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54, 55, 50, 59, and	40				qualified	and that adequate procedures exist to protect the public health and safety.	
					E6), U.S.	Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet	
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/	•////•///				Washingt	on, DC 20503. If a means used to impose an information collection does not	
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CONNECTICUT, DI	ELAWARE, DISTRIC	T OF COLUMBIA, MA	INE, MARYLAND,		ALASKA, A	RIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,	
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5 RADIOACTIVE	ATERIAL	ANT FAFEN, (NE					
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WARNING: 18	U.S.C. SECTION 100	1 ACT OF JUNE 25. 1	1948 62 STAT. 749 MAKES	TA CR	IMINAL OFFE	NSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO	
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Dr. Tomas Irizarry Western Radiosonics Calle de Diego #101 Este, Esquina Iglesia Mayaguez, PR 00680

February 13, 2006

Regional Administrator U.S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406

Dear Mr. Sir or Madam:

Please find enclosed a new application for a Radioactive Material License.

If you need any further information, please contact me at (787) 834-2145.

Sincerely,

Tomas Irizarry, MD

LL 31137 030 37158 022**01**

(52-31137-01)

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Western Radiosonics

CALLE DE DIEGO #101 - ESTE, ESQUINA IGLESIA MAYAGÜEZ, PUERTO RICO 00680 TEL. (787) 834-2145 FAX. (787) 833-0981

CURRICULUM VITAE

NAME : Tomás H. Irizarry-Concepción, M. D. **DATE OF BIRTH** PLACE OF BIRTH **CITIZENSHIP** MARITAL STATUS ADDRESS : De Diego #101, Esquina Iglesia BUSINESS Mayaguez, Puerto Rico 00680 : University of Puerto Rico **EDUCATION Rio Piedras, Puerto Rico Bachelor Degree in Science** (Cum Laude) ----President, Student Council 1960-62 ---Beta Beta Beta Biology 1964-68 **University of Puerto Rico School of Tropical Medicine** San Juan, Puerto Rico Degree – M. D. ---Phi Chi Medical Fraternity President, Graduating Class 1967-68 PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

Page 2 – Tomás H. Irizarry-Concepción, M. D.

POST GRADUATE TRAINING

INTERNSHIP	: Wilford Hall USAF Medical Center Lackland Air Force Base San Antonio, Texas July 1, 1960 – June 30, 1969
SERVICE SCHOOL	: Primary Course Aerospace Medicine School of Aerospace Medicine San Antonio, Texas July 1, 1970 – September 31, 1970
RESIDENCY	: Fitszimons Army Medical Center Denver, Colorado July 1, 1974 – June 30, 1977 Chief Resident 1977 Armed Forces Institute of Pathology August – November 1976
MILITARY STATUS	: Honorable Discharge U.S. Air Force July 1, 1978
SPECIAL BOARD	: American Board of Radiology December 9, 1977
STATE LICENSE	: Ohio License No. 40532 Puerto Rico License No. 4770
OCTOBER 1970-1971	: Vietnam Conflict, Stationed in Ubon, Thailand Chief, Aerospace Medicine Flight Surgeon 433rd. Tactical Fighter Squadron Decorations: Air Medal
NOVEMBER 1971	: Aviano Air Force Base Aviano, Italy

Page 3 – Tomás H. Irizarry Concepción

- **-**

TO JUNE 1977	:	Chief Aerospace Medicine Chief of Profesional Services Hospital Commander Decorations: Kamer Honor Award
PRESENT CURRENT IN	:	 Neuroradiology, Visceral Angiography Peripheral Embolization C.T. Scanning, Head and Body Special Procedures: Percutaneous Aspiration Biopsies Lung, Pancreas, Lymph nodes Percutaneous Cholangiogram Percutaneous Common Duct Stones Removal Percutaneous Nephrostomies Percutaneous Renal Cyst Punctures Arthrograms Nuclear Medicine Magnetic Resonance
TEACHING	:	Clinical Instructor in Radiology Wright State University School of Medicine Dayton, Ohio
PROFESSIONAL		
ORGANIZATIONS		American Medical Association Radiological Society of North America American College of Radiology American Institute of Ultrasound Interamerican College of Radiology Society for Magnetic Resonance Imaging American College of Nuclear Medicine Society for Magnetic Resonance Imaging American College of Nuclear Medicine Puerto Rico Chapter American Medical Assn. Western Regional Chapter A.C.R.
JULY 1, 1974 TO JULY 1, 1977	:	President Diagnostic Radiology Fitszimons Army Medical Center Denver, Colorado

.

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JULY 1, 1977	: Wright Patterson U.S. Air Force Medical Center Chief Neuroradiology and Special Procedures Assistant Chief Body C. T. And Ultrasound Honorable Discharge, Major, USAF
JULY 1, 1978 TO	
JUNE 30, 1979	: Staff Radiologist Medical Radiologists, Inc.
	C.T., U/S, Interventional Radiology,
	Special Procedures Department
	St. Elizabeth Medical Center
	Good Samaritan Hospital
	Dayton, Ohio

Page 5 - Tomas H. Irizarry Concepción

PRESENT AND PAST POSITIONS:

- : Director, Radiology Department Clinica de Cirugía Ambulatoria P. O. Box 3748, Marina Station Mayaguez, Puerto Rico 00681 (787) 833-4400
- : Director, Radiology Department Mayaguez Municipal Hospital 18 North, Post Street Mayaguez, Puerto Rico 00680 (787) 834-0050
- : Director, Radiology Department Perea Hospital P. O. Box 170 Mayaguez, Puerto Rico 00681 (787) 834-0101
- : Director, Radiology Department Tito Mattei Hospital Yauco, Puerto Rico (787) 856-2105
- : Director, Radiology Department Aguadilla Sub-Regional Hospital P.O. Box 3968 Aguadilla, Puerto Rico 00603 (787) 891-3000
- : Director, Radiology Department Arecibo Regional Hospital Carr. #129, P. O. Box 9976, Cotto Station Arecibo, Puerto Rico 00613 (787) 878-7272



