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

MONITORING REQUIREMENTS:

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

- Prior Experience: Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;
- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable ‘accident’ scenarios should also be evaluated);
- A calculation may be performed based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

INVESTIGATIONAL LEVELS:

The Radiation Safety Officer shall review all exposure reports of individuals at least quarterly.

Part of Body		
Whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
Hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
Lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Personnel dose less than Investigational Level I.

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

Personnel dose greater than Investigational Level I

The RSO or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence.

Personnel dose greater than Investigational Level II

The RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence and management should review the report of the actions to be taken to reduce the probability of occurrence.

Internal Exposure

It is required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in 1 year. **902 KAR 100:019** provides terms for radionuclide intakes by means of inhalation and ingestion (i.e., derived air concentration (DAC) and ALI) and these will be followed.

Iodine capsules shall be used in most cases; liquid iodine may be used if necessary due to patient considerations. If liquid iodine is used, bioassays will be performed as necessary.

If a bioassay is deemed necessary, the bioassay program in Appendix D of the Radiation Safety Manual shall be used.

PERSONNEL TRAINING PROGRAM

Any personnel likely to receive in a year, during the course of employment, an occupational dose in excess of 100 millirems (one (1) mSV) shall be:

1. Kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;
2. Informed of health protection problems, to the individual and potential offspring, associated with exposure to radioactive material or radiation, and instructed in precautions or procedures to minimize exposure and in the purposes and functions of protective devices employed;
3. Instructed in, and instructed to observe, to the extent within the worker's control, the applicable requirements of 902 KAR Chapter 100 and licenses issued thereunder for the protection of personnel from exposures to radiation or radioactive material;
4. Instructed of their responsibility to report promptly to the licensee or registrant a condition that may lead to or cause a violation of the Act, 902 KAR Chapter 100 or license conditions, or unnecessary exposure to radiation or radioactive material;
5. Instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material;
6. Informed of the radiation exposure reports that workers may request as authorized by 902 KAR 100:165, section 3.

In determining the individuals subject to the requirements of this section, administration shall take into consideration assigned activities during normal and abnormal situations involving exposure to radioactive material or radiation that can reasonably be expected to occur during the life of the radioactive material license. The extent of the instructions shall be commensurate with potential radiological health protection problems in the workplace.

ANCILLARY STAFF:

Ancillary staff include personnel such as janitorial, lab, security and life-safety services. Training may be given when deemed necessary for personnel with entry into controlled or restricted area. Topics may include:

- Storage, transfer, or use of radiation and/or radioactive materials
- Applicable provisions of Kentucky state regulations and the license
- Responsibility to promptly report any condition that may lead to or cause a violation of the regulations and license or unnecessary exposure to radiation and/or radioactive materials.
- Appropriate response to warnings made for unusual occurrences involving radiation.

AREA SURVEY PROCEDURE

(902 KAR 100:019, 902 KAR 100:072)

Procedures for ambient radiation level surveys (use of calibrated GM meter or ion chamber)

- **902 KAR 100:019** requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of **902 KAR 100:019** are met.
- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:
 - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 μ Ci).
- Notify radiation safety or the RSO immediately of radiation levels that exceed trigger/action levels. Trigger/action levels for restricted and unrestricted areas are presented below.

Area Surveyed	
Unrestricted	0.1 mR/hr
Restricted	5.0 mR/hr

Contamination Surveys – (use of calibrated well counter)

Contamination surveys will be performed by conducting a wipe test of the surface and counted in a well counter.

- Contamination surveys may be performed after any spill or contamination event.
- Other contamination surveys will be performed as deemed necessary by the technologist or Radiation Safety Officer.
- If contamination is found, the area should be decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated. (a report to the Radiation Health Branch may be required under 902 KAR 100:019)
- Contamination trigger levels are as listed below:

•

Nuclide ¹	
Iodine	1000
All other isotopes	2000

All surveys shall be recorded and retained for 3 years. The record shall include the date of the survey, results, instrument used to conduct the survey, and name of the individual performing the survey.

PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

902 KAR 100:019 and 040

The authorized user must authorize each request for radioactive materials, and ensure that ordered materials are authorized by the license for the requesting authorized user and that possession limits are not exceeded.

The RSO will establish a system for ordering and receiving radioactive materials and oversee its maintenance. The system must contain the following information: For routinely used materials, written records that identify the radionuclide, chemical form, activity and vendor will be referenced by appropriate personnel to confirm that received radioactive materials were ordered through proper channels. Any deviation will be reported to the RSO immediately. The written records will be referenced when opening or storing the radioactive material.

For specially used materials (e.g. therapeutic dosages), the authorized user who will perform the procedure will give a written request. The Nuclear Medicine or Radiation Oncology personnel or dosimetrist receiving the material will check the authorized user's written request to confirm that the material received is as ordered proper to any use of the material. Any deviation will be reported to the RSO.

Written records will be maintained for all ordering and receipt procedures.

For deliveries during normal working hours, all shipments will be delivered to the Nuclear Medicine, Nuclear Cardiology, PET imaging, Radiation Oncology, or Radiation Safety Office. Shipments after hours are delivered directly to the designated hot lab, by the contracted pharmacy, where they are secured in a locked "Hot Lab". No deliveries are received after normal working hours.

PROCEDURE FOR SAFELY OPENING PACKAGES OF RADIOACTIVE MATERIAL

902 KAR 100:019, section 28

1. Special requirements will be followed for packages as needed per 902 KAR 100:019 section 28. They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during normal working hours. The package shall be monitored within 3 hours if received during normal working hours, or within 3 hours after the start of the next business day. All shipments of liquids marked with a White I, Yellow II or Yellow III will be tested for leakage. The Kentucky Radiation Control Branch and the final carrier will be notified immediately if the removable contamination exceeds 6600 dpm/300 cm² or the external radiation levels exceed 10 mR/hr at 3 feet or 200 mr/hr at the package surface.

