APPENDICES I-W

MODEL PROCEDURES FOR INFORMATION PURPOSES ONLY

The following model procedures provide one method of complying with the regulations and are not intended to be the only means for satisfying the requirements for licensees.

These model procedures were originally developed for medical uses only. With implementation of the EPAct and addition of NARM materials and nonmedical uses, such as a 10 CFR 30.32(j) authorization, to medical use licenses, the model procedures may have to be supplemented to address the new materials and nonmedical uses. When adopting one of the model procedures, the applicant needs to ensure that all appropriate aspects of its licensed program are addressed.

APPENDIX I

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

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

_____ _____

Signature of Management Representative Date

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX J

Model Training Program

This Appendix was originally developed for medical uses only. With implementation of the EPAct and addition of NARM materials and nonmedical uses, such as authorizations under 10 CFR 30.32(j) to medical use licenses, the procedures may have to be supplemented in this Appendix to address the new materials and nonmedical uses.

Model Training Program

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

Note: With the implementation of the EPAct, the NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226. Personnel should be provided new training on the application of the NRC requirements and license conditions to these materials when NRC's waiver of August 31, 2005, is terminated for the medical use facility. The waiver was terminated on November 30, 2007, for Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana. The appropriate NRC Regional Office should be contacted to confirm the waiver termination date for other medical use facilities.

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

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

Training for Individuals Involved in the Medical Usage of Byproduct Material

Training for professional staff (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, *commensurate with their duties*:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA (10 CFR 20.1101);
- Risk estimates, including comparison with other health risks;
- Posting requirements (10 CFR 20.1902);
- Proper use of personnel dosimetry (when applicable);

- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802);
- Proper use of radiation shielding, if used;
- Patient release procedures (10 CFR 35.75);
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Occupational dose limits and their significance (10 CFR 20.1201);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208);
- Worker's right to be informed of occupational radiation exposure (10 CFR 19.13);
- Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12);
- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12);
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11);
- Proper recordkeeping required by NRC regulations (10 CFR 19.12);
- Appropriate surveys to be conducted (10 CFR 20.1501);
- Proper calibration of required survey instruments (10 CFR 20.1501);
- Emergency procedures;
- Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36);
- Dose to individual members of the public (10 CFR 20.1301); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing) (10 CFR 35.27, 10 CFR 30.32(a)(3)).

Training for Individuals Involved in Nonmedical Usage of Byproduct Material

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. Licensees authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to other medical use licensees in the consortium should also provide training on the production of PET radioactive drugs and special requirements in 10 CFR 30.32(j) and 10 CFR 30.34(j) for this activity. All training should be commensurate with the individual's duties.

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

Note: Byproduct material now includes accelerator-produced radionuclides and discrete sources of Ra-226.

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

- Leak testing of sealed sources (10 CFR 35.67);
- Emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Operating instructions (10 CFR 35.27, 10 CFR 35.610);
- Computerized treatment planning system (10 CFR 35.657);
- Dosimetry protocol (10 CFR 35.630);
- Detailed pretreatment quality assurance checks (10 CFR 35.27, 10 CFR 35.610);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410);
- Patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) (10 CFR 35.41);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.410, 10 CFR 35.610);
- Size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610);
- Previous incidents, events, and/or accidents; and

- For remote afterloaders, teletherapy units, and GSR units, initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:

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

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

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

Additional Training for Authorized Medical Physicists

Applicants for licenses to include AMPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 10 CFR 35.51(b)(1). Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of Sr-90 sources used for opthalmic treatments (10 CFR 35.433). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 10 CFR 35.51(c).

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

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, and 10 CFR 35.690, attention should be focused on the additional training and experience necessary for treatment planning and quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in Sections 35.390, 35.490, 35.491, and 35.690 of 10 CFR Part 35.

Training for Ancillary Staff

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

- Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12);

- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12);
- The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12);
- Radiation exposure reports that workers may request, as per 10 CFR 19.13 (10 CFR 19.12).

APPENDIX K

General Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

General Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Model procedures for describing the specifications for monitoring instruments and a program for calibration of survey instruments appear below. Applicants may either adopt these model procedures or adopt alternative procedures.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry, if required.

Equipment Selection

- Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.
- Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.
- Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (Table K.1) (except for items marked with an asterisk (*)), extracted from "The Health Physics & Radiological Health Handbook," Revised Edition, 1992, may be helpful in selecting instruments:

Table K.1 Typical Survey Instruments			
Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	mR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

*Not extracted from source handbook: "The Health Physics and Radiological Handbook," Revised Edition, 1992.

Model Procedure for Calibrating Survey Instruments

This model provides acceptable procedures for survey instrument calibrations. Licensees may either adopt these model procedures or develop their own procedures to meet the requirements of 10 CFR Part 20 and 10 CFR 35.61. (Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute at 25 West 43rd Street, 4th Floor, New York, NY 10036, or by ordering electronically from http://www.ansi.org.)

Procedures for calibration of survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with 10 CFR 35.61. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually, before first use, and after servicing or repairs that affect calibration. (Battery changes are not considered "servicing.") Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source would emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.
- Use a radioactive sealed source(s) that:
  - Approximates a point source;
  - Is a certified, NIST-traceable, standard source that has an activity or exposure rate accurate to within 5%; if the activity or exposure rate is determined by measurement, document the method used to make the determination and traceability to NIST;
  - Emits the type of radiation measured;
  - Approximates the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed; and
  - Provides a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- Use the inverse square and radioactive decay laws, as appropriate, to correct for changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061).
- Before use, perform a daily check (with a dedicated check source) and battery checks.
- Instrument readings should be within ± 10% of known radiation values at calibration points; however, readings within ± 20% are acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters should be calibrated as follows:
  - Calibrate Linear-Readout Instruments at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80%).
  - Calibrate Logarithmic-Readout Instruments at two points on each decade.
  - Calibrate Digital-Readout Instruments with either manual or automatic scale switching for indicating exposure rates at no fewer than two points on each scale. Check calibrations near the ends of each scale (at approximately 20% and 80% of each scale).
  - Calibrate Digital-Readout Instruments without scale switching for indicating exposure rates at two points on each decade.

  - Calibrate Integrating Instruments at two dose rates (at approximately 20% and 80% of the dose rate range).

- Readings above 1000 mR/hr (250 microcoulomb/kilogram of air per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Include in survey meter calibration records the procedure used and the data obtained. Record the following:
  - A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
  - A description of the NIST-traceable calibration source, including the calibration procedure, exposure rate, distance at which it was measured, and date of measurement;
  - For each calibration point, the calculated exposure rate, the indicated exposure rate, the calculated correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
  - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument);
  - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
  - For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument;
  - For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;
  - The exposure rate from a check source, if used;
  - The name of the person who performed the calibration and the date it was performed.
- The following information should be attached to the instrument as a calibration sticker or tag:
  - The source that was used to calibrate the instrument;
  - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);
  - Special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated);
  - The date of calibration and the next calibration due date;
  - The apparent exposure rate from the check source, if used.

Sensitivity of Counting System

Follow the procedures in Appendix Q to determine minimum detectable activity (MDA) if there is a question concerning the ability to measure small quantities of radioactivity.

Determining the Efficiency of NaI(Tl) Uptake Probes

Sodium iodide (thallium doped) [NaI(Tl)] uptake probes are commonly used for bioassays of personnel administering I-131 radionuclides in the form of sodium iodide. Refer to 10 CFR Part 20, Appendix B, for the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, μCi) when performing bioassays to determine thyroid burdens of radioiodines. Use the following procedure to calibrate the probe for uptake measurements:

- Frequency: perform calibrations annually, before first use, and after repairs that affect calibrations;
- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate the efficiency of the instrument.

  For example:

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

  where:

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

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

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

- The due date of the next efficiency test, and
- Results of efficiency calculation(s).

[1]The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and is much less dependent on the counting geometry.

Calculating the Gamma Well Efficiency of Counting Equipment

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

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

  For example,

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

  where:

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

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

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

- The due date of the next efficiency test, and;
- Results of efficiency calculation(s).

Reference: Draft RG FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

APPENDIX L

Model Medical Licensee Audit

This Appendix was originally developed for medical uses only. With implementation of the EPAct and addition of NARM materials and nonmedical uses, such as authorizations under 10 CFR 30.32(j) to medical use licenses, the procedures may have to be supplemented in this Appendix to address the new materials and nonmedical uses.

Model Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Also, the audit notes may not be complete for nonmedical uses authorized on the license. Licensees should review audit lists in other volumes of the NUREG 1556 series and information provided in Appendix AA of this volume, as appropriate, when completing the audit list that is specific to their nonmedical uses (e.g., production of PET radioactive drugs under 10 CFR 30.32(j)).

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, all audits must include these materials after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The waiver was terminated on November 30, 2007, for Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Date of This Audit: _____ Date of Last Audit: _____

Next Audit Date: _____

Auditor: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

All references are to 10 CFR Parts unless noted otherwise.

Audit History

A. Were previous audits conducted annually [20.1101]?

B. Were records of previous audits maintained [20.2102]?

C. Were any deficiencies identified during previous audit?

D. Were corrective actions taken? (Look for repeated deficiencies.)

Organization and Scope of Program

A. Radiation Safety Officer:

1. If the RSO was changed, was the license amended [35.13]?
2. Does the new RSO meet NRC training requirements [35.50, 35.57, 35.59]?

3. If the scope of the program expands, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?
4. Is the RSO fulfilling all duties [35.24]?
5. Is the written agreement in place for a new RSO [35.24(b)]?

B. Multiple places of use? If yes, list locations.

C. Are all locations listed on license? Includes locations of accelerator-produced radioactive materials and discrete sources of radium-226?

D. Were annual audits performed at each location? If no, explain.

E. Describe the scope of the program (staff size, number of procedures performed, etc.).

F. Licensed Material:

1. Isotope, chemical form, quantity, and use as authorized? Includes accelerator-produced radioactive materials and discrete sources of radium-226?
2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is the financial assurance adequate?
3. Calibration, transmission, and reference sources [35.65]?
   a. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicuries each [35.65(a) and (b)]?
   b. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries [35.65(c)]?
   c. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries or 1000 times the quantities in Appendix B of Part 30 [35.65(d)]?
   d. Technetium-99m in individual amounts as needed [35.65(e)]?
4. Unsealed materials used under 10 CFR 35.100, 35.200, and 35.300 are:
   a. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

OR

   b. Obtained from a producer of PET radioactive drugs under 10 CFR 30.32(j)?