Item 1 Address

- a) Mailing address Western Radiosonics Calle de Diego #101 Este, Esquina Iglesia Mayaguez, PR 00680 (787) 834-2145 Fax (787) 833-0981
- b) Main Office address Western Radiosonics Calle de Diego #101 Este, Esquina Iglesia Mayaguez, PR 00680 (787) 834-2145 Fax (787) 833-0981
- c) Physical location (storage/location of the radiation sources & records) (Nuclear Medicine) Western Radiosonics Calle Mendez Vigo #105, Este

Mayaguez, PR 00680 (787) 834-2145 Fax (787) 833-0981

The following is based on Medical Use Licenses, NUREG 1556 Vol 9, October 2002, Appendix C

YES	Radionuclide	Form or Manufacturer	Maximum Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100
	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.200
	Any byproduct material permitted by 10 CFR 35.300	Any	500 millicuries	Any uptake, dilution, and excretion study permitted by 10 CFR 35.300
	Any byproduct material permitted by 10 CFR 35.400	Sealed sources North American Model No. MED3631 (I-125)	500 millicuries	Any uptake, dilution, and excretion study permitted by 10 CFR 35.400
	Any byproduct material permitted by 10 CFR 35.500	Sealed sources Model No.	Ci/source	Diagnostic medical use of sealed source permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32 (g)
	I-131	Any	500 millicuries	Administration of I-131 sodium iodide.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	50 millicuries	In vitro studies
X	Cs-137	The Sealed Source and Device Registry number is CA0406S122S.	20 millicuries	The source will be used for quality control of our PET (Positron Emission Tomography) Camera.

Item 5 and 6: Materials to be Possessed and Proposed Uses

Item No. and Title	Re	sponse
7. Radiation Safety Officer.	×	Previously on license number: NRC 52-19873-01.
		or
Name: Tomas H. Irizarry, M.D.		Copy of the certification(s) for the board(s) recognized by the NRC and as applicable to the types of use for which he or she has RSO responsibilities.
		Or Description of the training and experience specified in 10 CFR 35.900(b). or
		Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.
	D	Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license has been achieved.
		and If applicable, description of recent related continuing education and experience as required by 10 CFR 35,59
		RSO Signature: and bate:
8. Authorized Users Names and	x	Previously on license number: NRC 52-19873-01.
Requested Uses for Each Individual.		or Copy of the certification(s) for the board(s) recognized by the NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.
Name:		or
Tomas H Irizarry M D		Description of the training and experience specified in 10 CFR 35.900(b).
		Description of the training and experience specified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.
		or A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested; and
		Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency to function independently as an AU for a medical uses authorized has been achieved.
		and If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59
9. Facility Diagram.	×	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:
		Drawing should be to scale and indicate the scale used
	Ç.	Location, room numbers, and principal use of each room or area where
		byproduct material is prepared, used or stored, as provided above the heading "Discussion";
	×	Location, room numbers, and principal use of each adjacent room (e.g., office,
		file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is restricted or unrestricted area as
		defined in 10 CFR 20.1003; and
		Provide shielding calculations and include information about the type,
		thickness, and density of any necessary shielding to enable independent

	verification of the shielding calculations including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.) In addition to the above, for teletherapy and GSR facilities, applicants should
	provide the directions of primary beam usage for teletherapy units and, in the case
	of an isocentric unit, the plane of beam rotation.
9. Radiation Monitoring Instrument.	 A person qualified to perform survey meter calibrations will calibrate radiation monitoring instruments. apd/or
Range 1-1000 mR/hr End window or pan probe	 We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61. and
	 A description of the instrument (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, LSC, proportional counter) that will be used to perform required surveys is indicated in the left column.
	and
	★ We reserve the right to upgrade our survey instrument as necessary as long as they are adequate to measure the type and level of radiation for which they are used.
0 Dage Cellibrates and Other Deserve	11 Emilian and the data and the second se
9. Dose Canorator and Other Dosage Measuring Equipment.	ationally recognized standards or the manufacturer's instructions.
10. Occupational Dose.	 Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide Dosimetry that meets the requirements listed under "Criteria" in NUREG 1556, Vol. 9, "Consolidated Guidance About Materials License: Program-Specific Guidance About Medical Use Licensees," dated October 2002.
	A description of an alternative method for demonstrating compliance with the referenced regulations.
10. Areas Surveys.	★ We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.
 Safe Use of Unsealed Licensed Material. 	We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 1301.
10. Spill Procedures and Minimization of Contamination.	★ We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.
10. Minimization of Contamination	× A response is not required.
11. Waste Management.	★ We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR Part 35.92.

RADIOACTIVITY REPORT ACCOMPANYING THE BODY*

Guidance and Safety Instruction Provide to Surgeons, Pathologist, and Funeral Directors

Patient's N	ame:		
Date:	<u> </u>		
Radiation S	Source		
Isotope	Target organ	Activity (mCi)	Procedure
I-131			Therapy
I-125	Prostate		Permanent Implant
Pd-103	Prostate		Permanent Implant
Ir-192			-
Au-198			
114 190	······	<u></u>	

Physicians

Name	Office number	Emergency number	

Please provide this form with the deceased individual until $(M/D/Y) _ / _ / _$. This form should be attached to the death certificate, autopsy permission slip, Pathologist, and Funeral Director.