2. For packages, personnel shall monitor the external surfaces of a labeled package for:
 - Radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form.
 - Radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity defined in 901 KAR 100:010
 - If there is evidence of potential contamination such as packages that are crushed, wet, or damaged, all of these packages will be monitored for radioactive contamination and radiation levels.
 - For packages needing to be monitored, the following procedures for opening packages will be carried out:
 1. Put on gloves to prevent hand contamination.
 2. Visually inspect packages for any signs of damage (e.g. wetness, crushed). If damage is noted, stop the procedure and notify the RSO.
 3. Measure the exposure rate at 3 feet from the package surface and record the result. If the reading is more than 10mR/hr, stop the procedure and notify the RSO.
 4. Measure the exposure rate at the surface of the package and record the result. If the reading is more than 200 mR/hr, stop the procedure and notify the RSO.
 5. Wipe the surface of the package and count the sample in a suitable counter and record the results in dpm/100 cm². If the wipe is greater than 6600 dpm/300 cm², stop and notify the RSO. Take precautions to prevent the spread of contamination.
 - Open the package with the following precautions:
 1. Open the outer package following the manufacturer's directions (if supplied) and remove the packing slip.
 2. Open the inner package and verify that the contents agree with the packing slip and the requisition, and in the case of therapy doses, also with the physician's written request.
 3. Visually inspect the integrity of the final source container. Look for broken seals or vials, loss of fluid or discoloration of the packaging material. Check also that the shipment does not exceed possession limits.
 - If external contamination is suspected, wipe the external surface of the final source container. Remove the wipe to a low background area (<0.05 mR/hr) and the wipe will be assayed in an appropriate instrument with sufficient sensitivity such as a calibrated well counter. If meter readings indicate removable contamination is present on the wipe, take precautions against the spread of this contamination as necessary.
 - Monitor the packing material and packages with a suitably sensitive G-M meter in a low background area. If the material is suspected to be contaminated, treat it as radioactive waste. If not, then obliterate all labels before discarding it in the regular trash.

The Manager of the Radiation Health Branch and the final delivery carrier shall immediately be notified if by telephone if:

- (a) Removable radioactive surface contamination exceeds the limits of 902 KAR 100:070, Section 17; or
- (b) External radiation levels exceed the limits of 902 KAR 100:070, Section 17.

RECORDS OF RADIOACTIVE MATERIAL USE

902 KAR 100:072, sections 22 and 902 KAR 100:042, section 11

Unit Dosage Use:

Unit doses are received by an approved nuclear pharmacy. Each patient dose shall be determined and the activity recorded before medical use. The determination shall be made by:

1. Directive measurement of radioactivity on a calibrated dose calibrator, OR
2. Decay correction based on the activity or activity concentration determined by the licensed nuclear pharmacy or manufacturer.

For other than unit dosages, direct measurement of radioactivity shall be made on a calibrated dose calibrator. A dosage that does not fall within the prescribed dose range or if the dosage differs from the prescribed dosage by more than 20%, the dose shall not be used unless otherwise directed by the authorized user.

Records of dosage:

Records of dosage determination shall be retained for at least 3 years. The record shall contain:

1. The radiopharmaceutical;
2. The patient's or human research subject's name, or identification number if one (1) has been assigned;
3. The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.11 MBq (30 μ Ci);
4. The date and time of the dosage determination; and
5. The initials of the individual who determined the dosage

RELEASE OF PATIENTS

Any patient who receives radioactive material, whether in radiopharmaceutical form, capsule, or sealed source shall be released based on U.S. NRC Regulatory Guide 8.39.

Most diagnostic procedures, patients can be released based on Table 1 in Reg Guide 8.29: Activities and Dose Rates for Authorizing Patient release:

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released *	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19

Other patient release shall either be listed on other charts in Reg. Guide 8.39, measurements of exposure from the patient based on Reg. Guide 8.39, or calculation of exposure to the public based on Reg. Guide 8.39. A copy of NRC Regulatory Guide 8.39 will be kept on file at the facility.

SEALED SOURCES

When handling sealed sources, the radiation safety and handling instructions supplied by the manufacturer will be followed.

LEAK TESTS

All sealed sources above 100 uCi will be:

- (a) Tested for leakage before its first use unless the a certificate from the supplier indicating that the source was tested within six (6) months before transfer to the licensee; and
- (b) Tested for leakage at intervals not to exceed six (6) months.

To satisfy the leak test requirements, the sample shall be measured so that the leak test can detect the presence of 185 Bq (0.005 μ Ci) of radioactive material in the sample.

- If the leak test reveals the presence of 185 Bq (0.005 μ Ci) or more of removable contamination, the facility will do the following:
 - Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in 902 KAR 100:019, 100:021, 100:040, and 100:058; and
 - File a report within five (5) days of the leak test in accordance with 902 KAR 100:072, Section 18

Leak tests do not need to be performed on:

- Sources containing only radioactive material with a half-life of less than thirty (30) days;
- Sources containing only radioactive material as a gas;
- Sources containing 3.7 MBq (100 μ Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 μ Ci) or less of alpha-emitting material;
- Sources stored and not being used. However, the licensee shall test each source for leakage before any use or transfer unless it has been leak tested within six (6) months before the date of use or transfer.

Records of leak tests will be maintained for three (3) years. The records shall include the model number and serial number, if one (1) has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

Leak tests will be performed by an organization authorized by RHB, the NRC, or another Agreement State to provide leak testing services to other licensees. Leak tests may be performed at the facility; please see Appendix A for leak test procedure.

INVENTORY

A semiannual physical inventory of all sealed sources will be performed.

Records of the semiannual physical inventory of sealed sources will be maintained for three (3) years. The inventory records shall contain the model number of each source, and serial number if one (1) has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

PROCEDURES FOR USE OF A THERAPEUTIC DOSE OF RADIOACTIVE MATERIAL

1. A written directive shall be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabecquerels (MBq) (Thirty (30) microcuries (μCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material.
 1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record.
 2. A written directive shall be prepared within forty-eight (48) hours of the oral directive.
2. The written directive shall contain the patient or human research subject's name and the following information:
 1. For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;
 2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
3. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material.
 1. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable. The oral revision shall be documented as soon as possible in the patient's record.
 2. A revised written directive shall be signed by the authorized user within forty-eight (48) hours of the oral revision.
4. The licensee shall retain a copy of the written directive as required by this section for three (3) years.

PRIOR TO ADMINISTERING THE PATIENT DOSE:

1. The patient's or human research subject's identity is verified before each administration; and
2. Verify each administration is in accordance with the written directive and the treatment plan, if applicable.
3. Check both manual and computer-generated dose calculations, if applicable.

Procedures shall be written for each therapy requiring a written directive to provide high confidence that the above requirements are met. A copy of the procedures required under 902 KAR 100:072 section 14 shall be kept for the duration of the license.

PROCEDURES FOR THERAPIES REQUIRING A WRITTEN DIRECTIVE FOR RADIOPHARMACEUTICAL THERAPY

Oral and written instructions will be given to each patient as required in 902 KAR 100:072 section 27 prior to treatment on actions recommended to maintain doses to other individuals as low as reasonably achievable. A record will be maintained on the basis for authorizing release of an individual given a therapeutic dosage of radioactive material.