OR

   c. Prepared by a physician AU, an ANP, or an individual under the supervision of an ANP or physician AU?

OR

   d. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?

5. Production of PET radioactive drugs
   - Authorized under 10 CFR 30.32(j)?
   - For internal use from licensee's PET radionuclide production facility as authorized in 10 CFR 35.100(b), 35.200(b), or 35.300(b)?

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registry (SSDR) certificate in 10 CFR 32.210, 35.400, 35.500, 35.600? Are copies of (or access to) SSDR certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

H. Are there sealed sources containing accelerator-produced radioactive materials or discrete sources of radium-226 that do not have an SSDR certificate? If the sealed source is not generally licensed or exempt from licensing, seek a license amendment providing information under 10 CFR 32(g)(2) or (3).

I. Are the actual uses of medical devices consistent with the authorized uses listed on the license?

J. If places of use changed, was the license amended [35.13(e)]?

K. If control of the license was transferred or bankruptcy filed, was NRC's prior consent obtained or notification made [30.34(b) and 30.34(h) respectively]?

Radiation Safety Program

A. Minor changes to program [10 CFR 35.26 or license condition for 10 CFR 35.1000 medical uses]?

B. Records of changes maintained for 5 years [35.2026]?

C. Content and implementation reviewed annually by the licensee [20.1101(c)]?

D. Records of reviews maintained [20.2102]?

E. Changes include addition of accelerator-produced radioactive materials or discrete sources of radium-226 to NRC-regulated Radiation Safety Program?

F. Changes include authorization to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium [10 CFR 30.32(j)]?

Use by Authorized Individuals

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

A. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59] (***Note:*** Does not apply to facilities that are registered with FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a) or registered with the State as a drug manufacturer or PET drug production facility with distribution regulated under 10 CFR 32.72):

_____ 1. Certified by specialty board?

_____ 2. Identified on NRC or Agreement State license?

_____ 3. Identified on permit issued by broad-scope or master materials licensee?

_____ 4. Identified on permit issued by master materials permittee of broad scope?

_____ 5. Identified as an ANP by a commercial nuclear pharmacy that has been authorized to identify ANPs?

_____ 6. Designated as an ANP in accordance with 10 CFR 32.72(b)(4)?

_____ 7. Meets requirements in 35.57(a)(3)?

_____ 8. Listed on facility license?

B. Authorized User [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690]:

_____ 1. Certified by specialty board?

_____ 2. Identified on NRC or Agreement State license?

_____ 3. Identified on permit issued by broad-scope or master materials licensee?

_____ 4. Identified on permit issued by master materials permittee of broad scope?

_____ 5. Meets requirements in 35.57(b)(3)?

_____ 6. Listed on facility license?

C. Authorized Medical Physicist [35.51, 35.57, 35.59]:

_____ 1. Certified by specialty board?

_____ 2. Identified on NRC or Agreement State license?

_____ 3. Identified on permit issued by broad-scope or master materials licensee?

_____ 4. Identified on permit issued by master materials permittee of broad scope?

_____ 5. Meets requirements in 35.57(a)(3)?

_____ 6. Listed on facility license?

D. Nonmedical use authorized users [30.33(a)(3)]:

_____ Listed on facility license for same materials and uses?

Mobile Medical Service

A. Operates services per 35.80, 35.647?

B. Compliance with 20.1301 evaluated and met?

C. Letter signed by management of each client [35.80(a)]?

D. Licensed material not delivered to client's address (unless client was authorized) [35.80(b)]?

E. Dosage measuring instruments checked for proper function before use at each address of use or on each day of use, if more frequent [35.80(a)]?

F. Survey instruments checked for proper operation before use at each address of use [35.80(a)]?

G. Survey of all areas of use prior to leaving each client address [35.80(a)]?

H. Additional technical requirements for mobile remote afterloaders per 35.647?

Amendments Since Last Audit [35.13]

A. Any Amendments since last audit [35.13]?

B. Security-related sensitive information was properly marked?

Notifications Since Last Audit [35.14]

A. Any Notifications since last audit [35.14]?

B. Appropriate documentation provided to NRC, for ANP, AMP, or AU, no later than 30 days after the individual starts work [35.14(a), 30.34(j)(4)]?

C. NRC notified within 30 days after: AU, ANP, AMP, 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 for 10 CFR 35.100 or 35.200 use, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from a PET radionuclide production area [35.14(b)]?

Training, Retraining, and Instructions to Workers

A. Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?

B. Have workers been informed of NRC's regulatory authority for accelerator-produced radioactive materials and discrete sources of radium-226?

C. Is the individual's understanding of current procedures and regulations adequate?

D. Is the training program implemented?

1. Operating procedures [35.27, 35.310, 35.410, 35.610]?
2. Emergency procedures [35.27, 35.310, 35.410, 35.610]?
3. Periodic training required and implemented [35.310, 35.410, 35.610]?
4. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [19.12]?
5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [35.27]?
6. Are initial and periodic training records maintained for each individual [35.2310]?

7. Briefly describe training program.

E. Do additional therapy device instructions/training include:

1. Unit operation, inspection, associated equipment, survey instruments?
2. License conditions applicable to the use of the unit?
3. Emergency drills [35.610]?

F. 10 CFR Part 20 – Are workers cognizant of requirements for:

1. Radiation Safety Program [35.24, 35.26, 20.1101]?
2. Annual dose limits [20.1201, 20.1301, 20.1302]?
3. NRC Forms 4 and 5?
4. 10% monitoring threshold [20.1502]?
5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
6. "Grave Danger" Posting [20.1902(c)]?
7. Procedures for opening packages [20.1906]?

G. Is supervision of individuals by AU and/or ANP in accordance with 10 CFR 35.27?

Training for Manual Brachytherapy and Use of Unsealed Byproduct Material for Which a Written Directive Is Required

A. Does safety instruction to personnel include [35.310, 35.410]:

1. Control of patient and visitors?
2. Routine visitation to patients in accordance with 10 CFR 20.1301?
3. Contamination control and size/appearance of sources?
4. Safe handling and shielding instructions?
5. Waste control?
6. RSO and AU notification if patient had a medical emergency or died?
7. Records retained [35.2310]?

Facilities

A. Facilities as described in license application?

B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?

C. Emergency source recovery equipment available [35.415, 35.615]?

D. Storage areas:

1. Materials secured from unauthorized removal or access [20.1801]?

2. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802]?

E. Therapy unit operation:

1. Unit, console, console keys, and treatment room controlled adequately [20.1801, 35.610(a)(1)]?
2. Restricted to certain source orientations and/or gantry angles?
3. Ceases to operate in restricted orientation(s)?
4. Only one radiation device can be placed in operation at a time within the treatment room [35.610(a)(3)]?

Dose or Dosage Measuring Equipment

A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [35.60] or PET radioactive drugs produced by licensee [30.34(j)]:

1. Types of equipment listed?
2. Approved procedures for use of instrumentation followed?
3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., ±10%)?
5. Records maintained and include required information [35.2060]?

B. Determination of dosages of unsealed byproduct material [35.63, 30.34(j)]?

1. Each dosage determined and recorded prior to medical use [35.63(a)]? Or transfer [30.34(j)]?
2. Measurement of unit dosages of photon- or beta-emitting radionuclides made either by direct measurement or by decay correction [35.63(b), 30.34(j)(2)(ii)]?
3. Measurement of unit dosage of alpha-emitting radionuclide by decay correction of the activity provided by the producer licensed in accordance with 10 CFR 32.72 or 30.32(j)?
4. For other than unit dosages of photon- or beta-emitting radionuclides, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [35.63(c), 30.34(j)(2)(ii)]?
5. For other than unit dosages of alpha-emitting radionuclide, measurement made by combination using the activity provided by the producer licensed in accordance with 10 CFR 32.72, or 30.32(j) volumetric measurement, and calculation [35.63(c)]?

C. Licensee uses generators?

1. First eluate after receipt tested for Mo-99 breakthrough [35.204(b)]?

2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [35.204(a)(1)]?
3. First eluate after receipt tested for strontium-82 and strontium-85 when eluting rubidium-82 [35.204(c)]?
4. No radiopharmaceuticals administered with strontium-82 concentrations over 0.02 μCi per mCi of rubidium-82 or strontium-85 concentrations over 0.2 μCi per mCi of rubidium-82 [35.204(a)(2)]?
5. Records maintained [35.2204]?

D. Dosimetry Equipment [35.630]:

1. Calibrated system available for use [35.630(a)]?
2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 10 CFR 35.630(a)(2)?
3. Calibrated within the previous 4 years [35.630(a)(2)]?
4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?
5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

Radiation Protection And Control of Radioactive Material (this now includes accelerator-produced radioactive materials and discrete sources of radium-226)

A. Use of radiopharmaceuticals and production of PET radioactive drugs:

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. Proper use of remote handling tools and radiation shields?

B. Leak tests and inventories:

1. Leak test performed on sealed sources and brachytherapy sources [35.67(b)(1) or leak test license condition]?
2. Inventory of sealed sources and brachytherapy sources performed semiannually [35.67(g)]?
3. Records maintained [35.2067]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with 10 CFR Part 20 and 10 CFR 30.33(a)(2):

1. Appropriate operable survey instruments possessed or available [10 CFR Part 20]?
2. Calibrations [35.61(a) and (b)]:
   a. Before first use, annually, and after repairs?
   b. Within 20% on each scale or decade of interest?
3. Records maintained [35.2061]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [20.1501, 35.70]? If producing PET radioactive drugs under 10 CFR 30.32(j) or 35.100(b), 35.200(b), or 35.300(b), the survey frequencies described below should be reviewed and adjusted as necessary.

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [35.70]?
2. Weekly in all areas where radiopharmaceuticals or waste are stored?
3. Weekly for wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
4. Trigger levels established?
5. Corrective action taken and documented if trigger level exceeded?
6. Techniques can detect 0.1 mR/hr, 2000dpm?
7. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry [35.652(a)] and records maintained [35.2652]?
   a. After new source installation?
   b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose (this now includes dose from accelerator-produced radioactive materials and discrete sources of radium-226)

A. Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year [20.1301(a)(1)]?

