APPENDICES

APPENDICES A-H

FORMS AND SAMPLES

APPENDIX A

NRC Form 313

“Application for Material License”

NRC FORM 313 **U.S. NUCLEAR REGULATORY COMMISSION**
(4-2004)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 10/31/2005**

Estimated burden per response to comply with this mandatory information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5-F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:
ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY	AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (4-2004) PRINTED ON RECYCLED PAPER

APPENDIX B

NRC Form 313A

“Medical Use Training and Experience and Preceptor Attestation”

NRC FORM 313A
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2005

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35).

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

3. CERTIFICATION

a. Provide a copy of the board certification. *(Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)*

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

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NRC FORM 313A
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

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U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
☐ N/A of _____ the RSO for License No. _____.

9. MEDICAL PHYSICIST -- ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics
☐ N/A (35.961) or medical physics (35.51) under the supervision of _____

and

☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described
☐ N/A and for topics identified in item 6a) for (specify use or device) _____
under the supervision of _____ who is a medical physicist (35.961) or meets
requirements for Authorized Medical Physicists (35.51) (specify use or device)
_____.

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U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of *(if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):*

A. Name of Supervisor

_____

B. Supervisor is:

☐ Authorized User ☐ Authorized Medical Physicist
☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) _____.
for medical uses in Part 35, Section(s) _____.

D. Address

E. Materials License Number

_____

PART II -- PRECEPTOR ATTESTATION

Note: *This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 35.590 or Part 35, Subpart J (except 35.980).*

I attest the individual named in Item 1:

11a.
☐ has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____,
as documented in section(s) _____ of this form.

11b. Select one

☐ meets the requirements in ☐ 35.50(e), ☐ 35.51(c), ☐ 35.390(b)(1)(ii)(G), ☐ 35.690(c) for _____
☐ N/A types of use, as documented in section(s) _____ of this form.

11c.
☐ has achieved a level of competency sufficient to operate a nuclear pharmacy (for 35.980); **or**

☐ has achieved a level of competency sufficient to function independently as an authorized _____ for _____ uses (or units); **or**

☐ has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **or**
☐ N/A

11d.
☐ I am an Authorized Nuclear Pharmacist; **or** ☐ I am a Radiation Safety Officer; **or**

☐ I meet the requirements of _____ section(s) of 10 CFR Part 35
or equivalent Agreement State requirements to be a preceptor ☐ AU or ☐ AMP
for the following byproduct material uses (or units): _____

A. Address

B. Materials License Number

_____

C. NAME OF PRECEPTOR (*print clearly*)	D. SIGNATURE -- PRECEPTOR	E. DATE

APPENDIX C

License Application Checklists

License Application Checklists

This Appendix contains checklists that may be used to assist in organizing an application.

Table C.1, Applicability Table, may be used to determine if particular information must be provided or if "N/A" (not applicable) may be the response to each item that follows. To determine those items to which you must respond, "highlight" the columns under the categories of materials you requested in Item 5 (e.g., 35.300, 35.400, etc.). If any "Y" beside an item is highlighted, you must provide detailed information in response to that item. If the letters "N/A" are highlighted, you may respond "N/A" on your application. If any "N" beside an item is highlighted, no information in response is required, but NRC regulations that apply to the given category apply to your type of license. If any "P" beside an item is highlighted, you should provide a commitment as described in the section referenced in the body of this document. If any "G" beside an item is highlighted, see subsequent sections for required responses. "APP" indicates that this document contains an appendix that addresses the item.

Table C.1 Applicability Table								
Item #	**Topic**	**35.100/200**	**35.300**	**35.400**	**35.500**	**35.600**	**35.1000**	**APP**
8.5	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
8.5	Unsealed Byproduct Material – Written Directive Required		Y					
8.5	Manual Brachytherapy			Y				
8.5	Sealed Sources for Diagnosis				Y			
8.5	Teletherapy Units					Y		
8.5	Remote Afterloader Units					Y		
8.5	Gamma Stereotactic Radiosurgery Units					Y		
8.5	Other Medical Uses						Y	
8.6	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
8.7	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.8	Purpose(s) for Which Licensed Material Will be Used	Y	Y	Y	Y	Y	Y	
8.9	Training and Experience	G	G	G	G	G	G	
8.10	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	I, D
8.11	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D
8.12	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.13	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	D
8.14	Facilities and Equipment	G	G	G	G	G	G	
8.15	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.16	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.17	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.18	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.19	Other Equipment and Facilities	N	N	N	N	Y	N	
8.20	Radiation Protection Program	G	G	G	G	G	G	
8.21	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.22	Occupational Dose	P	P	P	P	P	P	M
8.23	Area Surveys	P	P	P	P	P	P	R