If an autopsy is to be performed were the radiation source is located, the radiation source must be removed or shielded under the supervision of the physician listed above. If the deceased individual will be cremated, the physician listed above must be contacted prior to the cremation.

() This body does not contain significant amounts of radioactive materials. No special precautions are required if standard embalming procedures are employed.

() This body contains a significant amount of radioactive material. The following precautions are to be observed.

APPENDIX A

Training Program

MODEL PROGRAM

Personnel will be instructed:

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

Instruction for individuals in attendance will include the following subjects:

- 1. Applicable regulations and license conditions.
- 2. Areas where radioactive material is used or stored.
- 3. Potential hazards associated with radioactive material in each area where the employees will work.
- 4. Appropriate radiation safety procedures.
- 5. Licensee's in-house work rules.
- 6. Each individual 's obligation to report unsafe conditions to the Radiation Safety Officer.
- 7. Appropriate response to emergencies or unsafe conditions.
- 8. Worker's right to be informed of occupational radiation exposure and bioassay results.
- 9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by the regulations.
- 10. Question and answer period.

APPENDIX D

Model Personnel External Exposure Monitoring Program

MODEL PROGRAM

- 1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).
- 2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service. Processing when be done according to manufacturer recommendations.
- 3. All individuals who, on a regular basis, handle radioactively material that emits ionizing photons will be issued a film or TLD monitor that will be processed by a contract service.
- 4. All individuals who are occupationally exposed to radiation on, an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, will be issued a whole body monitor where caring for such patients.
- 5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personal who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

APPENDIX G

Maintaining Occupational Radiation Exposure ALARA

I. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified.. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that 'they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.
- 2. Radiation Safety Committee
 - a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of the materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

- (3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

- (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- c. Review of ALARA Program
 - (1) The RSC will encourage all users to review current procedures and develop now procedures as appropriate to implement the ALARA concept.
 - (2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table I	Investigational Levels (mrems per calendar quarter)		
	Level I	Level II	
Whole body; head and trunk; active blood-foming organs; lens of eyes; or gonads	125	375	
Hands and forearms; feet and ankles	1875	5625	
Skin of whole body	750	2250	

- (3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.
- 3. Radiation Safety Officer
 - a. Annual and Quarterly Review

- (1) Annual review of the radiation safely program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
- (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Table 1 of this program and will prepare a summary report for the RSC.
- (3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.
- b. Education Responsibilities for ALARA Program
 - (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
 - (2) The RSO will ensure that authorized users, workers, and ancillary personal who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.
- C. Cooperative Efforts for Development of ALARA Procedures

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

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.
- d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

- a. Now Methods of Use Involving Potential Radiation Doses
 - (1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
 - (2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
 - b. Authorized User's Responsibility to Supervised Individuals
 - (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
 - (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.
- 5. Individuals Who Receive Occupational Radiation Doses
 - a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
 - b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- 6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

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

The RSO will review the dose of each individual whose quarterly dose, equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter 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 Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

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

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses need 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 will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources

MODEL PROCEDURE

- 1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
- 2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
- 3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
 - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
 - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
 - c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crossbars. Also wipe the primary and secondary collimators and trimmers.
 - d. If you are testing radium sources at the same time you are testing NRC-licensed sources, they should also be checked for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.
- 4. The samples will be analyzed as follows:
 - a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For g4mma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

- b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity the supplier certifies. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
- c. Assay the wipe sample. It must be in the same geometry relative -to the detector as was the certified check source.
- d. Record the wipe sample counts per minute. 'Then calculate and record the estimated activity in microcuries on the wipe sample.
- e. Continue the same analysis procedure for all wipe samples.
- f. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the agencies must be notified.
- g. The RSO must sign the list of sources, data, and calculations.

APPENDIX I

Rules for Safe Use of Radiopharmaceuticals

MODEL RULES

- 1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- 2. Wear disposable gloves at all times while handling radioactive materials.
- 3. Either after each procedure or before leaving the area, monitor your hands; for contamination in a low-background area with a survey meter or nuclear medicine camera.
- 4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through Use of a butterfly valve).
- 5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- 6. Do not-store food, drink, or personal effects in areas where radioactive material is stored or used.
- 7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
- 8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.
- 9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- 10. Never pipette by mouth.
- 11. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

- 12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.
- 13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
- 14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you 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.
- 15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- 16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

<u>APPENDIX J</u>

Spill Procedures

MODEL PROCEDURES

Minor Spills of Liquids and Solids

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

Major Spills of Liquids and Solids

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

7. The RSO will supervise the cleanup of the spill and will complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey.

The following is not part of the model spill procedure:

Major Spills and Minor Spills

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

APPENDIX K

Ordering and Receiving Radioactive Material

MODEL GUIDANCE

- 1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials (non-medical use) and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.
- 2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
 - a. For routinely used materials
 - (1) Written records that identifies the authorized user or department, isotope, chemical form, activity, and supplier will be made.
 - (2) The above records will be checked to confirm that material received was ordered through proper channels.
 - b. For occasionally used materials (e.g., therapeutic dosages)
 - (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.
 - (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.
- 3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.
- 4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

APPENDIX L

Procedure for Safely Opening Packages Containing Radioactive Material

MODEL PROCEDURE

- Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in of 10 CFR Part 20 (e.g., more than 20 curies of Mo-99, Tc-99m, uncompressed Xe-133, or more than 3 curies of Xe-133, I-131, Cs-137, Ir-192, I-125, or more than 0.001 curie of Ra-226). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours. The PR Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100 cm2.
- 2. For packages received under the specific license, the following procedure for opening each package will be followed:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
 - c. Measure the exposure rate from the package at I meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II' or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface. The surface dose rate for such packages should not exceed 200 millirem per hour for YIII and 50 millirem per hour for YII. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface.
 - d. Open the package with the following precautionary steps:
 - (1) Remove the packing slip.
 - (2) Open the outer package following the supplier's instructions, if provided.
 - (3) Open the inner package and verify that the contents agree with the packing slip.
 - (4) Check the integrity of the final source container. Look -for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - (5) If anything is other than expected, stop and notify the RSO.