B. Has a survey or evaluation been performed per 20.1501(a)?

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 1 hour [20.1301(a)(2)]?

E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [20.1801 and 20.1802]?

F. Are records maintained [20.2103, 20.2107]?

Patient Release

A. Individuals released when TEDE is less than 0.5 rem [35.75(a)]?

B. Instructions to the released individual, including breast-feeding women, include required information [35.75(b)]?

C. Release records maintained [35.2075(a)]?

D. Records of instructions given to breast-feeding women maintained, if required [35.2075(b)]?

Unsealed Byproduct Material for Which a Written Directive Is Required (this now includes written directives for accelerator-produced radioactive materials and discrete sources of radium-226)

A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [35.315(a)]?

B. RSO and AU promptly notified if patient had a medical emergency or died [35.315(b)]?

Brachytherapy or Brachytherapy Source Use

A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [35.415]?

B. Survey immediately after implant [35.404(a)]?

C. Patients surveyed immediately after removing the last temporary implant source [35.404(b)]?

D. RSO and AU promptly notified if patient had a medical emergency or died [35.415(c)]?

E. Records maintained [35.2404]?

Radioactive Waste (this now includes waste containing accelerator-produced radioactive materials and discrete sources of radium-226)

A. Disposal:

1. Decay-in-storage [35.92]?
2. Procedures followed?

3. Labels removed or defaced [20.1904, 35.92]?

B. Special procedures performed as required?

C. Authorized disposals [20.2001]?

D. Records maintained [20.2103(a), 20.2108, 35.2092]?

E. Effluents:

1. Release to sanitary sewer [20.2003]?

a. Material is readily soluble or readily dispersible [20.2003(a)(1)]?

b. Monthly average release concentrations do not exceed 10 CFR Part 20, Appendix B, Table 2 values?

c. No more than 5 Ci of H-3, 1 Ci of C-14, and 1 Ci of all other radionuclides combined, released in a year [20.2003]?

d. Procedures to ensure representative sampling and analysis implemented [20.1501]?

2. Release to septic tanks [20.2003]? Within unrestricted limits [10 CFR Part 20, Appendix B, Table 2]?

3. Waste incinerated?

a. License authorizes [20.2004(a)(3)]?

b. Exhaust directly monitored?

c. Airborne releases evaluated and controlled [20.1302, 20.1501]?

4. Air effluents and ashes controlled [20.1101, 20.1201, 20.1301, 20.1501, 20.2001]? (See also IP 87102, RG 8.37.) If applicable, includes air effluent releases from production of PET radioactive drugs?

a. Air effluent less than 10 mrem constraint limit [20.1101]?

i. If no, reported appropriate information to NRC?

ii. If no, corrective actions implemented and on schedule?

b. Description of effluent program:

i. Monitoring system hardware adequate?

ii. Equipment calibrated, as appropriate?

iii. Air samples/sampling technique (e.g., charcoal, HEPA) analyzed with appropriate instrumentation?

F. Waste storage:

1. Protection from elements and fire?

2. Control of waste maintained [20.1801]?

3. Containers properly labeled and area properly posted [20.1902, 20.1904]?

4. Package integrity adequately maintained?

G. Waste disposal:

1. Sources transferred to authorized individuals [20.2006, 20.2001, 30.41]?
2. Name of organization: _____ .

H. Records of surveys and material accountability maintained [20.2103, 20.2108, 35.2092]?

Receipt and Transfer of Radioactive Material (this now includes receipt and transfer of accelerator-produced radioactive materials and discrete sources of radium-226)

A. Description of how packages are received and by whom?

B. Written package-opening procedures established and followed [20.1906(e)]?

C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [20.1906(b)(1)]?

D. Incoming packages surveyed [20.1906(b)(2)]? When authorized for return, includes "empty" transport radiation shields from other consortium members receiving PET radioactive drugs under 10 CFR 30.32(j) authorization?

E. Monitoring in (C) and (D) performed within time specified [20.1906(c)]?

F. Transfer(s) performed per [30.41]?

G. If authorized under 10 CFR 30.32(j) for production and noncommercial transfer of PET radioactive drugs, all transfers of these drugs for medical use are to medical use licensees within the consortium?

H. All sources surveyed before shipment and transfer [20.1501(a)]?

I. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51]?

J. Package receipt/distribution activities evaluated for compliance with 20.1301?

Transportation (10 CFR 71.5(a) and 49 CFR 171-189)

A. Shipments, including shipments of accelerator-produced radioactive materials and discrete sources of radium-226, and PET radioactive drugs produced for noncommercial transfer to other medical use licensees in the consortium, are:

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

B. Return radiopharmacy doses to drug manufacture or commercial nuclear pharmacy or sealed sources to source or device manufacturer? ***Note:*** Licensees authorized under 10 CFR 30.32(j) for production and noncommercial transfer of PET radioactive drugs are

not authorized to receive unused dosages or empty syringes and vials back from consortium members.

1. Licensee assumes shipping responsibility?
2. 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, Yellow-III) with Transport Index (TI), Nuclide, Activity, and Hazard Class?
4. Properly marked (Shipping Name, UN Number, Package Type, Reportable Quantity, "This End Up" (liquids), Name and Address of consignee)?
5. Closed and sealed during transport?

D. Shipping Papers:

1. Prepared and used?
2. Contain proper entries (Shipping Name; Hazard Class; Identification Number (UN Number); Total Quantity; Package Type; Nuclide; Reportable Quantity; Physical and Chemical Form; Activity; Category of Label; TI; Shipper's Name, Certification and Signature; Emergency Response Telephone Number; "Limited Quantity" (if applicable); "Cargo Aircraft Only" (if applicable))?
3. Readily accessible during transport?

Teletherapy and Gamma Stereotactic Radiosurgery Servicing

A. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [35.655(a)]?

B. Needed service arranged for as identified during the inspection?

C. Service performed by persons specifically authorized to do so [35.655(b)]?

Full Calibration-Therapeutic Medical Devices

A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40)?

B. Performed prior to first patient use [35.632(a)(1), 35.633(a)(1), 35.635(a)(1)]?

C. At intervals not to exceed 1 year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding 1 quarter for HDR, MDR, and PDR remote afterloaders [35.632(a)(3)], 35.633(a)(3) and (4), 35.635(a)(3)]?

D. Whenever spot-checks indicate output differs from expected by ±5% [35.632(a)(2)(i), 35.635(a)(2)(i)]?

E. After source exchange, relocation, and major repair or modification [35.632(a)(2), 35.633(a)(2), 35.635(a)(2)]?

F. Performed with properly calibrated instrument [35.632(c), 35.633(c), 35.635(c)]?

G. Includes:

1. For teletherapy:
   a. Output measured within ±3% of expected for the range of field sizes, range of distances [35.632(b)(1)]?
   b. Coincidence of radiation field and field light localizer [35.632(b)(2)]?
   c. Uniformity of radiation field and beam angle dependence [35.632(b)(3)]?
   d. Timer accuracy and linearity over the range of use [35.632(b)(4)]?
   e. On-off error [35.632(b)(5)]?
   f. Accuracy of all measuring and localization devices [35.632(b)(6)]?
2. For remote afterloaders:
   a. Output measured within ±5% of expected [35.633(b)(1)]?
   b. Source positioning accuracy within ±1 millimeter [35.633(b)(2)]?
   c. Source retraction with backup battery upon power failure [35.633(b)(3)]?
   d. Length of source transfer tubes [35.633(b)(4)]?
   e. Timer accuracy and linearity over the typical range of use [35.633(b)(5)]?
   f. Length of the applicators [35.633(b)(6)]?
   g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [35.633(b)(7)]?
   h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [35.633(e)]?
3. For gamma stereotactic radiosurgery:
   a. Output measured within ±3% of expected [35.635(b)(1)]?
   b. Helmet factors [35.635(b)(2)]?
   c. Isocenter coincidence [35.635(b)(3)]?
   d. Timer accuracy and linearity over the range of use [35.635(b)(4)]?
   e. On-off error [35.635(b)(5)]?

f. Trunnion centricity [35.635(b)(6)]?

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [35.635(b)(7)]?

h. Helmet microswitches [35.635(b)(8)]?

i. Emergency timing circuit [35.635(b)(9)]?

j. Stereotactic frames and localizing devices (trunnions) [35.635(b)(10)]?

H. Output corrected mathematically for decay [35.632(e), 35.633(g), 35.635(e)]?

I. Records maintained [35.2632]?

Periodic Spot Checks For Therapeutic Devices

A. Performed at required frequency [35.642(a), 35.643(a), 35.645(a)]?

B. Procedures established by AMP [35.642(b), 35.643(b), 35.645(b)]?

C. Procedures followed?

D. Medical physicist reviews results within 15 days [35.642(c), 35.643(c), 35.645(b)]?

E. Performed with properly calibrated instrument [35.642(a)(5), 35.645(c)(2)(i)]?

F. Output and safety spot checks include:

1. For teletherapy:

a. Timer accuracy and linearity over the range of use [35.642(a)(1)]?

b. On-off error [35.642(a)(2)]?

c. Coincidence of radiation field and field light localizer [35.642(a)(3)]?

d. Accuracy of all measuring and localization devices [35.642(a)(4)]?

e. The output for one typical set of operating conditions [35.642(a)(5)]?

f. Difference between measured and expected output [35.642(a)(6)]?

g. Interlock systems [35.642(d)(1)]?

h. Beam stops [35.642(d)(2)]?

i. Source exposure indicator lights [35.642(d)(3)]?

j. Viewing and intercom systems [35.642(d)(4)]?

k. Treatment room doors, inside and out [35.642(d)(5)]?

l. Electrical treatment doors with power shut off [35.642(d)(6)]?

2. For remote afterloaders:

a. Interlock systems [35.643(d)(1)]?

b. Source exposure indicator lights [35.643(d)(2)]?

c. Viewing and intercom systems, except for low dose-rate (LDR) [35.643(d)(3)]?

d. Emergency response equipment [35.643(d)(4)]?

e. Radiation monitors used to indicate source position [35.643(d)(5)]?

f. Timer accuracy [35.643(d)(6)]?

g. Clock (date and time) in the unit's computer [35.643(d)(7)]?

h. Decayed source(s) activity in the unit's computer [35.643(d)(8)]?