Prior to administration, a written directive issued by an authorized user will be prepared. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

- Patient's name
- Patient identification number, if available
- Radioactive drug
- Sign and dated by authorized user

AND

For administration of I-131 greater than 30 microcuries:

- The dosage

For administration of therapeutic dosage of Sm-153 and Sr-89:

- The dosage
- Route of administration

1. Each administration will be in accordance with the written directive.
2. The physician or nuclear medicine technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification.
3. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose.
4. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive.
5. The dose shall be verified either by the documentation received by the pharmacy using the decay method or by assaying the dose in a dose calibrator.
 - a. If a dose calibrator is used for the dose amount verification, the dose calibrator will be calibrated for the specific dose and geometry that is used for the dose.
6. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration, etc.) are in accordance with the written directive.
 - a. If the information obtained does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive evidence is obtained that this agent/procedure is intended for the patient in question.

7. Prior to administration, the patient's identity is verified as the patient named in the written directive. The person responsible for the administration will complete the verification. Verification of identity must include at least one of the following methods:
 - The patient shall be asked to state and spell their name.
 - The patient shall be asked to state their birth date.
 - The patient shall be asked to state their social security number.
 - The patient shall be asked to state their address.
 - The patient shall be asked for identification, i.e. driver's license.
 - The patient's wrist identification band shall be checked for name and patient number.
 - For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any the methods listed above does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification is obtained.

8. Oral and written instructions will be given to the patient when required.
 - a. For Sr-89: Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public

Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is documented in writing as soon as possible in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. (See 902 KAR 100:072, Sections 15 &16)

PROCEDURE FOR THE SAFE USE OF RADIOACTIVE MATERIAL IN AN INPATIENT

902KAR100:072, sections 27, 24, and 35

If an individual receiving radiopharmaceutical therapy cannot be released under 902 KAR 100:072 section 27 certain safety precautions need to be followed as listed below:

1. The patient's room will be a private room.
2. The patient's door will be visibly posted with a "Radioactive Materials" sign.
3. It must be noted either on the door or in the patient's chart where and how long visitors may stay in the patient's room
4. Monitoring of the material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding must be done, or all items may be handled as radioactive waste.
5. The personnel handling the patient shall notify the radiation safety officer, or his/her designee, and the authorized user as soon as possible if the patient has a medical emergency or dies.

Prepare the room for the procedure as follows:

- a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags if it is felt to be needed.
 - b. Several plastic bags may be used for garbage, linens, etc.
 - c. The patient may use the sanitary sewer system, but it is suggested they be informed to flush a few times after using the facility.
 - d. Showers are not suggested as it is very difficult to decontaminate.
 - d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
6. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
 7. Supply the nurses with film badges or TLDs.
 8. Brief the nurses on radiation safety precautions. Instruction must include but is not limited to:
 - Patient control (patient must stay in the room and may not wander out)
 - Visitor control (this may differ for each patient)
 - Contamination control
 - Waste control
 - Notification of the RSO and the authorized user if the patient has a medical emergency or dies.*Record of this instruction must be maintained and kept for 3 years. Records must include the topics covered, individuals present, instructor, and the date of the instruction.
 9. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

10. Only those persons needed for medical, safety, or training purposes should be present during the administration.
11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until either the exposure rate from the patient is less than 7 millirem per hour at 1 meter or the retained radioactivity is less than 33 millicuries. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office. Any items contaminated must be held for decay prior to waste disposal or another use. Record of the holding must be recorded as listed in the "STORAGE AND DISPOSAL OF RADIOACTIVE MATERIAL"
Clean contaminated areas until removable contamination is less than 200 dpm/100 cm².

PROCEDURES FOR THERAPIES REQUIRING A WRITTEN DIRECTIVE FROM SEALED SOURCES

Oral and written instructions will be given to each patient with permanent implants as required in 902 KAR 100:072 section 27 prior to treatment on actions recommended to maintain doses to other individuals as low as reasonably achievable.

Prior to administration, a written directive issued by an authorized user will be prepared. A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. The written directive should contain the following information:

BEFORE IMPLANTATION:

- Patient's name
- Patient identification number, if available
- Authorized user and date AND

FOR ALL OTHER BRACHYTHERAPY (I-125 SEEDS, SR-90, P-32):

- Treatment site
- Radionuclide
- Dose

AFTER IMPLANTATION BUT BEFORE COMPLETION OF PROCEDURE:

- Radionuclide
- Treatment site
- Number of sources
- Total source strength
- Exposure time or total dose

Each administration will be in accordance with the written directive. The physician or authorized medical physicist shall read the written directive before preparing or administering the brachytherapy dose. If any portion of the written directive is unclear, the specific authorized user must be contacted to provide clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the person administering the dose. If the person preparing the dose is different from the one administering the dose, both shall read and understand the written directive. The persons who prepare and administer the dose shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration, etc.) are in accordance with the written directive.

Prior to administration, the patient's identity is verified as the patient named in the written directive. The person responsible for the administration will complete the verification. Verification of identity must include at least one of the following methods:

- The patient shall be asked to state and spell their name.
- The patient shall be asked to state their birth date.
- The patient shall be asked to state their social security number.
- The patient shall be asked to state their address.
- The patient shall be asked for identification, i.e. driver's license.
- The patient's wrist identification band shall be checked for name and patient number.
- For patients unable to respond, an accompanying relative or friend may attest to the patient's identity. Record name and relationship of same.

If the information obtained from any the methods listed above does not correspond to the information on the written directive, the brachytherapy dose shall not be administered until conclusive verification is obtained.

Prior to administration, verification will be made that the administration is in accordance with the treatment plan, if applicable, the written directive. When applicable, both manual and computer-generated dose calculations will be verified along with verification of any computer-generated dose calculations transferred into the consoles of therapeutic medical units.

Oral directives are permissible only when a patient's medical condition is such that their health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive is documented in writing as soon as possible in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

If any unintended deviation from the written directive is identified, it is evaluated and appropriate action taken. (See 902 KAR 100:072, Sections 15 &16)

SURVEYS AFTER SOURCE IMPLANT AND REMOVAL

Immediately after implanting sources in a patient, a survey will be performed to locate and account for all sources that have not been implanted when applicable.

Immediately after removing the last temporary implant source from the patient, a survey shall be performed of the patient with a radiation detection survey instrument to confirm that all sources have been removed.

A record of the surveys that are required as listed above will be retained for 3 years and include the date, results of the survey, survey instrument used and the name of the individual who performed the survey.

BRACHYTHERAPY SOURCE ACCOUNTABILITY

The facility shall maintain accountability at all times for all brachytherapy sources in storage or use.

For the **permanent implants**, a record of accountability shall include:

- The number and activity of sources removed from storage
- Date removed from storage
- Name of the individual who removed them from storage AND
- Number and activity of sources permanently implanted

Immediately after implanting sources in the patient, a survey will be performed to locate and account for all sources that have not been implanted. A record of the survey will be retained for 3 years. Each record shall include:

- Date
- Results of survey
- Survey instrument used
- Name of the individual who made the survey

For the **temporary implants**, after removal from the patient, the sources will be returned to the secured storage area as soon as possible. A record of accountability shall include:

- Number and activity of sources removed from storage
- Time and date they were removed from storage
- Name of individual who removed them

- Location of use
- Number and activity of sources returned to storage
- Time and date they were returned to storage
- Name of individual who returned them

Calibration measurements of brachytherapy sources and use of therapy-related computer systems will be performed as stated in 902 KAR 100:072 section 42 and 43.