- e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(TI) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.
- f. Check the user request to ensure that the material received is the material that was ordered.
- 9. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.
 - (1) If contaminated, treat this material as radioactive waste.
 - (2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
- h. Make a record of the receipt.

APPENDIX M

Records of Radioactive Material Use

MODEL PROCEDURE

M.1 Records of Unit Dosage Use

For each unit dosage received from a supplier, make a record of the:

- 1. Radionuclide;
- 2. Generic name or its abbreviation or trade name;
- 3. Date of receipt;
- 4. Supplier;
- 5. Lot number or control number, if assigned;
- 6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
- 7. Date of administration or disposal;
- 8. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual),
 - b. Measured activity in millicuries or microcuries and date and time of measurement,
 - c. Patient name and identification number if one has been assigned;
- 9. If discarded, the date and method of disposal; and
- 10. Initials of the individual who made the record.

MODEL PROCEDURE

M.2 Records of Multidose Vial Use

For each multidose vial that you receive from a supplier or that you prepare, make a record of the:

- 1. Radionuclide;
- 2. Generic name or its abbreviation or trade name;
- 3. Date of receipt or preparation;
- 4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
- 5. Supplier or kit manufacturer;
- 6. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual),
 - b. Date and time dosage was drawn and measured,
 - c. Calculated volume that is needed for the prescribed dosage,
 - d. Measured activity in millicuries or microcuries,
 - e. Patient name and identification number if one has been assigned;
- 7. If discarded, the method of disposal and date; and
- 8. Initials of the individual who made the record.

MODEL PROCEDURE

M.3 Measuring and Recording Molybdenum Concentration

Each time a generator is eluted, make a record of the:

- 3.. Date the generator was received;
- 2. Date and time of elution;
- 3. Measured Mo-99 activity in microcuries;
- 4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;
- 5. Measured Tc-99m activity in millicuries;
- 6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.07 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. In conformance with regulations, the licensee must notify the PR if a

leaking generator is detected.) [The 0.07 action level allows for the quicker decay of the Tc-99m through the day of use. It is assumed that the material will be used within 6 hours, at which time the concentration of Mo-99 to Tc-99m would have doubled.]

7. Initials of the person who made the record.

MODEL PROCEDURE

M.4 Inventory of Implant Sources

- 1. Use a locking installed cabinet or safe to store all implant sources.
- 2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.
- 3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
- 4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
- 5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name., and the time and date they were removed from storage; initial the record.,
- 6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.
- 7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX N

Procedure for Area Surveys

MODEL PROCEDURE

Ambient Dose Rate Surveys

1. Survey Areas

- a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.
- C. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.
- d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.
- 2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

- 1. Survey Areas
 - a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
 - b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.
 - c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.
- 2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm2 of removable contamination (200 dpm/100 cm2 for isotopes of iodine). You must use, a radioactive source with a known amount of -activity to convert

sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3 Immediately notify the RSO-if you find unexpectedly high levels.

Records

- 1. Keep a record of dose rate and contamination survey results. It must include the following information:
 - a. The date, area surveyed, and equipment used.
 - b. The name or initials of the person who made the survey.
 - c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO.
 - d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm², as appropriate.
 - e. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.
- 2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

APPENDIX R

Procedure for Waste Disposal

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta and generally licensed in vitro kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material

General Guidance

- 1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- 2. Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
- 3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- 4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in regulation for radioactive material. The material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy are exempt from all the above limitations.) Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and from the sink or toilet at which the material was released.

- 2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Annex I of the regulations. These limits apply at the boundary of the restricted area. Make a record, of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.
- 3. Liquid scintillation counting media containing 0.05 millicurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

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

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

- 1. Consider using separate containers for different types of waste, e.g.. capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.
- 2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the-container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
- 3. Decay the material for at least 10 half-lives.
- 4. Prior to disposal as in-house waste, monitor each container as follows:
 - a. Check your radiation detection survey meter for proper operation;
 - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;
 - C. Remove any shielding from around the container;
 - d. Monitor all surfaces of each individual container;
 - e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

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

PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

PROCEDURE FOR RETURNING SOURCES TO THE MANUFACTURER

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

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).
- 2. Assemble the package in accordance with the manufacturer's instructions.
- 3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.
- 4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

APPENDIX S EMERGENCY PROCEDURES

All accidents involving radioactive material must be immediately reported to the Radiation Safety Officer. If the accident is serious in nature and occurs at night, contact Security Service.

RADIATION SPILLS

Spills of radioactive materials, no matter how minor, must be cleaned up immediately. It is the responsibility of the person causing a spill to clean it up. The Radiation Safety Officer will provide guidance and waste containers for all contamination incidents, but the persons involved in the incident should carry out the actual decontamination procedure.

Decontamination efforts should always be conducted in a manner, which minimizes the dose to workers, both from external exposure and from contamination and intake.

For most spills, ordinary detergents and water applied with disposable cleaning materials will be adequate. Commercially available decontamination solutions are usually strong detergents to which complex agents or surfactants have been added. They may need to be diluted before use.