3. For gamma stereotactic radiosurgery:

a. Treatment table retraction mechanism [35.645(c)(1)(i)]?

b. Helmet microswitches [35.645(c)(1)(ii)]?

c. Emergency timing circuits [35.645(c)(1)(iii)]?

d. Stereotactic frames and localizing devices [35.645(c)(1)(iv)]?

e. The output for one typical set of operating conditions [35.645(c)(2)(i)]?

f. Difference between measured and expected output [35.645(c)(2)(ii)]?

g. Source output compared against computer calculation of output [35.645(c)(2)(iii)]?

h. Timer accuracy and linearity over the range of use [35.645(c)(2)(iv)]?

i. On-off error [35.645(c)(2)(v)]?

j. Trunnion centricity [35.645(c)(2)(vi)]?

k. Interlock systems [35.645(d)(1)]?

l. Source exposure indicator lights [35.645(d)(2)]?

m. Viewing and intercom systems [35.645(d)(3)]?

n. Timer termination [35.645(d)(4)]?

o. Radiation monitors used to indicate room exposures [35.645(d)(5)]?

p. Emergency off buttons [35.645(d)(6)]?

G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [35.642(e), 35.643(e), 35.645(f)]?

H. Records maintained [35.2642, 35.2643, 35.2645]?

Installation, Maintenance, and Repair of Therapy Devices

A. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [35.605, 35.655]? Name of organization/individual.

B. Records maintained [35.2605, 35.2655]?

Operating Procedures For Therapy Devices

A. Instructions on location of emergency procedures and emergency response telephone numbers posted at the device console [35.610(c)]?

B. Copy of the entire procedures physically located at the device console [35.610(b)]?

C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [35.610(a)(4)]?
2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [35.610(a)(4)]?
3. The names and telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally [35.610(a)(4)]?

D. Radiation survey of patient is performed to ensure source is returned to shielded position [35.604(a)]?

E. Records of radiation surveys maintained for 3 years [35.2404]?

F. AMP and AU:

1. Physically present during initiation of patient treatment with remote afterloaders? (***Note:*** for MDR and PDR, an appropriately trained physician under the supervision of the AU may be physically present instead of the AU) [35.615(f)(1) and (2)].
2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [35.615(f)(3)]?

Personnel Radiation Protection (this now includes exposures from accelerator-produced radioactive materials and discrete sources of radium-226)

A. Exposure evaluation performed [20.1501]? Includes evaluation for uses of accelerator-produced radioactive materials and discrete sources of radium-226?

B. ALARA program implemented [20.1101(b)]?

C. External Dosimetry:

1. Monitors workers per [20.1502(a)]? Includes workers using or working near accelerator-produced radioactive materials and discrete sources of radium-226?
2. External exposures account for contributions from airborne activity [20.1203]?
3. Supplier _____ Frequency _____
4. Supplier is NVLAP-approved [20.1501(c)]?
5. Dosimeters exchanged at required frequency?

D. Internal Dosimetry:

1. Monitors workers per 20.1502? Includes workers using or working near accelerator-produced radioactive materials and discrete sources of radium-226?
2. Program for monitoring and controlling internal exposures [20.1701, 20.1702] briefly described?
3. Monitoring/controlling program implemented (includes bioassays)?
4. Respiratory protection equipment [20.1703]?

E. Review of Records and Reports:

1. Reviewed by _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses [20.2104]?
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organs _____
6. Maximum CEDE
7. Internal and external summed [20.1202]?
8. Occupational limits met [20.1201]?
9. NRC forms or equivalent [20.2104(d), 20.2106(c)]?
   a. NRC-4 Complete:
   b. NRC-5 Complete:
10. If a worker declared her pregnancy during the audit period, was the dose in compliance [20.1208] and were the records maintained [20.2106(e)]?

F. Any planned special exposures (number of people involved and doses received) [20.1206, 20.2104, 20.2105, 20.2204]?

G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 20.2103, 20.2106]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events, including those with accelerator-produced radioactive materials and discrete sources of radium-226, [criteria in 35.3045] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

1. Event date _____ Information Source
2. Notifications:

   NRC Ops Center NRC Region

   Referring Physician Patient

   In writing/By telephone

   If notification did not occur, why not?
3. Written Reports [35.3045]: Submitted to Region within 15 days?

Notification and Reports (this now includes notifications and reports for accelerator-produced radioactive materials and discrete sources of radium-226)

A. In compliance with 10 CFR 19.13, and 10 CFR 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?

B. In compliance with 10 CFR 20.2201, and 10 CFR 30.50 (theft or loss)?

C. In compliance with 10 CFR 20.2202, and 10 CFR 30.50 (incidents)?

D. In compliance with 10 CFR 20.2203, and 10 CFR 30.50 (overexposure and high radiation levels)?

E. Aware of NRC Operations Center telephone number?

F. In compliance with 10 CFR 20.2203 (constraint on air emissions)?

Posting and Labeling

A. NRC Form 3, "Notice to Workers" is posted [19.11]?

B. 10 CFR Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to 10 CFR Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6]?

C. Other posting and labeling per 10 CFR 20.1902, 20.1904, and not exempted by 20.1903, 20.1905?

Recordkeeping for Decommissioning (this now includes records for accelerator-produced radioactive materials and discrete sources of radium-226 produced before, on, or after the August 8, 2005 EPAct).

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)]?

B. Records include all information outlined in 10 CFR 30.35(g)?

Bulletins and Information Notices

A. Bulletins, Information Notices, NMSS Newsletters, etc., received?

B. Appropriate action in response to Bulletins, Generic Letters, etc.?

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

1. If authorized for the production and noncommercial distribution of PET radioactive drugs under 10 CFR 30.32(j), review the program for conformance with the requirements in 10 CFR 30.34(j).
2. If authorized for 10 CFR 35.1000 medical uses, review the program for conformance with license application commitments, license conditions, and regulations.
3. Other

B. Evaluation.

Audits and Findings

A. Summary of findings.

B. Corrective and preventive actions.

APPENDIX M

Model Procedures for an Occupational Dose Program

Model Procedures for an Occupational Dose Program

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, after NRC's waiver of August 31, 2005, is terminated for medical use facilities, occupational dose programs must also include occupational doses to workers if they are only exposed to the radiation from these materials. Previously, the dose from these materials was only included for NRC purposes if the worker was exposed to radiation from NRC-regulated materials which excluded NARM materials. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for an external occupational dose program and references for developing an internal occupational dose program. Applicants may either adopt these model procedures for an external occupational dose program or develop alternative procedures to meet the requirements of 10 CFR 20.1101 and Subparts C and F of 10 CFR Part 20. The model includes guidance as well as a discussion of regulatory requirements that are to be reflected in the elements of an occupational dose program.

"Dosimetry" is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 10 CFR 20.1502(a). The occupational dose limits for adults are provided in 10 CFR 20.1201, while 10 CFR 20.1502 provides, in part, that adults likely to receive in 1 year a dose in excess of 10 percent of those dose limits must be provided with dosimetry. Definitions of relevant terms such as Total Effective Dose Equivalent (TEDE), deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in 10 CFR 20.1003, "Definitions." In addition, if monitoring is required pursuant to 10 CFR 20.1502, each licensee shall maintain records of doses received (see 10 CFR 20.2106), and individuals must be informed of their doses on at least an annual basis (see 10 CFR 19.13(b)).

If an individual, including an individual only exposed to accelerator-produced radioactive materials or discrete sources of radium-226 or radiation from these materials, is likely to receive more than 10% of the annual dose limits, the NRC requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his/her dose.

The As-Low-As-Reasonably-Achievable "ALARA" Program

Section 10 CFR 20.1101 states that "each licensee shall develop, document, and implement a Radiation Protection Program commensurate with the scope and extent of licensed activities..." and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Additionally,

10 CFR 20.1101 requires that licensees periodically review the content of the Radiation Protection Program and its implementation.

External Exposure

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.

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

There are three dose limits included in 10 CFR 20.1201 that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in 10 CFR 20.1003, the DDE to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Under 10 CFR 20.1502(a), the use of individual monitoring devices is required for the following:

- Adults likely to receive, in 1 year, from sources external to the body, a dose in excess of 10% of the occupational dose limits in 10 CFR 20.1201(a). Monitoring devices are accordingly required for adults with an annual dose in excess of:
  - 0.5 rem (0.005 Sv) DDE,
  - 1.5 rem (0.015 Sv) eye dose equivalent,
  - 5 rem (0.05 Sv) shallow-dose equivalent to the skin,
  - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of:
  - 0.1 rem (1.0 mSv) DDE,
  - 0.15 rem (1.5 mSv) eye dose equivalent,
  - 0.5 rem (5 mSv) shallow-dose equivalent to the skin, or
  - 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.
- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.
- Individuals entering a high- or a very-high-radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, including those working with or near accelerator-produced radioactive materials or discrete sources of radium-226, it must be demonstrated that doses will not exceed

10% of the applicable limits. In these cases, the NRC does not require licensees to monitor radiation doses for this class of worker.

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

- Prior Experience: Reviews of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% 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);
- The licensee performs a reasonable calculation, based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters, or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by 10 CFR 20.1501.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (10 CFR 20.1201(c)). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly nonuniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

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

Under 10 CFR 20.2106, individual monitoring must be recorded on NRC Form 5 or equivalent. The Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the Radiation Protection Program, it is important that users return dosimeters on time. Licensees should be vigorous in their effort to

recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record in order to demonstrate compliance with occupational dose limits in 10 CFR 20.1201. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does nonroutine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

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

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

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table M.1 (i.e., 10% of the annual limit for occupational exposure), 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. When the cumulative annual exposure exceeds Investigational Level II in Table M.1 (i.e., 30% of the annual limit for occupational exposure), 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.

Table M.1 Investigational Levels

Part of Body	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
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, knees, legs below the knee, or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record on NRC Form 5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table M.1 are reached:

- Personnel dose less than Investigational Level I.

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

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

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

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

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

- Reestablishment of Investigational Level II to a level above that listed in Table M.1.

Declared Pregnancy and Dose to Embryo/Fetus

Section 10 CFR 20.1208 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). This includes exposure to accelerator-produced radioactive materials or discrete sources of radium-226 or radiation from these materials. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

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

References:

- Methods for calculating the radiation dose to the embryo/fetus can be found in Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus."
- NUREG/CR-5631, PNL-7445, Rev. 2, "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses" (1996).