EMERGENCY PROCEDURES

Emergency Procedures

Emergencies range from minor spills of radioactivity, involving relatively no personal hazard to major radiation incidents involving extreme hazards. Because of the wide range and variety of hazards and the numerous possible complicating factors, set rules of emergency procedures cannot be made to cover all possible situations. In any emergency, however, the primary concern must always be the protection of personnel from radiation hazards. If radioactive contamination is involved, all persons who were in the area at the time of the incident shall be assembled and monitored for contamination.

Minor Spills

- NOTIFY: Notify persons in the area that a spill has occurred.
- PREVENT THE SPREAD: Cover the spill with absorbent paper. Always wear gloves and protective clothing during cleanup of radioactive materials.
- CLEAN-UP: Wipe up spill using absorbent paper. Place all contaminated items: absorbent paper, gloves, etc, into bag and place in a radioactive waste container.
- SURVEY: With a low-range, thin-window G.M. survey meter sufficiently sensitive to detect the radionuclide(s) spilled. Check the area around the spill, hands and clothing for contamination.
- Report the incident to the RSO.

Major Spills

- CLEAR THE AREA: Notify persons not involved in the spill to vacate the room.
- PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel, potentially contaminated to prevent the spread and clearly indicate boundaries of the spill.
- SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
- CLOSE THE ROOM: Leave the room and lock or secure the door to prevent entry.
- CALL FOR HELP: Notify the Radiation Safety Officer or Alternate immediately.
- PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly with lukewarm water and wash with mild soap. If still contaminated, consider inducing perspiration re-wash with mild soap and lukewarm water.

Areas must be cleaned until levels are below 0.1 mR/hr. If survey cannot indicate below this level, the area must be secured until enough time has passed for survey to be below 0.1 mR/hr

EMERGENCY CONTACT:

Sarah Hughes, RSO	502-852-5231; 502-552-5454
Nuclear Medicine:	502-562-3166
Radiation Health Branch:	502-564-3700 during normal business hours
	1-800-255-2587 after hours

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

Radionuclide	Millicuries	Radionuclide	Millicuries
F-18	100		
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Yb-169	10
Ga-67	10	Hg-197	10
Se-75	1	Au-198	10
Sr-85	10	Tl-201	100
Sm-153	10	Sr-89	1

Notification Requirements

The following incidents must be reported to the Radiation Safety Officer as soon as possible after their occurrence:

- Any major spill of radioactive material.
- Contamination of personnel
- Accidental human intake of significant amounts of radioactivity
- Exposure of individuals to excessive levels of radiation
- Theft or loss of radioactive material
- Large releases of radioactive material into the air or water

INCIDENTS INVOLVING AIRBORNE RADIOACTIVE MATERIAL:

- A. Notify all personnel to vacate the room immediately.
- B. Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
- C. Vacate the room. Seal the area, if possible.
- D. Notify the RSO immediately.

- E. Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
- F. Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.
- G. Promptly report suspected inhalations and ingestions of licensed material to the RSO.
- H. Decontaminate the area only when advised and/or supervised by the RSO.
- I. Allow no one to return to work in the area unless approved by the RSO.
- J. Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- K. Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

DEFINING INCIDENTS OR EMERGENCIES:

The following may constitute an incident or emergency:

- A. Loss or theft of any radioactive material or radiation producing device.
- B. High or potentially high radiation exposure to an employee or member of the general public. For example:
 - 1. Greater than 1000 mrem whole-body in one month to an occupationally exposed individual;
 - 2. Greater than 10000 mrem in one month to the extremities of an occupationally exposed individual; or
 - 3. Greater than 100 mrem to any member of the general public.
- C. Intake of radioactive material by inhalation, ingestion, skin absorption, or injection through the skin or wound.
- D. Deceptive or potentially deceptive exposure of a dosimeter.
- E. Personnel contamination which cannot be removed after two washes with soap and water.
- F. Spills involving significant activities of ^{125}I or ^{131}I with the potential for inhalation.
- G. Removable contamination in unrestricted areas (e.g. hallways, offices, vehicles, etc.) which exceed 200 dpm/100 cm².
- H. Radiation fields in unrestricted areas which exceed the limits specified for members of the general public of 2 mR/hr.
- I. Accidental or unmeasured releases of radioactive material to the environment.
- J. Fire or floods which threaten to release radioactive material to the environment or which threaten to expose emergency response personnel.

RADIATION EMERGENCY PROCEDURES

Type	Hazard	Immediate Precautions	Follow Up
Minor Spills	Low	<ol style="list-style-type: none"> 1) Notify all persons in room. 2) Confine spill immediately. 3) Decontaminate (see Radiation Safety Manual) 4) Retain decontamination report in records for review 	Survey personnel and area. Notify RSO of the spill as soon as possible.
Major Spills	Radiation and Contamination hazard may be significant	<ol style="list-style-type: none"> 1) Notify all persons in room. 2) Confine spill immediately. 3) Barricade area of contamination. 4) Notify Radiation Safety Officer 5) Proceed with decontamination with RSO supervision 	Further decontamination may be necessary as determined by RSO.
Accidents involving airborne radioactivity	Uptake of radioactive material possible	<ol style="list-style-type: none"> 1) Shut off source of contamination, if possible. 2) Notify others to vacate. 3) Shut windows and doors. 4) Call Radiation Safety Officer 5) Shut off air conditioning, if possible. 6) Call Engineering. 	Do not re-enter area until authorized by RSO. Decontamination may be necessary.
External contamination (skin, eyes, wounds)	Potential hazard greatest with wounds	<ol style="list-style-type: none"> 1) Flush wound and eyes, wash skin with soap and water. 2) Prompt action is necessary to minimize radiation dose and uptake. 3) Notify Radiation Safety Officer. 	For additional decontamination procedures, see Radiation Safety Manual
Accidental uptake of radioactivity	Hazard varies with uptake and toxicity of isotope	<ol style="list-style-type: none"> 1) Contact Radiation Safety Officer immediately. 2) Action varies depending on isotope and chemical form. 	For additional decontamination procedures, see Radiation Safety Manual
Fires involving radioactivity	Internal hazard from airborne activity	<ol style="list-style-type: none"> 1) Notify all persons in area. 2) Activate nearest fire alarm. 3) Notify Security. 4) Attempt to extinguish fire if radiation and fire hazard is not serious. 5) Notify Radiation Safety Officer. 	After fire is extinguished, area must be decontaminated under RSO supervision (as necessary)
For Emergencies		Radiation Safety Officer – Sarah Hughes, MS, DABR Radiation Control Branch	(502) 552-5454 (502) 564-3700 (800) 255-2587

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
3. The Radiation Safety personnel or representative will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
2. An autopsy will be performed only after consultation and permission from the RSO. Proper personnel should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high energy beta rays in cases involving therapy with radioactive material as needed.
4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

Reference: NRC Report No. 111, “*Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities*”, 1991, contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095. NCRP’s telephone numbers are: (301) 657-2652 or 1-800-229-2652.