Use the following guidelines in decontamination efforts:

1. Notify individuals in the immediate work area of the spill so they can avoid contamination.

2. Call the Radiation Safety Officer for assistance if you have doubts about how to proceed.

3. Use appropriate protective clothing: gloves, lab coat, protective goggles, shoe covers, and a face mask if conditions are dusty.

4. Use dosimeters if radionuclides other than H-3, C-14, or other low-energy beta emitters are involved. Protect them from contamination. Wear ring dosimeters under protective gloves.

5. If there is personnel decontamination take care of this first then decontaminate the work area.

- Flush the skin with soap and water - DO NOT ABRADE SKIN.

- Remove any decontaminated clothing and store in a plastic bag.

6. Use disposable materials for cleaning: paper towels, kimwipes, and plastic bags.

7. Dampen dry spills with water (e.g., by application of a dampened paper towel, being careful not to spread contamination). Absorb wet spills immediately with paper towels or kimwipes.

8. Work from the least contaminated area at the perimeter of the spill to the most contaminated area. Do not increase the contaminated area any more than necessary.

9. Place contaminated items in approved radioactive waste containers.

10. Use time, distance, and shielding strategies to minimize dose. Use long-handled tools for spills of energetic beta or gamma emitters. Avoid hand contact.

11. For tritium (H-3) spills, monitor your progress by wiping the area with filter paper. Put the filter paper into a scintillation vial, add counting media, and count in a liquid scintillation counter. H-3 is NOT detectable with a survey meter.

12. If you have a survey meter, use it to check your progress, surveying slowly enough to detect small differences in count rates. If you do not have a survey meter, wipe test the area as described in 11, above, USE CAUTION NOT TO CONTAMINATE YOUR SURVEY METER.

13. The limits for removable contamination are very conservative. Any activity that you detect with ordinary survey instruments will probably exceed the limits. If the activity is not removable (as determined by wipe testing the area), call the Radiation Safety office for advice on how to proceed.

14. Do not use equipment which was contaminated or which was used in the decontamination effort until it has been checked.

15. Complete the Incident Report and return it to the Radiation Safety Office.

POSSIBLE OVEREXPOSURE

Any incident involving a possible overexposure from cobalt, x-rays or any device labeled as a radiation hazard must be reported immediately to the Radiation Safety Office. The individual with which the overexposure is suspected should report to the Office as soon as possible, with their radiation badge. The badge will be returned to the supplier for an emergency reading. The individual will be notified as soon as a badge reading is obtained.

APPENDIX T

NURSING CARE OF PATIENTS RECEIVING RADIOACTIVE MATERIALS

1.1 GENERAL PRINCIPLE OF RADIOACTIVE MATERIAL USE

a. Hazards may arise from three sources:

- 1. Contamination of the skin with radioactive materials.
- 2. Inhalation or injection of radioactive materials in the body.

3. Irradiation of the body from outside by radiations emitted from radioactive materials.

b. In general, no precautions are needed for those patients who have received tracer doses of radioactive materials for diagnostic tests.

c. Information regarding special hazards will be given when necessary by the physicians responsible for the administration of the radioactive material and/or the Radiation Safety Officer (RSO).

1.2 PRINCIPLES OF RADIATION PROTECTION

a. Skin contamination, injection, or inhalations are prevented, in part, by practicing good housekeeping, hand washing, and clean work habits. Radioactive material should not be allowed to come in contact with the skin.

b. Where radioactivity is present, personnel should not be allowed to eat or smoke.

c. Monitoring, i.e., checking equipment or work areas with suitable radiation detectors, is necessary when contamination is suspected.

1.3 GENERAL PRECAUTIONS

a. In general, it is not necessary to limit the time of attending personnel spent near the patient. If such limitations are necessary, the physician and/or the Radiation Safety Officer will specify them.

b. Wash hands after contact with the patient giving particular attention to fingernails. Personnel with open cuts should avoid working with patients unless adequate protection is afforded by wearing gloves.

c. The RSO shall be informed if articles are likely to be contaminated. If the RSO is not immediately available the articles shall be stored in a suitable marked container provided and will be monitored later by the RSO.

1.4 CARE OF PATIENTS RECEIVING DIAGNOSTIC DOSES OF RADIOACTIVE MATERIALS

a. There is no danger in carrying out routine nursing care.

b. Patients are allowed visitors in accordance with usual Medical Center rules.

c. Precautions may be necessary if urine or stools are spilled or are to be saved for clinical studies (notify the Radiation Safety Office as soon as possible and confine the area).

d. If the patient should vomit within the first few hours of oral ingestion of radioactive material, call the responsible physician and/or the RSO as soon as possible.

e. No special precautions are needed for dishes, instruments, or utensils.

f. If there are any special instructions for a particular case, they will be noted on the patient's order sheet.

g. When cleaning up vomitus or handling contaminated articles, the nurse or aid should wear rubber gloves. The RSO should be called for disposal of contaminated paper towels or other articles, and these items should not be disposed of by routine methods.

1.5 NURSING CARE OF PATIENTS RECEIVING DOSES OF RADIOACTIVE IODINE (I-131)

a. Radioactive Iodine (131) is administered orally. Usually more than 50% of the orally administered radio-iodine is excreted in the urine within the first day or two of treatment. Feces, sweat, and saliva may contain additional amounts of radioactive iodine. Biological specimens and articles in contact with the patient may become contaminated with radioactivity.

b. Precautions which must be taken depend entirely upon the amount of radio-iodine administered.

c. Except under unusual conditions (see below), routine nursing care may be employed, and patients may be allowed visitors in accordance with usual Medical Center regulations.

d. The patient must be isolated from other patients.

e. Any radioactive urine, vomit, etc. can be disposed down the sewer unless otherwise noted by the physician or RSO.

f. Patients who have received very large doses (30 millicurie or more) of radio-iodine for the treatment of cancer will have special precautions posted and special instructions given to personnel at the time of treatment (Appendix L). Chief, Nuclear Medicine Service or RSO may initiate special precautions at doses lower than 30 mCi and in line with the ALARA (As Low As Reasonably Achievable) concept. The following rules apply in these cases:

1. Visitors should be limited to the time posted on the door.

2. Nursing personnel should attend the patient for routine purposes, but if special nursing care is required, the problem of nursing personnel exposure will be worked out by the RSO.