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material, including accelerator-produced radioactive materials or discrete sources of radium-226, 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 (10 CFR 20.1502). Terms for radionuclide intakes by means of inhalation and ingestion (i.e., derived air concentration (DAC) and ALI) are provided in 10 CFR Part 20.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in μCi/ml that, if an occupational worker were to be continuously exposed to it for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in Appendix B of 10 CFR Part 20.

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

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The ALI and DAC numbers in 10 CFR Part 20 reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole-body risk-weighted "effective dose." Per 10 CFR Part 20, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

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

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

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

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," dated July 1993; Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," dated July 1992; and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.2106. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data." Because these documents were developed before the EPAct, they may not include examples or values for all accelerator-produced radioactive materials or discrete sources of Ra-226 that NRC now regulates.

Summation of External and Internal Doses

Pursuant to 10 CFR 20.1202, the external and internal doses must be summed if required to monitor both under 10 CFR 20.1502.

Two documents that contain helpful information regarding occupational doses are:

- NRC Regulatory Issue Summary 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," and
- NRC Regulatory Issue Summary 2002-10, "Revision of Skin Dose Unit in 10 CFR Part 20."

Copies of Regulatory Issue Summaries are available on the NRC Web site in the Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/.

APPENDIX N

Model Emergency Procedures

This Appendix was originally developed for medical uses only. With implementation of the EPAct and addition of NARM materials and nonmedical uses, such as authorizations under 10 CFR 30.32(j) to medical use licenses, the procedures may have to be supplemented in this Appendix to address the new materials and nonmedical uses.

Model Emergency Procedures

Model Spill/Contamination, Emergency Surgery, and Autopsy Procedures

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, after NRC's waiver of August 31, 2005, is terminated for medical use facilities, procedures for responding to spills, emergency surgery, and autopsies must also include responses when accelerator-produced radioactive materials and discrete sources of radium-226 are involved. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Model Spill/Contamination Procedures – Low- and High-Dose Unsealed Sources (this now includes spills of and contamination from accelerator-produced radioactive materials or unsealed discrete sources of radium-226)

This model provides acceptable procedures for responding to medical use emergencies. This model does not address responding to emergencies associated with the production of PET radioactive drugs and their transfer. Applicants may either adopt this model or develop alternative procedures to meet the requirements of 10 CFR 20.1101. A medical use applicant that will produce PET radioactive drugs may need to supplement these model procedures to meet the requirements in 10 CFR 20.1101.

Minor Spills of Liquids and Solids (this now includes spills of and contamination from accelerator-produced radioactive materials or discrete sources of radium-226)

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wear gloves and protective clothing such as a lab coat and booties, and clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a bag labeled "caution radioactive material" for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids (this now includes spills of or contamination from accelerator-produced radioactive materials or discrete sources of radium-226)

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

2. Prevent the spread of contamination by covering the spill with absorbent paper labeled "caution radioactive material," but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

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

For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill/contamination procedure may be to restrict access pending complete decay.

Note: A report to NRC may be required pursuant to 10 CFR 30.50.

Use Table N.1 as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. All spills/contaminations of radium-226 will be considered major spills.

Table N.1 Relative Hazards of Common Radionuclides

Radionuclide	Millicurie	Radionuclide	Millicurie
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	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Estimate the amount of radioactivity spilled. Initiate a major or minor spill/contamination procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor. Spills involving curie quantities of PET radionuclides should initially be considered major spills; either downgrade to a minor spill after decay or restrict access pending complete decay.

Spill/Contamination Kit

Assemble a spill/contamination kit that may contain the following items:

- Disposable gloves and housekeeping gloves,
- Disposable lab coats,
- Disposable head coverings,
- Disposable shoe covers,
- Roll of absorbent paper with plastic backing,
- Masking tape,
- Plastic trash bags with twist ties,
- "Radioactive Material" labeling tape,
- Marking pen,
- Pre-strung "Radioactive Material" labeling tags,
- Contamination wipes,
- Instructions for "Emergency Procedures,"
- Clipboard with copy of Radioactive Spill Report Form,
- Pencil, and
- Appropriate survey instruments, including batteries.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides (this now includes therapeutic amounts of accelerator-produced radioactive materials or any discrete sources of radium-226)

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 staff 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 (this now includes therapeutic amounts of accelerator-produced radioactive materials or any discrete sources of radium-226)

The following procedures should be followed:

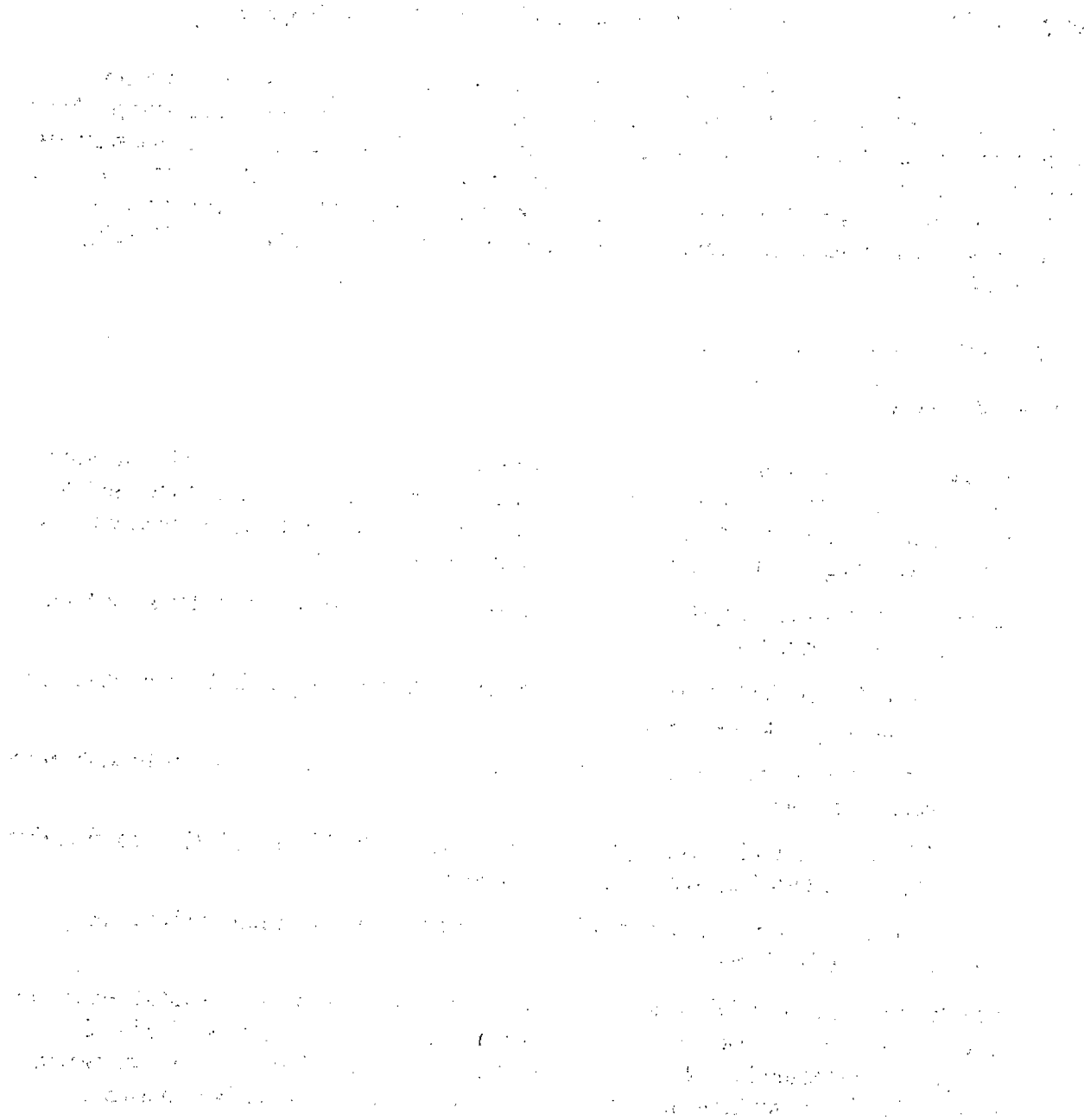
1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
3. Protective eye wear 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 P-32 and Y-90.
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.

References: NRCP 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.

APPENDIX O

Model Procedures for Ordering and Receiving Packages

This Appendix was originally developed for medical uses only. With the implementation of the EPAct and the addition of NARM materials and nonmedical uses, such as authorizations under 10 CFR 30.32(j) to medical use licenses, the procedures in this Appendix may have to be supplemented to address the new materials and nonmedical uses.



Model Procedures for Ordering and Receiving Packages

This model provides acceptable procedures for ordering and receiving packages containing licensed material. As a result of the EPAct, licensed materials now include accelerator-produced radioactive materials and discrete sources of radium-226. A medical use applicant that requests authorization for the production and noncommercial transfer of PET radioactive drugs may need to supplement these model procedures by developing procedures for filling orders for these drugs from other consortium members, to meet the requirements in 10 CFR 30.41, 30.32(j), and 30.34(j).

Applicants may either adopt this model or develop alternative procedures.

Model Guidance

- Authorize, through a designee (e.g., RSO), each order of radioactive materials, including orders of accelerator-produced radioactive materials and discrete sources of radium-226, and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.
- Establish and maintain a system for ordering and receiving radioactive material; include the following information:
  - Records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier;
  - Confirmation, through the above records, that material received was ordered through proper channels.
  - When ordering PET radioactive drugs produced under 10 CFR 30.32(j), confirm that the medical use licensee is a member of the consortium.
- For deliveries during normal working hours, tell carriers to deliver radioactive packages directly to a specified area.
- For deliveries during off-duty hours, tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Room ___. Unlock the door, place the package on top of the counter, and relock the door.