RADIOACTIVE WASTE DISPOSAL

Procedure for Decay-In-Storage

Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- Containers used for contaminated waste will be sufficient for the material it holds; i.e. needle boxes for sharps, etc.
- When the container is full it shall be sealed and documented with the seal date and the longest-lived radionuclide in the container.
- Prior to disposal as in-house waste, monitor, and record the results of monitoring of each container as follows:
 - Use a survey instrument that is appropriate for the type and energy of the radiation being measured;
 - Check the radiation detection survey meter for proper operation and current calibration status;
 - Monitor in a low-level radiation (<0.05 millirem per hour) area away from all sources of radioactive material, if possible;
 - Take bag of waste out of container or any shielding for the survey.
 - Monitor, at contact, all surfaces of each individual container;
 - Remove or deface any radioactive material labels
 - Discard as in-house waste only the waste that cannot be distinguished from background.
 - Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal;
 - Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized radioactive material recipient.

Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- Prior to sending any material back to an authorized recipient, obtain a copy of the transferee's RHB, NRC, or another Agreement State license that authorizes the radioactive material
- Retain the records needed to demonstrate that the package qualifies as a USA DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with **902 KAR 100:015** and **902 KAR 100:040**.

APPENDIX A – August 19, 2016

PROCEDURE FOR SEALED SOURCE LEAK TESTING AND INVENTORY

The Kentucky Cabinet for Health Services Radiation Health Branch requires that all sealed sources containing 50 MBq or greater of radioactive material be monitored to assess the integrity of the material containing the source. By definition a sealed source provides a level of assurance that the radioactive material cannot escape and result in contamination or an inadvertent exposure. Unfortunately due to age, use or damage the integrity of the housing material can be compromised resulting in a potential serious situation. In evaluating the risk verses the probability of an incident there are set a graduated leak test frequency schedule taking into account when sources are in storage, incorporated into devices, or in use.

Frequency

The frequency of leak testing is as follows:

- immediately after an event which may have resulted in the sealed source or shielding being damaged;
- immediately before using a source that had been in storage for a period of 12 consecutive months or greater;
- every 6 months for sealed sources in use and not incorporated into a device;
- every 12 months for sealed sources incorporated into a device;
- every 24 months when a source is in storage

REGULATIONS:

Licensees in possession of any sealed source must follow the radiation safety and handling instructions supplied by the manufacturer. Licensees in possession of a sealed source must:

- (1) Test the source for leakage before its first use, unless tested within 6 months before transfer to licensee; and
- (2) Test (and record) the source for leakage at intervals not to exceed 6 months; leak test must be capable of detecting 0.005 μCi (185 Bq).

If the leak test reveals the presence of $>0.005 \mu\text{Ci}$ (185 Bq) of removable contamination, the licensee must immediately withdraw the source from use and store, dispose, or cause it to be repaired. A report must be filed within 5 days.

Licensees are not required to perform a leak test on the following sources:

- (1) Sources containing material with a half-life <30 days;
- (2) Sources containing only gaseous material;
- (3) Sources containing 100 μCi (3.7 MBq) or less of beta- or gamma-emitting material; or
- (4) Sources stored and not being used.

Leak testing is an effective means of evaluating the integrity of a sealed source and minimizing the potential spread of radioactive contamination. Although regulations pertain only to byproduct material, a well-managed safety program would leak test all sealed sources. Diagnostic nuclear medicine licensees, for the most part, use sealed sources that pose minimal risk of radioactive contamination.

Licensees are required to inventory and leak test these sealed sources. Leaking sources must be immediately withdrawn from use. These steps serve to minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

LEAK TEST PROCEDURE:

The licensee must wipe for removable radioactive contamination all sealed sources in its possession that are required to be tested for leakage at intervals not to exceed 6 months. (These will usually be the ^{57}Co flood source and the ^{57}Co and ^{137}Cs check sources for the dose calibrator; see section 9.10 for the necessity of dose calibrator). The following procedure should be used:

- (1) A separate wipe sample (e.g., cotton swab, injection prep pad, or filter or tissue paper) should be obtained from each sealed source and appropriately identified. The individual performing the wipes must wear gloves and proper protective clothing. Wipe the most accessible area (but not directly from the surface of the source) where contamination would accumulate if the sealed source were leaking.
- (2) Select an instrument that is sensitive enough to detect 185 Bq (0.005 uCi) of the radionuclides and ensure that its calibration is current. A separate background count rate should also be obtained and recorded.
- (3) The activity (in microcuries) of each wipe sample should then be determined according to:

$$\text{Activity } (\mu\text{Ci}) = \frac{\text{M e a s u r e d w i p e (c p m) - b a c k g r o u n d (c p m)}}{\text{Detector efficiency} \times 2.22 \times 10^6 \text{ dpm}/\mu\text{Ci}}$$

- detector efficiency is the efficiency of the well counter.

- (4) Record activity in microcuries of each wipe sample. It must be $<0.005 \mu\text{Ci}$. If not, the leaking source must be removed from use and stored, disposed, or caused to be repaired. A report must be filed within 5 days in accordance with 902 KAR 100:060
- (5) The leak test results must be recorded and must include the model number and serial number (if one has been assigned) of each source tested, the identity of each source by radionuclide and its estimated activity, the results of the test, the date of the test, the name of the individual who performed the test, and any action taken.
- (6) Determine Minimum Detectable Activity (MDA) – the counter used to perform leak tests must be able to detect activity below 0.005 uCi. Determine this by calculating the MDA:

$$\text{MDA} = \frac{3.29 \left((R_b/T_b) + (R_b/T_s) \right)^{0.5}}{\text{Efficiency of the counter}} \quad (\text{multiply the answer by } 2200000 \text{ dpm}/\mu\text{Ci})$$

R_b = background count;

T_b = time of bkg count;

T_s = time of sample count

Appendix B

Calibration Procedures for Radiation Detection Equipment

If any units are out of service for calibration or repair and one is not available for use, a calibrated unit shall be purchased or used until returned.