3. The nurses in attendance should obtain and wear a film badge or other monitoring device. These may be obtained from the RSO and will be collected as directed. A monitoring device shall be worn only by the nurse to whom it is issued and should not be exchanged between nurses.

g. A container with a laundry bag inside should be provided by the RSO to collect linen where there is possible contamination by I-131. The disposal of possibly contaminated linen should be determined by the RSO.

h. A disposal can suitably marked should be placed in each room with I-131 therapy cases to collect wastes. This will be monitored for contamination and collected by the RSO.

i. Rubber gloves should be worn while cleaning contaminated equipment. These gloves should be washed with soap and running water while on the hands and dried before removal and disposal.

j. A designated sink (by RSO) on the floor should be used for washing contaminated equipment. This sink should be washed after each use with soap and water and scrubbed with a brush to prevent collection of radioactivity and subsequent dissemination of the contamination.

k. Thoroughly wash with soap and running water, items such as bed pans, urinals, and basins. Use items for same patient until treatment is complete. Have this equipment monitored by the RSO before it is used for other patients.

1.6 HANDLING OF BODY EXCRETIONS

a. Use rubber gloves whenever handling excretion of a patient or contaminated materials.

b. Urine:

1. Urine should be collected when requested directly via funnel into the bottle provided which is kept shielded by lead at the bedside. This urine will be disposed of by the RSO.

2. A balloon catheter may be inserted in the bladder before treatment.

3. In cases where urine is not to be retained, it may be disposed of in the usual way, taking care not to spill.

4. Any spillage should be immediately and thoroughly wiped with paper towels while wearing gloves and all contaminated material should be placed in the marked radioactive disposal can. The RSO shall be notified immediately.

5. Encourage the patient to take care of his own collection, if possible.

c. Stools:

1. Usually there is very little radioactivity in stools. They may be disposed of in the usual way, unless retention is requested.

d. Sputum and Vomitus:

1. Should the patient vomit during the first 48 hours after the therapy was administered, the vomitus (and sputum) should be collected in a waterproof cardboard container and saved in a lead shielded container. It should be labeled with the name of the patient, dated, and the time of vomiting. The RSO should be notified.

2. If the vomitus is spilled, it should be wiped up with paper towels by personnel wearing rubber gloves. All linens soiled by vomitus and the contaminated rubber gloves should be deposited in the special container for such items.

e. Soiled Tissues and Sponges:

1. Place soiled tissues and sponges in a paper bag attached to the patients bed (or radioactive waste disposal can). This should then be transferred to the disposal can for monitoring by the RSO.

f. Incontinence:

1. If there has been a large spill of urine or vomitus, immediately notify the physician and/or the RSO. Do not handle the damp bed clothes without rubber gloves.

2. Remember that distance, heavy metal shielding, and short exposure times are the best methods of personnel protection.

1.7 PATIENT BATH

a. Unless specifically ordered by the responsible physician, the bath should be postponed for the first 48 hours.

1.8 EMERGENCY SITUATIONS

a. If there are any questions of contamination, techniques for handling contamination, or personnel exposure the Radiation Safety Officer should be contacted.

1.9 NURSING CARE OF PATIENTS RECEIVING THERAPEUTIC DOSES OF RADIO-PHOSPHORUS (P-32)

a. General:

1. If the P-32 is given intravenously, there is no special radiation hazard near the patient and no special precautions are necessary.

2. If the P-32 is given orally, there is no radiation hazard unless the patient vomits during the first 12 hours after administration. If this does occur, instructions for handling this situation are given in the following section.

3. If the P-32 is used for intracavity therapy, no special precautions are necessary unless a previous surgical wound incident to the cavity is reopened. In this event, the attending physician and the RSO shall be notified immediately. (instructions given in the following section should be followed) Urine should be handled as per instructions in the following section.

4. Nurses may spend whatever time necessary near the patient for routine nursing care.

5. Patients are allowed visitors in accordance with the Medical Center regulations.

6. No special precautions are needed for sputum, stools, dishes, instruments, or bedding. Urine usually contains radioactivity (P-32) and should be handled with care using rubber gloves.

b. Specific Instructions:

1. If the P-32 has been given intravenously, and the patient vomits, no special precautions are necessary.

2. If the P-32 has been given orally and the patient vomits within 12 hours, the vomitus and any soiled clothing, bedding, and utensils should be collected and put into a metal can provided by the RSO. Wear rubber gloves when handling contaminated items. Before removing them, wash them with soap and water at any sink. Use plenty of water to wash down the sink. After removal, place the gloves with other contaminated items.

3. If a urinal or bedpan is used, care should be taken to avoid spillage in transferring the urine to the toilet. Rubber gloves are advised when handling the urine. If urine collection has been ordered, carefully transfer it to a five-pint bottle. The bottle should be labeled with the patient's name, number, and time of collection and sent to the ordering physician in a suitable shielded container as advised by the RSO. Urine should be wiped up with proper tissues and these may be flushed down the toilet. The urinal should be thoroughly washed at any sink before reuse.