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

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

	Name	**Home Telephone**
Radiation Safety Officer:		
Director of Nuclear Medicine:		
Nuclear Medicine Technologist Supervisor:		
Nuclear Medicine Technologist on call		
(call/page operator at extension _____)		
Nuclear Medicine Physician on call		
(call/page operator at extension _____)		

APPENDIX P

Model Procedure for Safely Opening Packages Containing Radioactive Material

Model Procedure for Safely Opening Packages Containing Radioactive Material

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, after NRC's waiver of August 31, 2005, is terminated for medical use facilities, all procedures for the safe opening of packages containing radioactive materials must also be used for packages containing accelerator-produced radioactive materials and discrete sources of radium-226. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of 10 CFR 20.1906.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in Table A.1 of 10 CFR Part 71. Such packages must be received expeditiously when the carrier offers them for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of 10 CFR 20.1906(c). The appropriate NRC Regional Office and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) and
- External radiation levels exceed the limits of 10 CFR 71.47.

Model Procedure

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and immediately notify the RSO (or the designee of the RSO if the RSO is not present).
3. Monitor the external surfaces of a labeled[1] package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10 CFR 71.4.
4. Monitor the external surfaces of a labeled[1] package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A to 10 CFR Part 71.

[1]Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations.

5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.
9. Check the integrity of the final source container. Notify the RSO (or the RSO's designee) of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. ***Note:*** *a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.
11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. Make a record of the receipt.

For packages received under the general license in 10 CFR 31.11, implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO (or the RSO's designee) immediately.
2. Check to ensure that the material received is the material that was ordered.

For "empty" transport radiation shields being returned from consortium members, implement the following procedure for opening each package:

1. Monitor the package for radioactive contamination .
2. Visually inspect the contents to ensure that the transport radiation shield is empty. Notify the RSO if the transport radiation shield is not empty.

APPENDIX Q

Model Leak Test Program

Model Leak Test Program

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, all leak test procedures must also be applied to these materials used after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting or alpha-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μCi) of radioactivity.

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

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Number each container to correlate information for each source.
- Wear gloves.
- Put each Ra-226 sealed source into a separate small, gas-tight container with activated carbon or two cotton filters.
- Leave source in airtight container for 24 hours.
- Remove source.
- Close container.
- Measure immediately the activity of the Absorber. (See "Model Procedure for Analysis of Gaseous Emanation and Leak Test" below for: how to analyze the absorber, required records, leakage determination, and required response to a leaking source.)

- If activity corresponds to less than 1 nanocurie of radon or daughter products, the source is considered leak-free.

Model Procedure for Performing Leak Testing (on all sealed sources except individual Ra-226 sealed sources)

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.

Model Procedure for Analysis of Gaseous Emanation and Leak Test (for all sources)

- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) should be determined. The MDA may be determined using the following formula:

$$MDA = \frac{3 + 4.65(bkg/t)^{1/2}}{E}$$

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

For example:
where:
bkg = 200 cpm
E = 10%, or 0.1
t = 2 minutes

$$MDA = \frac{3 + 4.65(200 \text{ cpm}/2 \text{ minutes})^{1/2}}{(0.1)}$$
$$= 495 \text{ dpm}$$

- Calculate efficiency of the instrument.

  For example,

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

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

- Analyze each wipe (or absorber for a Ra-226 sealed source) sample to determine net count rate.
- For each sample, calculate the activity in microcuries and record.
- The activity on the wipe (or absorber) sample is given by:

$$\frac{[(cpm\ from\ wipe\ sample) - (cpm\ from\ bkg)]}{(Eff\ in\ cpm/microcuries)}$$

$$= activity\ on\ wipe\ sample\ in\ microcuries$$

- Leak test records (which include the gaseous emanation test) will be retained in accordance with 10 CFR 35.2067 or standard license condition for 3 years. Licensees should include the following in records:
  - The model number and serial number (if assigned) of each source tested;
  - The identity of each source radionuclide and its estimated activity;
  - The measured activity of each test sample expressed in microcuries;
  - A description of the method used to measure each test sample;
  - The date of the test; and
  - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005μCi) [or 37 Bq (1 nano Ci) of radon] or greater:
  - Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired in accordance with the requirements in 10 CFR Parts 20 and 30 [10 CFR 35.67 or standard license condition].
  - File a report within 5 days of the leak test in accordance with 10 CFR 35.3067 or standard license condition.

APPENDIX R

Model Procedure for Area Surveys

This Appendix was originally developed for medical uses only. With the implementation of the EPAct and the addition of NARM materials and nonmedical uses, such as authorizations under 10 CFR 30.32(j) to medical use licenses, the procedures in this Appendix may have to be supplemented to address the new materials and nonmedical uses.

Model Procedure for Area Surveys

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, after NRC's waiver of August 31, 2005, is terminated for medical use facilities, all procedures for area surveys must also be used for surveying areas where accelerator-produced radioactive materials and discrete sources of radium-226 are (were) present. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for medical use area surveys. This model addresses some, but not all, area survey procedures associated with the production of PET radioactive drugs and their transfer or with other nonmedical uses. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70. A medical use applicant that will produce or transfer PET radioactive drugs or have other nonmedical uses may need to supplement the model procedures for those activities to meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1501. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

Ambient Radiation Level Surveys (this now includes surveys for accelerator-produced radioactive materials or discrete sources of radium-226)

Procedures for ambient radiation level surveys (reference 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70):

- Perform surveys of dose rates in locations where:
  - Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
  - An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- Section 10 CFR 20.1301 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 1 hour. Appropriate surveys will be conducted to ensure that the requirements of 10 CFR 20.1301 are met. ***Note:*** As a result of the EPAct, licensed operations now include the possession and use of accelerator-produced radioactive materials and discrete sources of radium-226.
- 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 μCi).

— Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μCi at a time).

— Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

— Survey quarterly all sealed-source and brachytherapy-source storage areas.

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

Table R.1 Ambient Dose Rate Trigger Levels

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

Contamination Surveys (this now includes surveys for accelerator-produced radioactive materials or discrete sources of radium-226)

Facilities and equipment for contamination surveys:

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

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

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of materials, including unsealed accelerator-produced radioactive materials or unsealed discrete sources of radium-226, are used:

  — To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;

  — After any spill or contamination event;

  — When procedures or processes have changed;

  - To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
  - In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly; and
  - In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables R.2 for restricted areas and R.3 for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:
  - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
  - Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries at a time).
  - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.
- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted areas are presented in Table R.2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table R.2 Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)

Area, clothing	alpha emitters	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	200	2000	20000

Table R.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)			
Nuclide[1]	**Average[2, 3, 6]**	**Maximum[2, 4, 6]**	**Removable[2, 5, 6]**
I-125, I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000	15000	1000
Ra-226	100	300	20

[1] Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

[2] As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] Measurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[4] The maximum contamination level applies to an area of not more than 100 cm^2.

[5] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

[6] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables R.1 and R.2:

Alternate action levels for cleanup of contamination in restricted areas may be developed without prior NRC approval if:

- acceptable unrestricted area trigger levels are implemented (e.g., Tables R.1 and R.3);
- the action levels maintain occupational doses ALARA; and
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

Alternate Survey Frequency

A sample alternate survey frequency is described below using Tables R.4, R.5, and R.6. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Table R.4 Isotope Groups	
Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-230 Pa-231 Pu-238 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252 Ra-226
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 (13 y) Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230
Group 3	Be-7 C-14 F-18 Na-24 C1-38 Si-31 P-32 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-31m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-31 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171 Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-l91 Pt-193 Pt-197 Au-196 Au-198 Au-l99 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222
Group 4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-9lm Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m

Table R.5 Classification of Laboratories for Alternate Survey Frequency			
	Survey Frequency Category		
Group	Low	Medium	High
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day.

Proportional fractions are to be used for more than one isotope.

Table R.6 Modifying Factors for Alternate Survey Frequency	
Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of nonoccupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

Contents of Survey Records

- A diagram of the area surveyed,
- A list of items and equipment surveyed,
- Specific locations on the survey diagram where wipe tests were taken,
- Ambient radiation levels with appropriate units,
- Contamination levels with appropriate units,
- Make and model number of instruments used,
- Background levels, and
- Name of the person making the evaluation and recording the results and date.

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

APPENDIX S

Model Procedures for Developing, Maintaining, and Implementing Written Directives

Model Procedures for Developing, Maintaining, and Implementing Written Directives

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the requirements for written directives and procedures to assure that administrations are in accordance with these written directives also apply to the medical use of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for administrations that require written directives (WDs). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of 10 CFR 35.40 and 10 CFR 35.41.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 10 CFR 35.41 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in 10 CFR 35.40 and be retained in accordance with 10 CFR 35.2040.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt.

Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials, including the administration of accelerator-produced radioactive materials and discrete sources of radium-226, can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each such modality for which 10 CFR 35.40 requires, or would require, a WD (as defined in 10 CFR 35.2), the licensee should develop, implement, and maintain written procedures to meet the requirements and/or objectives of 10 CFR 35.40, 35.41, and 35.63, outlined below:

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

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide, Including Doses or Dosages of Accelerator-Produced Radioactive Materials and Discrete Sources of Radium-226, or Any Dosage of Quantities Greater than 30 Microcuries of I-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of 10 CFR 35.40 and 10 CFR 35.41:

- An AU must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.
- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an

appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources (this now includes sources containing accelerator-produced radioactive materials or discrete sources of radium-226)

Licensees are required under 10 CFR 35.40 and 10 CFR 35.41 to have WDs for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.

B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

C. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

   1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
   2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
   3. For manually-generated dose calculations, verifying:
      a. No arithmetical errors;
      b. Appropriate transfer of data from the WD, treatment plan, tables, and graphs;
      c. Appropriate use of nomograms (when applicable); and
      d. Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

D. After implantation but before completion of the procedure: record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by 10 CFR 35.40(b)(6). For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The WD may be maintained in the patient's chart.

E. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

F. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:

1. An individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630); or
2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.

G. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

H. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

I. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

J. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive (this now includes administrations of accelerator-produced radioactive materials or discrete sources of radium-226)

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

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

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

Reports of Medical Events (this now includes reports of events involving accelerator-produced radioactive materials or discrete sources of radium-226)

Notify by telephone the NRC Operations Center[1] no later than the next calendar day after discovery of a medical event and submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. Also notify the referring physician and the patient as required by 10 CFR 35.3045.

[1]The commercial telephone number of the NRC Operations Center is (301) 816-5100. The Center will accept collect calls.