Dose Calibrators:

In the case of a dose calibrator being used to measure patient doses, it shall be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. When patient doses are received in unit dosages of radioactive material and it is not split or altered, the dosages may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

Well Counters/other detection equipment used in Nuclear Medicine Radiation Oncology:

Equipment shall be calibrated by appropriate personnel using nationally recognized standards or the manufacturer's instructions.

Instruments used for diagnostic procedures:

Equipment used for diagnostic procedures will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

The Radiation Safety Office and research labs employ equipment to monitor contamination and external radiation levels. The most commonly used equipment is the GM meter. This requires annual calibration; the procedure is listed below. Any other equipment used will be maintained per manufacturer's recommendations; pulsar calibration is used a most equipment; procedures are listed below.

Survey Meter Calibration Procedure

PULSER CALIBRATION OF COUNT RATE INSTRUMENTS

1. All information will be recorded on the following form, "Instrument Calibration Record– Count Rate".
2. Record the instrument type, serial#, probe type, calibration date, and the person calibrating.
3. Check the instrument high voltage and battery. Replace battery if necessary. Verify 'high voltage' is appropriate for the detector. Record the battery status and the high voltage.
4. If the instrument will be calibrated with the detector connected (it is preferable that the instrument be calibrated with the detector disconnected), record the instrument reading on its lowest normally used scale. This will be the background which will be subtracted from each reading.
5. If the detector will be calibrated with the detector disconnected verify that the instrument reads zero with no pulses applied. If the meter does not read zero adjust the meter face and record the initial and final readings.
6. Determine the input sensitivity using the following method:
 - a) Select the most sensitive amplitude range on the pulser
 - b) Set the pulse frequency to the midpoint of one of the counting ranges.

- c) Observe the meter on the survey instrument.
- d) Set the pulse amplitude to zero
- e) Increase pulse amplitude, switching to next higher range if necessary, until the rate meter indicates a stable reading (i.e., further increases of pulse amplitude do not cause an increase in the meter reading). Now decrease the pulse height until the meter reading drops. Record this pulse height as the input sensitivity.

1. For calibration purposes set the pulse height to twice the input sensitivity of the detector. Record the pulse height, pulse polarity, pulser model#, and the pulser serial #.
2. All instruments will be calibrated at two points on each scale. The points shall be in the lower and upper third of the normally used span. If a range is not calibrated, note this on the instrument and on the instrument record. The instrument may then be used only on the calibrated ranges. (This is aimed at probes whose useful range is smaller than the range the instrument is capable of measuring).
3. If the detector does not automatically perform a dead time correction proceed to step 10. If the instrument performs a correction for detector dead time this will need to be compensated for at high count rates, otherwise a perfectly good instrument will appear to be over responding. The dead time correction becomes significant (>2%) at a count rate that depends on the dead time setting.

Dead time (usec)	Significant Count rate (cpm)
1	1,175,000
5	235,000
10	117,000
20	59,000
30	39,000
50	23,500
80	14,700
100	11,700
110	10,700
120	9,800
130	9,000

To compensate for dead time consult the appropriate instrument manual.

4. Apply a pulse rate appropriate for the calibration point. If the meter reading fluctuates, the meter reading will be defined as the center point of the needle movement, or in the case of digital meters, as the average of several meter readings. Record the meter range, the pulser reading (and if applicable, the desired reading) and the net meter reading (meter reading less background).
5. Repeat step 10 for each calibration point.
6. An instrument will be considered passing if it agrees to within +/- 10% of the pulser reading. If an instrument fails at any calibration point it will be removed from service until repaired or adjusted.
 1. For GM probes, expose the detector to a radiation source. Verify the detector responds to the radiation. Indicate yes or no on "probe check" space on record sheet. If probe fails, meter will be removed from service until probe is repaired or replaced.
 2. For NaI probes, expose the detector to a low energy gamma check source. Verify the detector responds to the radiation. Indicate yes or no on "probe check" space on record sheet. If probe fails, meter will be removed from service until probe is repaired or replaced.

3. Expose the probe to the instrument's dedicated check source (if available). Record the indicated value onto the calibration record. This will be used to verify daily operation by the user. If, during daily check, the reading varies by more than +/- 20% of the indicated value, the instrument will be removed from service until repaired or adjusted.
4. Factory calibrations will be evaluated on a case by case basis. If the calibration is judged to have been performed acceptably it will be accepted by Uof L RSO.
5. Probe efficiency will not be calculated until RSO acquires NIST traceable calibration source for mid range beta.

13. Enclosure 1 follows on next page.

Instrument Calibration Record – Count Rate

Owner _____ Calibration Date _____
Meter Make _____ Model _____ S/N _____
Probe Type _____ Battery Check _____ Audio Check _____
High Voltage Setting _____

Pulsar: Ludlum Model 500, S/N 189504

Input Sensitivity _____ Input Signal _____ Scale Range _____ - _____

Scale Lower end Expected _____ Upper end Expected _____

X 0.1	_____	_____
X 1.0	_____	_____
X 10	_____	_____
X 100	_____	_____
X 1000	_____	_____

Probe Check _____ Probe Efficiency _____ % for _____

Check Source Reading _____ cpm

Notes: _____

Calibrated by: _____
University of Louisville
Radiation Safety Office, DEHS
HSC, Commons Bldg., Room 102
319 Abraham Flexner Way
Louisville, KY 40202

CALIBRATION OF DOSE RATE INSTRUMENTS

1. All information will be recorded documented.
2. Record the instrument type, serial#, probe type, calibration date, and the person calibrating.
3. Check the instrument high voltage and battery. Replace battery if necessary. Verify high voltage is appropriate for the detector. Record the battery status and the high voltage.
4. Print a decay/output table for the Amersham Model 77302 calibration source, serial number S-706 [Cs137: 142.7 mCi, reference date 01-29-1990], for the week of calibration. The source certificate is kept on file at RSO.
5. Meters that have linear read dials two points on each scale on the meter to be calibrated are chosen for calibration checks. These points are generally approximately 1/3 from lower side of scale and 1/3 from upper side of scale. These points are found on the decay/output table, or as close as possible, and recorded on the calibration log sheet, as well as how far from the calibration source they occur in centimeters.
6. Meters with logarithmic readout several points on the scale are chosen. These points should cover the entire range of the meter from the lower decade to the upper decade. These points are found on the decay/output table, or as close as possible, and recorded on the calibration log sheet, as well as how far from the calibration source they occur in centimeters.
7. The meter and/or probe, as needed, is placed the correct distance from the calibration source, the sensor is placed so as to make the correct distance 1 centimeter inside of the detector. The detector is then raised to the correct height, center point of detector in line with center point of source output, using a lab ring stand and equipment clamp. Note distance from source is marked on calibration table in centimeters and height is verified using ruler kept with the calibration source.
8. Once the meter is at the predetermined distance from the calibration source, the source is unlocked and opened. The correct combination of attenuators is place in front of the output point to provide the desired reading for the calibration source for the scale being read; generally the lower point is read first followed by the upper point. The reading on the meter is checked to verify that it falls within + or – 10% of desired. If the reading is outside of the +or– 10% range the other point on the scale is checked and appropriate adjustments are made using the calibration controls for that scale. As adjustments are made the scale is checked at both the upper and lower point to gain the best result for both points. If it is not possible to bring the scale to within the 10% range but within +or– 20% a correction factor maybe calculated and applied. This information is then recorded on the calibration log sheet. Once a scale has been satisfactorily calibrated the next scale is checked and adjusted as needed. Calibration is generally conducted from the farthest point from the calibration source and moved in as needed. If it is not possible to bring any give scale to within the +or- 20% range that scale is listed as out of service and the meter it taken out of service pending repair and recalibration.
9. Once a meter has been successfully calibrated a calibration certificate is prepared for the meter with name of the user, the calibration date, date of next calibration, calibration source output @ 1 meter, the check source value and the name and title of the person performing the calibration. A small copy of this is attached to the meter and a full size copy is provided to the user for their records. Once this is done the meter is either returned to the lab or the lab is contacted to pick up their meter.