4. If the P-32 is used topically (i.e. direct application to the skin under as surgical dressing) DO NOT TOUCH the dressing. If the dressing becomes loose or needs changing, call the attending physician or the Radiation Safety Officer.

5. P-32 should not be used for intracavity therapy if there is any evidence of fluid localization or any possibility of mechanical leakage from a surgical wound site. In the event, however, that a previously closed surgical wound should reopen or there is any possibility of leakage of the radioactive P-32, call the attending physician and the RSO immediately.

c. EMERGENCY SITUATIONS: In the case of loose dressings or any problem or question not answered above, call the attending physician, and/or the Radiation Safety Officer.

APPENDIX U

User responsibility (Physician and Technologist)

- a. Possessing a copy of the policies and procedures (P&P) and having a thorough understanding of its contents.
- b. Assuring that the individual users under his/her supervision are familiar with the contents of the P&P.
- c. Complying with all Puerto Rico Regulations for the safe use and handling of radioactive material as described in the P&P.
- d. Instruction of personnel under his/her supervision in the safe use and handling of radioactive materials.
- e. Instruct personnel under his/her supervision to attend Radiation Safety seminars for continuing education on a yearly basis.
- f. Direction of all personnel under his/her supervision to comply with all recommendation which are designed to reduce their radiation exposure.
- g. Adequate planning of an experiment or procedure to assure that proper radiation safety precautions are taken.
- h. Notifying the Radiation Safety Office regarding changes in protocol, techniques, and changes in physical location that might lead to increased personnel radiation exposure or increased contamination in the laboratory or increased release of radionuclides to the environment.
- i. Limiting the use of radionuclides to only those individuals authorized to use radioactive material. The User is also responsible for notifying the Radiation Safety Office of changes in personnel.
- j. Maintaining current inventory records including receipt, use, and disposal of radionuclides and of all laboratory monitoring and surveys.
- k. Must have access to radiation monitoring equipment.
- 1. Prohibit eating, drinking, smoking, and applying cosmetics in laboratories that radioactive materials are stored or used.
- m. Assure that film badges (if required), gloves, and protective clothing are worn.
- n. Assure that the rooms, storage areas, hoods, refrigerators, sinks, and trash containers are properly labeled.

- o. Post a "Notice to Employees" sign so all personnel under his/her supervision are able to read it.
- p. The User must instruct female personnel concerning prenatal radiation exposure. The User shall immediately notify the Radiation Safety Office in writing of any pregnancy or suspected pregnancy of personnel involved with the handling of radionuclides.
- q. Insuring that personnel under his/her supervision are appropriately monitored for exposure to radiation.
- r. Reporting spills or accidents involving radioactive material immediately to the Radiation Safety Office and submit an Incident Report within two weeks.
- s. If the User is absent for an extended time, a qualified individual must be responsible for any work that is continued in their absence. This does not relieve the User of his/her responsibility for the regulatory requirements.
- t. The design of all facilities involving the use, handling, or storage of radioactive materials shall be reviewed by the Radiation Safety Officer to assure maintenance of adequate environmental protection. New proposed procedures and techniques will be likewise reviewed.
- u. No person should be recruited as a radiation worker during the period of pregnancy.
- v. Must comply with all conditions of the Radioactive Material License and Puerto Rico Regulations.

Procedures For Minimizing Exposure and Contamination

- a. All radioactive materials are to be confined within zones with adequate boundaries and facilities suitable to prevent dispersal or exposure beyond the zone. These zones are confined to authorized rooms.
- b. Protective clothing, such as laboratory coats, shoe covers, gloves, etc., should be worn by personnel whenever handling radioactive material or whenever radiation hazards exist.
- c. SMOKING, DRINKING, EATING OR APPLICATION OF COSMETICS IN LABORATORIES OR WORK ROOMS IN WHICH UNSEALED FORMS OF RADIOACTIVE MATERIALS ARE STORED OR USED IS PROHIBITED.
- d. Pipetting by mouth is prohibited.
- e. Food product containers shall not be used to hold radioactive material.
- f. Storage of food or beverages in refrigerators, freezers, cold rooms, or laboratories marked for and/or containing radioactive materials is prohibited. Any food or beverages found will be considers contaminated and have to be disposed of as radioactive waste.

- g. Personal items such as purses, combs, cosmetics, etc., shall not be stored where radioactive materials are used.
- h. Telephones, papers, calculators, etc., shall not be handled if there is a possibility of contaminating them.
- i. Whenever feasible, radioactive material (particularly strong beta emitters and gamma emitters) shall not be manipulated with the fingers. Forceps or tongs of suitable length shall be used.
- j. If a radiation shield is applicable, be sure to consider all sides (front, back, sides, top and bottom). Do not assume that the floor or a wall is adequate shielding as there is a possibility that other personnel are working in the adjoining area. The Radiation Safety Officer can advise you on the shielding.
- k. All radioactive materials and samples shall be conspicuously labeled to include the chemical content, the amount of radioactivity and the date on which the radionuclide was assayed. (see Notices and Caution Signs)
- 1. Unused radioactive material and samples shall be returned to well-shielded storage areas when not in use. Please consult the Radiation Safety Officer if there is question about shielding.
- m. Only discharge radioactive material into the sanitary sewer that is authorized by Appendix H.
- n. Disposal of radioactive material in ordinary trash is prohibited.
- o. Dispose of sharp objects (syringe needles, razor blades, scalpel blades, broken glass, etc) only within puncture proof containers.
- p. Do not mix contaminated objects with uncontaminated objects. Follow the Radioactive Waste Policy, see Appendix I.
- q. A catch pan of unbreakable material shall be placed under any vessel or equipment which may leak, burst or spill a radioactive material. The area of the work bench where radioactive liquids are used should be covered with absorbent material. The absorbent material should be changed frequently; e.g., following completion of a procedure or series of procedures.
- r. Before beginning any new procedure, develop a detailed plan for carrying out the various steps. If the procedure involves hazardous levels of radiation, e.g., mCi quantities of I-131 or P-32, rehearse the procedure without radioactive materials before undertaking the actual experiment.
- s. Sources of radiation must be secured against unauthorized removal from the place of storage.
- t. Each individual using radioactive materials is responsible for being familiar with this P&P. Also a copy of P&P is available for review in the Radiation Safety Office.