APPENDIX T

Model Procedures for Safe Use of Unsealed Licensed Material

This Appendix was originally developed for medical uses only. With the implementation of the EPAct and the addition of NARM materials and nonmedical uses, such as authorizations under 10 CFR 30.32(j) to medical use licenses, the procedures in this Appendix may have to be supplemented to address the new materials and nonmedical uses.

Model Procedures for Safe Use of Unsealed Licensed Material

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the procedures for the safe use of unsealed licensed material also apply to the medical use of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for safe use of unsealed licensed material used for medical uses. This model addresses some of the procedures for the safe use of unsealed licensed material associated with the production of PET radioactive drugs and their transfer or with other nonmedical uses.

Applicants may either adopt this model procedure or develop their own procedure. If applicants will produce PET radioactive drugs for transfer under 10 CFR 30.32(j) or are authorized for other nonmedical uses, they may need to supplement this model procedure that was developed for medical use for those activities. (Some of the health physics practices listed below may also apply to sealed sources.)

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.

- Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey with a radiation detection survey meter all areas of licensed material use (which now includes use of accelerator-produced radioactive materials or discrete sources of radium-226), including the generator storage, kit preparation, and injection areas, daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 10 CFR 35.70 (except when administering therapy dosages in patients' rooms when patients are confined).
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904.
- Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to Part 20, the syringe or vial need only be labeled to identify the radioactive drug (10 CFR 35.69). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63).
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an AU.
- When measuring the dosage, licensees need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a WD, the patient's identity must be verified and the administration must be in accordance with the WD (10 CFR 35.41).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material, including accelerator-produced radioactive materials and discrete sources of radium-226, when not under the constant surveillance and immediate control of an individual authorized under the NRC license (or such individual's designee).

APPENDIX U

Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the procedures for releasing patients administered radioactive materials also apply to the medical administration of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Section 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material," of 10 CFR Part 35, "Medical Use of Byproduct Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)." ***Note:*** As a result of the EPAct, byproduct material now includes accelerator-produced radioactive materials and discrete sources of radium-226.

In this Appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Release Equation

The activity at which patients could be released was calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides." This report uses the following equation to calculate the exposure until time t at a distance r from the patient:

Equation U.1:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_P\,(1 - e^{-0.693t/T_P})}{r^2}$$

where:
- D(t)= Accumulated exposure at time t, in roentgens
- 34.6= Conversion factor of 24 hrs/day times the total integration of decay (1.44)
- Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
- Q_0 = Initial activity of the point source in millicuries, at the time of the release
- T_p = Physical half-life in days
- r = Distance from the point source to the point of interest, in centimeters
- t = Exposure time in days.

This Appendix uses the NCRP equation (Equation U.1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1\text{-}e^{-0.693t/Tp})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A of Table U.5 in this Appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation U.1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation U.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E, of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation U.2:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (0.25)}{(100\ cm)^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation U.3:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1)}{(100\ cm)^2}$$

Equations U.2 and U.3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see "Internal Dose," of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Item U.1.1, "Release of Patients Based on Administered Activity."

U.1 Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements. As a result of the EPAct, the unsealed byproduct material or implants now include accelerator-produced radioactive materials or discrete sources of radium-226.

U.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table U.1. The activities in Table U.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is approximately equal to the external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Item U.3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table U.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table U.1. In this case, 10 CFR 35.75(c) requires a record because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table U.1 were calculated using either Equation U.2 or U.3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table U.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation U.2 or U.3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table U.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table U.1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Items U.2.2 and U.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

U.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table U.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U.1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table U.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisieverts (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation U.2 or U.3, as appropriate, because the dose rate at 1 meter is equal to Γ Q / 10,000 cm^2.

U.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisievert (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table U.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table U.1 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	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
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Footnotes for Table U-1

† The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Item U.3.1, "Records of Release," for information on records.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

U.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. Licensees may either adopt these model instructions or develop their own instructions to meet the requirements of 10 CFR 35.75.

U.2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released.[1] Column 1 of Table U.2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table U.2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Item U.2.2, "Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release").

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table U.2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation U.2 or U.3, as appropriate, may be used.

U.2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.[1] The purpose of the instructions (e.g., on interruption or discontinuation) is

[1]NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table U.3 was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table U.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table U.3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table U.3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (see Reference).

U.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to U.2.3.1 and U.2.3.2).

Table U.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5

Table U.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release* *(continued)*				
Radionuclide	**COLUMN 1 Activity Above Which Instructions Are Required**		**COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required**	
	(GBq)	**(mCi)**	**(mSv/hr)**	**(mrem/hr)**
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

Footnotes for Table U.2

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The values for activity were calculated using Equations U.2 or U.3 and the physical half-life. The values given in SI units (gigabecquerel values) were using conversion factors.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

Table U.3 Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding an Infant or Child

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 MBq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.3	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell *In Vivo* Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell *In Vitro* Labeling	1000	30	6000	150	

Table U.3 Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding an Infant or Child *(continued)*

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
Tc-99m Sulfur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

Footnotes for Table U.3

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

U.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, the NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in providing detailed instructions and recommendations.

U.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for_____days.

- Stay at a distance of _____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
  - — Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
  - — Place the container with the seed or pellet in a location away from people.
  - — Notify _____ at telephone number _____ .

U.3 Records

U.3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table U.1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this Appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, the date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality; that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

U.3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table U.3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

U.4 Summary Table

Table U.4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table U.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained

Patient Group	Basis for Release	Criteria for Release	Instructions Needed?	Release Records Required?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤Column 1 of Table U.1	Yes – if administered activity > Column 1 of Table U.2	No
	Retained activity	Retained activity ≤ Column 1 of Table U.1	Yes – if retained activity > Column 1 of Table U.2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table U.1	Yes – if dose rate > Column 2 of Table U.2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes – if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table U.3 or Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table U.3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

Implementation

The purpose of this section is to provide information to licensees and applicants regarding NRC staff's plans for using this Appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this Appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

Supplement A

Table U.5 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide	Physical Half-Life (days)[1]	Exposure Rate Constant[2] (R/mCi-h at 1 cm)
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant[3]	60.14	1.114
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant[3]	74.02	4.594
P-32	14.29	N/A[5]
Pd-103 implant[4]	16.96	0.865
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sn-117m	13.61	1.48
Sr-89	50.5	N/A[5]
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A[5]
Yb-169	32.01	1.83

Footnotes for Table U.5

[1] K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

[2] Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, p. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D. E. Barber, J. W. Baum, and C. B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

[3] R. Nath, A. S. Meigooni, and J. A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

[4] A. S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

[5] Not applicable (N/A) because the release activity is not based on beta emissions.

References

National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095.)

S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.

"Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table U.1 of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, a record of the basis of the release is required by 10 CFR 35.75(c). The following equation can be used to calculate doses:

Equation B-1:

$$D(t) = \frac{34.6\ \Gamma\ Q_0\ TE\ (1 - e^{-0.693t/T_P})}{r^2}$$

where: D(t) = Accumulated dose to time t, in rem;
34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);
Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm;
Q_0 = Initial activity at the start of the time interval;
T_p = Physical half-life, in days;
E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;
r = Distance in centimeters. This value is typically 100 cm; and
t = Exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table U.1

In Table U.1 in this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)), suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter may not be appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table U.1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E, at 1 meter, may be useful for patient-specific calculations:

- E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- E = 0.25 when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
  - Maintain a prudent distance from others for at least the first 2 days;
  - Sleep alone in a room for at least the first night;
  - Do not travel by airplane or mass transportation for at least the first day;
  - Do not travel on a prolonged automobile trip with others for at least the first 2 days;
  - Have sole use of a bathroom for at least the first 2 days; and
  - Drink plenty of fluids for at least the first 2 days.
- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
  - Follow the instructions for E = 0.25 above;
  - Live alone for at least the first 2 days; and
  - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to 1 day but is greater than 1 day for the other component, it is more

justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_P\ E}{r^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6\ (2.2\ R \cdot cm^2/mCi \cdot hr)(60 mCi)(8.04\ d)(0.125)}{(100\ cm)^2}$$

$$D\ (\infty) = 4.59 \text{ millisieverts } (0.459 \text{ rem})$$

Since the dose is less than 5 millisievert (0.5 rem), the patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained, pursuant to 10 CFR 35.75(c), because an occupancy factor of less than 0.25 at 1 meter was used.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75. The effective half-life is defined as:

Equation B-2:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p}$$

where: T_b = Biological half-life of the radionuclide and
T_p = Physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The

effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations.

Equation B-3:

$$T_{1eff} = \frac{T_{b1} \times T_P}{T_{b1} + T_P}$$

Equation B-4:

$$T_{2eff} = \frac{T_{b2} \times T_P}{T_{b2} + T_P}$$

where: T_{b1} = Biological half-life for extrathyroidal iodide;
T_{b2} = Biological half-life of iodide following uptake by the thyroid; and
T_p = Physical half-life of iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at t = 8 hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0}{(100\,cm)^2}\left\{E_1\,T_p\,(0.8)(1-e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p}E_2\,F_1\,T_{1eff} + e^{-0.693(0.33)/T_p}\,E_2\,F_2\,T_{2eff}\right\}$$

where: F_1 = Extrathyroidal uptake fraction;
F_2 = Thyroidal uptake fraction;
E_1 = Occupancy factor for the first 8 hours; and
E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1, T_{1eff}, F_2, and T_{2eff} are shown in Table U.6 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by 10 CFR 35.75(c) is described in Item U.3.1 of this Appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose will be calculated by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table U.5. The uptake fractions and effective half-lives are from Table U.6. An occupancy factor, *E*, of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations," of this Supplement).

Table U.6 Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

	Extrathyroidal Component		Thyroidal Component	
Medical Condition	**Uptake Fraction F_1**	**Effective Half-Life T_{1eff} (day)**	**Uptake Fraction F_2**	**Effective Half-Life T_{2eff} (day)**
Hyperthyroidism	0.20[1]	0.32[2]	0.80[1]	5.2[1]
Post-Thyroidectomy for Thyroid Cancer	0.95[3]	0.32[2]	0.05[3]	7.3[2]

Footnotes for Table U.6

1 M. G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.

2 International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer

patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.