Appendix C

Criteria for Evaluating Users Qualifications for the Use of Radioactive Materials

Authorized Users

An authorized user is an individual who by virtue of position, training and experience is designated by the RSC as a user of radioactive material under the University of Louisville broad radioactive material license. This authorization permits the procurement and use of radioactive material within a defined protocol or work activity under the supervision of the authorized user provided that the materials are used within the guidelines of safe practice, and within the rules, regulations and recommendations of the RSC and U of L policy.

HOW TO BECOME AN AUTHORIZED USER

Anyone who would like to become an authorized user must complete the “Application for Authorization to Use Radioactive Material”, and sign the “Radiation Protection Guidelines”. The completed forms, and approved certification or documentation of training or another radioactive material license listing the proposed user as an authorized user must be sent to the Radiation Safety Office for review. The RSO, the Radiation Safety Committee Chair and at least half of the Committee must sign and approve the Authorized use of radioactive material.

AMENDMENT TO AN AUTHORIZATION

An Authorized User must submit an amendment request if other radionuclides are to be used or if procedures change that will significantly alter radiological hazards. A memo to the Radiation Safety Officer must be submitted for an increase in possession limits, changes in use and storage areas and other minor changes.

GUIDELINES FOR THE HUMAN USE OF RADIONUCLIDES IN NON-ROUTINE OR INVESTIGATIONAL PROCEDURES:

An applicant must already be authorized for Human use. In addition, review and approval guidelines of applications for experimental and non-routine medical uses of radioactive material have been adopted by the Committee. It should be emphasized that approval of the University Human Studies Committee is also mandatory prior to performing these procedures. When non-routine or investigational medical use proposals fall under the authority of U.S. Food and Drug Administration (FDA) regulations, the investigator shall satisfy all FDA requirements, including the filing of an Investigative New Drug (IND) application or become approved as an investigator under a sponsor's IND. The Committee will accept as adequate evidence for approval of the study, copies of the forms material, protocols and reports required to satisfy FDA requirements.

AUTHORIZED MEDICAL PHYSICISTS

Anyone who would like to be considered and Authorized Medical Physicist shall submit their proper certification and/or required training. Approval of the use of manual brachytherapy devices shall include the documentation of training or experience with the devices. The required documentation shall be submitted to the Radiation Safety Office and the Radiation Safety Committee will evaluate the criteria and make an evaluation to approve the authorization. Authorization shall be based on the training and experience as listed in 902 KAR 100:072 section 65.

**ACCEPTABLE TRAINING AND EXPERIENCE FOR
MEDICAL USES OF RADIOACTIVE MATERIAL
(902 KAR 100:072, Sections 63 – 78)**

General Criteria

Any human use of radioactive material (i.e., the internal or external administration of radioactive material, or the radiation there from, to human beings) must be carried out by or under the supervision of a physician.

902 KAR 100:072 allows the Radiation Safety Officer and Radiation Safety Committee, or the facility administration if a Committee is not required, to approve any new authorized users and authorized medical physicists who meet the requirements for training as listed in the chapter regulations. The Radiation Safety Office will keep files on all authorized users and authorized medical physicists for review during inspections by the state Radiation Control Branch.

A copy of certification or training will be kept on file at the facility location.

Criteria for Approval

A. Training for Routine Diagnostic Procedures (902 KAR 100:072, Sections 69 and 70)

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Sections 30 and 31 in 902 KAR 100:072, a physician must have the following number of hours (hours are in terms of class, laboratory, or clinical experience rather than semester hours) in the topics listed.

1. Imaging and Localization Studies (minimum 700 hours of training and experience)

- (a) Training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. This training must include laboratory and classroom training in the following areas:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Chemistry of radioactive material for medical use
 - (5) Radiation biology

- (b) Work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is being made, or equivalent involving:
 - (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
 - (3) Calculating, measuring and safely preparing patient dosages
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
 - (6) Administering dosages of radioactive drugs to patients or human research subjects
 - (7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the elute for radionuclidic

purity, and processing the elute with reagent kits to prepare labeled radioactive drugs.

1. Uptake, Dilution and Excretion Studies (minimum 60 hours of training and experience)

- (a) Training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution and excretion studies. This training should consist of laboratory and classroom instruction in the same topics described in Section A.1.(a) of this procedure.
- (b) Work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is being made, or equivalent.
 - (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
 - (3) Calculating, measuring and safely preparing patient dosages
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
 - (6) Administering dosages of radioactive drugs to patients or human research subjects

Alternatives

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

- 1. Verification of certification by an appropriate recognized medical specialty board, or
- 2. A copy of an Agreement State or NRC license on which the individual has been named as approved user of the isotopes to be used by the institution.

B. Training for Therapy Procedures Involving Radiopharmaceuticals (902 KAR 100:072 Section 71, 72 and 73)

1. The use of unsealed radioactive material for which a written directive is required (minimum of 700 hours of training and experience)

- (a) Training in basic radioisotope handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. This training must include classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Chemistry of radioactive material for medical use
 - (5) Radiation biology

(These requirements are in lieu of, not in addition to, those Section A.1.(a) above.)

- (b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. The work experience must involve:
 - (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) ***Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters***
 - (3) Calculating, measuring and safely preparing patient dosages
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
 - (6) Eluting generator systems, measuring and testing the elute for radionuclidic purity, and processing the elute with reagent kits to prepare labeled radioactive drugs
 - (7) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
 - (i) Oral administration of less than or equal to 33 mCi of I-131
 - (ii) Oral administration of greater than 33 mCi of I-131
 - (iii) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV
 - (iv) Parenteral administration of any other radionuclide

2. Oral administration of I-131 requiring a written directive in quantities less than or equal to 33 mCi (minimum of 80 hours of classroom and laboratory training):

- (a) Training applicable to the medical use of I-131 for procedures requiring a written directive:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Chemistry of radioactive material for medical use
 - (5) Radiation biology

(These requirements are in lieu of, not in addition to, those Section A.I.(a) above.)