Safe Handling of Cadavers Containing Radioactive Materials/Implants

Introduction

This procedure is designed to supplement your policy and procedures for diagnostic nuclear medicine procedures, therapeutic procedures, permanent implants and temporary implants. It is the responsibility of the physician to inform the patient regarding the "Guidance and Safety Instructions for Surgeons, Pathologist, and Funeral Directors"

Precautions to be taken are dependent on the nature and quantity of the radioactive material present. The next question is whether the cadaver is going through a simple embalming procedure for burial, cremation, or planned for an autopsy/surgery. In general, no appreciable hazard exists unless the body is will go through the autopsy and/or surgery or cremation.

EMBALMING

Embalming will be by the injection method and the likelihood of contamination is extremely small. Nevertheless, all individuals involved in the procedure to avoid the possibility of contamination by radioactive fluids from the body should follow universal precautions.

CREMATION

In modern crematories, the combination of high temperatures and forced draft is used in the incineration process. All soft body parts are completely disposed of as smoke or very finely divided ash. At the end of the process, only the bone ash remains on the cremation tray. Therefore three types of items that must be considered:

- 1. Radioactive materials that may be concentrated in the bone ash.
- 2. The crematorium employees in the vicinity of the crematorium.
- 3. The general population in the vicinity of the crematorium.

The two primary hazards are from the radioactivity emitted with the stack gases and the handling of the bone ash. To understand the full potential risk to the hazard, we must consider a variety of factors:

- 1. Volatility of the various isotopes
- 2. Dilution by the combustion gases
- 3. Dilution of the combustion gases with the atmosphere
- 4. Proximity of dwellings to the exhaust stack top
- 5. Average wind velocity
- 6. Concentration of the ash in the air during the handling process
- 7. Time required to collect the ashes

In reviewing all of the above factors, it is determined that no radiation hazard would exist if each crematorium were to handle a few number of bodies each year as long as the over activity did not exceed the following:

- 1. Diagnostic procedures used for Nuclear Medicine.
- 2. The radioactive isotopes listed in Regulatory Guide 8.39
- 3. P-32 (<200 mCi)
- 4. Y-90 (<200 mCi)

Autopsy and or Surgery

As long as the body remains unopened, the radiation received by any individual near the cadaver is almost due to the gamma radiation and the dose rate will remain very low. This is on an average of less than 5 mRem/hr. The change in emphasis is when an autopsy or surgery is to be performed.

The main general principle is to remove the main source of the radiation hazard as soon as possible without causing major contamination in the morgue. If this cannot be done, regions of high activity should be avoided or shielded. The Nuclear Medicine/Oncology physician can provide information regarding the area of the radiation hazard(s) within the cadaver. This information must be communicated prior to the autopsy/surgical procedure.

Temporary implants do not pose any radiation hazard since the Oncology department upon notification can easily do the removal of the source if a patient dies in the hospital room.

Permanent implants need only to be removed if the autopsy or the surgical procedure is performed near the implant area.

A Nuclear Medicine therapy deals with a specific organ. Removal of the organ will reduce the radiation exposure significantly but a small percentage will still remain and the likelihood of contamination from body fluids will still be present.

Recommended Guidelines

Therapies					
Isotope	Activity	Consideration	Time		
I-131	<200 mCi	During the 10 day treatment period	32 days*		
I-131	<200 mCi	After the 10 day treatment period	None**		

*Body fluids and target organ will be radioactive

**Mainly the target organ will be radioactive

If the thyroid has been removed, than all of the radioactive material will be removed within the 10 days.

Permanent Implants			
Isotope	T 1/2	10 * t1/2	
Pd-103	17 days	170 days	
I-125	60 days	600 days	
Ir-192	74.2 days	742 days	
Au-198	64.8 hrs	27 days	

If possible, hold the cadaver for 10 half lives or remove the sources for incineration

This is to acknowledge the receipt of your letter/application dated

 $\frac{2/23/2006}{1000}$, and to inform you that the initial processing which includes an administrative review has been performed.

There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

138533 Your action has been assigned Mail Control Number When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI) (6-96)

Sincerely, Licensing Assistance Team Leader

	:	(FOR LFMS USE)
	:	INFORMATION FROM LTS
BETWEEN:	:	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
	:	
License Fee Management Branch, ARM	:	Program Code: 02201
and	:	Status Code: 3
Regional Licensing Sections	:	Fee Category:
	:	Exp. Date: 0
	:	Fee Comments:
	:	Decom Fin Assur Reqd: _

LICENSE FEE TRANSMITTAL

A. REGION \mathcal{I}

- 1. APPLICATION ATTACHED Applicant/Licensee: WESTERN RADIOSONICS Received Date: 20060306 Docket No: 3037158 Control No.: 138533 License No.: 52-3i/37-01 Action Type: New Licensee
- 2. FEE ATTACHED \$2,100.00 Amount: Check No.: 557394

3. COMMENTS

Signed <u>M. C. Corkins</u> Date <u>3/7(2006</u>

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

 Correct Fee Paid. Application may be processed for: Amendment

Renewal	
License	

3. OTHER

Signed ______ Date _____