[3] The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC Medical Visiting Fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6)\ (2.2)\ (150)}{(100\ cm)^2}\ \{(0.75)\ (8.04)\ (0.8)\ (1 - e^{-0.693\ (0.33)\ /\ 8.04})$$
$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.95)\ (0.32)$$
$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.05)\ (7.3)\}$$

$$D(\infty) = 3.40\ \text{mSv}\ (0.340\ \text{rem})$$

Therefore, thyroid cancer patients to whom 5550 megabecquerels (150 millicuries) of iodine-131 or less have been administered would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient to whom 2035 megabecquerels (55 millicuries) of iodine-131 have been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, the dose will again be calculated using Equation B-5, Table U.5, and Table U.6, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$D(\infty) = \frac{(34.6)\ (2.2)\ (55)}{(100\ cm)^2}\ \{(0.75)\ (8.04)\ (0.8)\ (1 - e^{-0.693\ (0.33)\ /\ 8.04})$$
$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.20)\ (0.32)$$
$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.80)\ (5.2)\}$$

$$D(\infty) = 4.86\ \text{mSv}\ (0.486\ \text{rem})$$

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 have been administered would not have to remain under licensee control and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6:

$$D_i = Q\,(10^{-5})(DCF)$$

where:
- D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;
- Q = Activity administered to the patient in millicuries;
- 10^{-5} = Assumed fractional intake; and
- DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 have been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv } (0.017 \text{ rem})$$

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv (0.5 rem). Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose is again calculated using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv } (0.08 \text{ rem})$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 millisieverts (0.34 rem), while the internal dose would be about 0.80 millisievert (0.08 rem). Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose; 4.2 millisieverts (0.42 rem).

References for Supplement B

B-1. S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, NUREG-1492, February 1997.

B-2. K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.

B-4. R. C. T. Buchanan and J. M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.

B-5. A. P. Jacobson, P. A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.

B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

Regulatory Analysis

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, February 1997) provides the regulatory basis and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at NRC's Public Document Room, 2120 L Street NW, Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

APPENDIX V

Guidance for Mobile Medical Services

Guidance for Mobile Medical Services

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, all the requirements for mobile medical services also apply to the mobile medical use of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Before submitting information to the NRC, review Section 5.2 of this document for guidance on identifying and protecting sensitive information. All security-related information in the application should be identified and properly marked.

Mobile medical service providers must comply with all applicable sections of 10 CFR Part 35 as well as DOT regulations with regard to approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, mobile medical service providers offering remote afterloaders must comply with Subpart H of 10 CFR Part 35.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of byproduct material within a transport vehicle (e.g., in-van use). A second type is transportation of byproduct material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use). As a result of the EPAct, byproduct material now includes accelerator-produced radioactive materials and discrete sources of radium-226.

Whether a PET mobile medical service provider that uses a "quiet room" in the client's facility is authorized for "in-van use" or " transport and use" depends on whether the PET patients meet the criteria for release in 10 CFR 35.75 while they are in the "quiet room." If they do not, then the "quiet room" is an area of use for the mobile service licensee.

For the first and second types, which include use by the service provider, the service provider should apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the byproduct material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the byproduct material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the byproduct material use and patient treatments upon transfer of the byproduct material to the client's possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a), which states that the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use

of byproduct material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by 10 CFR 35.80(c) and 10 CFR 35.2080. Additionally, as required by 10 CFR 35.80(a)(4), the licensee must survey to ensure compliance with the requirements in 10 CFR Part 20 (e.g., ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes, have been removed) before leaving a client's address.

The locations of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, noninstitutional medical practice, commercial facility, or mobile van. Applicants should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (nonlicensee) located within a licensed medical institution (e.g., hospital). As required by 10 CFR 30.33 and 10 CFR 35.12, applicants must submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 8.14 through 8.19 of this report. The description and diagram of the proposed facility should demonstrate that the building (or van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the licensed material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226), receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van, the description of the van should address radiation levels in the van driver's compartment to demonstrate compliance with 10 CFR 20.1201, "Occupational dose limits for adults."

- Applicants may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the byproduct material storage, provide for the following:
  - — Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
  - — Secured storage facilities available for storage of byproduct material and radioactive waste if the van is disabled; and

  - Byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226) delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.

- If a base facility is located in a residential area, provide the following information:
  - Justification of the need for a private residence location rather than for a commercial location.
  - Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
  - A description of the program demonstrating compliance with 10 CFR 20.1301, "Dose limits for individual members of the public."
  - Verification that restricted areas do not contain residential quarters.
- Perform surveys necessary to show that exposure rates do not exceed 2 mrem in any 1 hour nor 100 mrem per year.

Client Site

This section applies only to therapeutic uses of byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained byproduct material services (e.g., in-van), the following additional facility information should be provided:

- For therapy treatments with byproduct material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by 10 CFR 35.80(a), that location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If transportable services will be provided to the client's site for use within the client's facility by the mobile medical service's employees, the following client facility information and commitment should be provided:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 8.14 through 8.19 of this report. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
- A commitment, as delineated in the letter required by 10 CFR 35.80(a), that the mobile medical service licensee has full control of the treatment room during byproduct material use for each client.
- The initial installation records and function checks of a remote afterloader device for each site of use, as required by 10 CFR 35.633, 10 CFR 35.643, and 10 CFR 35.647.

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, ensure the following:

- Each client is properly licensed for medical use of byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). If applicable, licensees should ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.
- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of byproduct material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the byproduct material for patient treatments. The responsibilities for supervising individuals who use the byproduct material, set forth in 10 CFR 35.27, transfer to the client's AUs upon transfer of the device to the client by the mobile medical service provider.
- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- As required by 10 CFR 30.51, a formal record of the transfer of control of the byproduct material from the mobile medical service provider to the client, and from the client back to

the mobile medical service provider, must be made for each transfer of byproduct material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

In addition to the requirements in 10 CFR 19.12, 10 CFR 35.27 requires that instructions be given to supervised individuals in written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). Additionally, 10 CFR 35.27 requires the supervised individual to:

- Follow the instructions of the supervising AU for medical uses of byproduct material;
- Follow the instructions of the supervising ANP or supervising AU for preparation of byproduct material for medical uses;
- Follow the written radiation protection procedures and written directive procedures established by the licensee; and
- Comply with the provisions of 10 CFR Part 35 (e.g., 10 CFR 35.80 and 10 CFR 35.647 (if applicable)), and the license conditions with respect to the mobile medical use of byproduct material.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (as applicable). The training for these individuals will include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by 10 CFR 35.80, instruments should be checked for proper operation before use at each address of use. Dosage measurement instruments should be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Byproduct Material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226)

Byproduct material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of byproduct material ordered. Delivery of byproduct material to a van that is not occupied by the mobile medical service personnel will not be permitted.

Alternatively, licensees may pick up the byproduct material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with the Radiation Protection Program required by 10 CFR 20.1101. Indicate typical response times of the RSO and AU in the event of an incident and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as wind, water, or fire, that results in damage to exterior or interior portions of the vehicle or the byproduct material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous-material (HAZMAT)-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel;
- The emergency contact numbers for NRC's Operation Center and all appropriate State radiological protection agencies;
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;
- Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers;
- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios;
- Preplanned decontamination procedures, including ready access to all necessary materials;
- A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys;
- Security of the transport vehicle against unauthorized access, including the driver's compartment; and
- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 10 CFR 30.50, will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

Note: The type of response should be consistent with the level of the incident. The response may range from telephone contact for minor spills to prompt onsite response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170–189. Procedures will include:
  - — Use of approved packages,
  - — Use of approved labeling,
  - — Conduct of proper surveys,
  - — Complete and accurate shipping papers,
  - — Bracing of packages,
  - — Security provisions, and
  - — Written emergency instructions.
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226) is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. Describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised, and the device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management (this now includes waste containing accelerator-produced radioactive materials and discrete sources of radium-226)

If waste will be stored in vans, the vans must be properly secured and posted as byproduct material storage locations. Ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a byproduct material storage area.

Develop, document, and implement final waste disposal procedures in accordance with Section 8.28 of this report.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewer system,

in accordance with 10 CFR 20.2003. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewer system. If restroom facilities are provided in the van for patient use, submit the following information for NRC review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van, and the driver of the van; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any I-131 will be held in the tank.
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 10 CFR 20.1201 and 20.1301, that the external surfaces of the van do not exceed 2 mrem/hour, and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.
- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services With Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Conduct safety checks on a remote afterloader device and facility. The procedure will include the periodic spot checks required by 10 CFR 35.643 and the additional spot checks required by 10 CFR 35.647 before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly.
- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.
- Such tests should be performed in accordance with written procedures.
- As required by 10 CFR 35.2647 and 10 CFR 35.2643, records showing the results of the above safety checks must be maintained for NRC inspection and review for a period of 3 years.
- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of a high dose-rate unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

APPENDIX W

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the procedures for waste disposal by decay-in-storage, generator return, and licensed material return also apply to the medical accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for waste disposal. Note that some short half-life radionuclide products (e.g., Tc-99m/Mo-99 generator columns and some Y-90 microspheres) contain long half-life contaminants that may preclude disposal by decay-in-storage. Applicants may either adopt these model procedures or develop alterative procedures to meet the requirements of Subpart K to 10 CFR Part 20, 10 CFR 20.1101, and 10 CFR 35.92.

Model Procedure for Decay-In-Storage (this now includes decay-in-storage of accelerator-produced radioactive materials)

Section 10 CFR 35.92 describes the requirements for decay-in-storage. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.
- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area.
- 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.
  - Remove any shielding from around the container or generator column.

- Monitor, at contact, all surfaces of each individual container.
- Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in 10 CFR 35.92).
- Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

  Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

Model Procedure for Returning Generators to the Manufacturer (this now includes generators containing accelerator-produced radioactive materials)

Used Mo/Tc-99m or Sr-82/Ru-82 generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and DOT regulations. Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container,
- Assemble the package in accordance with the manufacturer's instructions,
- Perform the dose-rate and removable-contamination measurements,
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions, and
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.

Model Procedure for Return of Licensed Material to Authorized Recipients (this now includes return of accelerator-produced radioactive materials or discrete sources of radium-226)

Note: Licensees authorized to produce and noncommercially transfer PET radioactive drugs to consortium members are not authorized to receive unused dosages or empty syringes or vials from consortium members.

Perform the following steps when returning licensed material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226) to authorized recipients:

- In accordance with 10 CFR 30.41(a)(5), confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's NRC license or Agreement State license that authorizes the byproduct material).

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.