- (b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category as the individual requesting authorized user status. The work experience must involve:
 - (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) ***Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters***
 - (3) Calculating, measuring and safely preparing patient dosages
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
 - (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures

- (6) Administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of less than or equal to 33 mCi of I-131

3. Oral administration of I-131 requiring a written directive in quantities greater than 33 mCi (minimum of 80 hours of classroom and laboratory training):

- (a) Training applicable to the medical use of I-131 for procedures requiring a written directive:

- (1) Radiation physics and instrumentation
- (2) Radiation protection
- (3) Mathematics pertaining to the use and measurement of radioactivity
- (4) Chemistry of radioactive material for medical use
- (5) Radiation biology

(These requirements are in lieu of, not in addition to, those Section A.I.(a) above.)

- (b) Work experience under the supervision of an authorized user with experience in administering dosages in the same dosage category as the individual requesting authorized user status. The work experience must involve:

- (1) Ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys
- (2) *Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters*
- (3) Calculating, measuring and safely preparing patient dosages
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material
- (5) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
- (6) Administering dosages of radioactive drugs to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi of I-131

Alternatives

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

1. Verification of certification by an appropriate recognized medical specialty board, or
2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

C. Training for use of manual brachytherapy sources (902 KAR 100:072, Section 74)

1. To qualify as adequately trained to use or directly supervise the use of manual brachytherapy sources, a physician must have:

- (a) Training in basic radioisotope handling techniques applicable to the use of manual brachytherapy sources. This training must include a minimum of 200 hours of classroom and laboratory training in the following areas:

- (1) Radiation physics and instrumentation
- (2) Radiation protection
- (3) Mathematics pertaining to the use and measurement of radioactivity

- (4) Radiation biology
- (b) 500 hours of work experience under the supervision of an authorized user with the types and quantities of radioactive material for which the application is made, or equivalent involving:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
 - (2) Checking survey meters for proper operation
 - (3) Preparing, implanting, and removing brachytherapy sources
 - (4) Maintaining running inventories of material on hand
 - (5) Using administrative controls to prevent a medical event involving the use of radioactive material
 - (6) Using emergency procedures to control radioactive material.
- (c) 3 years of supervised clinical experience under the supervision of an authorized user as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. Clinical experience may be obtained concurrently with the supervised work experience.

Alternatives

In lieu of submitting the above, a physician may be named on a license by submitting one of the following:

- 1. Verification of certification by an appropriate recognized medical specialty board, or
- 2. A copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

A. Training for ophthalmic use of Sr-90 (902 KAR 100:072, Section 75)

- 1. To qualify as adequately trained to use or supervise the use of Sr-90 for ophthalmic radiotherapy, a physician must have:
 - (a) 24 hours of classroom and laboratory training applicable to the ophthalmic use of Sr-90. This training must include:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Radiation biology
 - (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Sr-90 for the ophthalmic treatment of 5 individuals. This supervised clinical training must involve:
 - (1) Examination of each individual to be treated
 - (2) Calculation of the dose to be administered
 - (3) Administration of the dose
 - (4) Follow up and review of each individual's case history

Alternative

In lieu of submitting the above, a physician may be named on a license by submitting a copy of an Agreement State or NRC license on which the individual has been named as an approved user of the isotopes to be used by the institution.

Appendix D

BIOASSAY PROGRAM

The following bioassay schedules apply to volatile forms of licensed material or forms that have a potential for ingestion, inhalation or skin absorption and are based upon investigation levels (A) for each radionuclide, the probability of an incorporation of an investigation level, the ease of detection and the type of procedures in which these radionuclides are used. Additional bioassays will be performed when indicated by findings of surface or airborne contamination. Bioassays shall be performed if an individual is likely to receive, in excess of, 10% of the applicable ALI.

Nuclide Use Level	Frequency	Method	ALI*
I-131 1 mCi \leq A	Unusual Situations	Direct	30 μ Ci**
	Thyroid Count		50 μ Ci***

* Annual Limits on Intake from 10 CFR Part 20. Appendix B

** Non-stochastic dose limit to thyroid by ingestion

*** Non-stochastic dose limit to thyroid by inhalation

Bioassays will be performed on individuals using material from the above table in the presence of unusual or an unexpected occurrence. I-131 is routinely administered in a capsule form. If the capsule becomes crushed or otherwise damaged, staff involved with the administration will perform bioassays. If the patient vomits the capsule after swallowing then staff involved in clean-up of the vomited capsule shall perform bioassays

If bioassay results indicate that an ALI is exceeded, an investigation will be performed by the RSO and/or his delegate to assess ways to prevent recurrence of exposure.

PROCEDURE AND CALCULATION

The following is an example procedure and calculation for performing a direct thyroid count bioassay.

A. Instrumentation

The uptake probe may be used to determine thyroid burden.

B. Bioassay measurement

Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) and count for at least 1 minute to establish background. The count results are recorded. Hold probe at thyroid area and count for at least 1 minute to establish thyroid uptake.

C. Investigation Limits

1. The RSO shall be notified whenever the thyroid burden at the time of measurement exceeds 0.03 μ Ci of I-125 or 0.04 μ Ci of I-131. The RSO shall perform an investigation into the cause of the exposure and the potential for further exposure, and develop corrective actions to prevent recurrence.
2. The RSO shall be notified immediately whenever the thyroid burden at the time of measurement exceeds 0.09 μ Ci of I-125 or 0.14 μ Ci of I-131. The RSO must perform an investigation, as

described above, and must perform weekly bioassays on the individual until the individual's thyroid burden is less than 0.04 μCi of I-131.

D. Measure Thyroid Gland

1. Perform measurements in a low-background area.
2. Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a count. Record results.
3. Hold probe in the center of neck near Adam's apple for required amount of time. Record results.
4. Subtract background from thyroid count to obtain net counts. Record results.
5. Calculate and record the amount of radioactivity in thyroid by using the equation:

$$\text{Net counts (CPM)} \times 100 = \text{_____ } \mu\text{Ci}$$

$$\% \text{ Efficiency} \times 2.2 \times 10^6 \text{ DPM}/\mu\text{Ci}$$

6. If results are less than the investigation limits established in E.1 above, record results.
7. If results are more than the investigation limits established in E.2 above, notify the RSO immediately. The RSO may restrict the employee's further handling of I-131 until the thyroid burden is measured to be below the reporting limits established in table above.