Table C.1 Applicability Table

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.24	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.25	Spill Procedures	P	P	P	N/A	N/A	P	N
8.26	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.27	Minimization of Contamination	N	N	N	N	N	N	
8.28	Waste Management	P	P	P	P	P	P	W
8.29	Fees	Y	Y	Y	Y	Y	Y	
8.30	Certification	Y	Y	Y	Y	Y	Y	
8.31	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	J
8.32	Public Dose	N	N	N	N	N	N	
8.33	Opening Packages	N	N	N	N	N	N	
8.34	Written Directive Procedures	N/A	N	N	N/A	N	N	S
8.35	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	U
8.36	Mobile Medical Service	N	N	N	N	N	N	V
8.37	Audit Program	N	N	N	N	N	N	L
8.38	Operating and Emergency Procedure	N	N	N	N	N	N	N
8.39	Material Receipt and Accountability	N	N	N	N	N	N	
8.40	Ordering and Receiving	N	N	N	N	N	N	O
8.41	Sealed Source Inventory	N	N	N	N	N	N	
8.42	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.43	Recordkeeping	N	N	N	N	N	N	X
8.44	Reporting	N	N	N	N	N	N	Y
8.45	Leak Tests	N	N	N	N	N	N	Q
8.46	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
8.47	Transportation	N	N	N	N	N	N	Z

* Y beside item 8.13 for use under 35.400 applies to Sr-90 only.
** N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for type of radioactive material requested and purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the “yes” column next to 10 CFR 35.100 and 35.200 in Table

C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	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 permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	Any byproduct material permitted by 10 CFR 35.300	Any	___ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Strontium-90	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.500 Check all that apply: " Gd-153; " I-125; " Other, describe	Sealed source or device (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Iridium-192	Sealed source or device (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____Model No. _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No._____)	___ curies per source and ___ curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	___ millicuries	*In vitro* studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	For use in a Manufacturer _____ Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries per source and ___ millicuries total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicuries per source and ___ grams total	As a component of Manufacturer _____ Model No. _____, nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or Manufacturer/ Model No. _____	___ millicuries	Purpose of use _____.

Table C.3 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name(s) of Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: _____	*For an individual previously identified as an RSO on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the a license or a permit (if issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope) that authorized the uses requested and on which the individual was named as the RSO.	”
	For an individual qualifying under 10 CFR 35.50(a):	
	Copy of certification by a speciality board whose certification process has been recognized[1] by the NRC or an Agreement State under 35.50(a). **AND**	”
	Written attestation, signed by a preceptor RSO, that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	”
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	”
	For an individual qualifying under 10 CFR 35.50(b):	
	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 the applicant seeks approval of an individual to serve as RSO. **AND**	”
	Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	”

[1] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	For an individual qualifying under 10 CFR 35.50(c):	
	Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized[2] by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 35.50(c)(1) demonstrating that the proposed RSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **AND**	”
	Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval; has satisfactorily completed and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	”
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **OR**	”
	Copy of the licensee’s license indicating that the individual is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee’s license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO. **AND**	”
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”

[2] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, copy of the certification(s) by a board whose certification process has been listed by the NRC in 10 CFR 35.900(a) **OR**	”
	Until October 24, 2005, a description of the classroom and laboratory training and experience specified in 10 CFR 35.900(b)(1), and the full-time experience specified in 10 CFR 35.900(b)(2). **OR**	”
	Until October 24, 2005, a copy of the identification as an authorized user on the licensee’s license as specified in 10 CFR 35.900(c). **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
7: Authorized Users Name(s), and, Requested Uses for Each Individual _____ _____ _____	*For an individual previously identified as an AU on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	”
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board certified:	
	Copy of the certification(s) by a specialty board(s) whose certification process has been recognized[3] by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested. **AND**	”
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought. **AND**	”

[3] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board certified:	
	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**	”
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought. **AND**	”
	Written attestation, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Authorized Nuclear Pharmacists Name(s): _____	*For an individual previously identified as an ANP on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the license or permit (if issued by an Agreement State or by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on which the individual was specifically named ANP.	”
	For an individual qualifying under 10 CFR 35.55:	
	Copy of the certification(s) of the specialty board whose certification process has been recognized[4] under 10 CFR 35.55(a). **AND**	”
	Written attestation, signed by a preceptor ANP, that training and experience required for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved. **OR**	”
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience. **AND**	”
	Written attestation, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, copy of certification as a nuclear pharmacist by the Board of Pharmaceutical Specialities. **OR**	”

[4] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Until October 24, 2005, description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed ANP is qualified by training and experience for the use requested. **AND**	”
	Written attestation, signed by a preceptor ANP, that training and experience required for certification has been satisfactorily completed and that a level of competency sufficient to independently operate a nuclear pharmacy has been achieved. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
Item 7: Authorized Medical Physicists Name(s): _____	*For an individual previously identified as an AMP on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on which the individual was specifically named an AMP for the uses requested.	”
	For an individual qualifying under 10 CFR 35.51:	
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized[5] under 10 CFR 35.51(a). **AND**	”
	Written attestation, signed by a preceptor AMP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved. **AND**	”
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system. **OR**	”

[5] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested. **AND**	”
	Written attestation, signed by a preceptor AMP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved. **AND**	”
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	”
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, copy of the certification(s) by a board whose certification process has been listed in 10 CFR 35.961(a) or (b). **OR**	”
	Until October 24, 2005, a description of the training and experience specified in 10 CFR 35.961(c), demonstrating that the proposed AMP is qualified by training and experience to serve as an AMP. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 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:	”
	C Drawings should be to scale, and indicate the scale used.	”
	C Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading “Discussion”;	”
	C 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 a restricted or unrestricted area as defined in 10 CFR 20.1003; and	”
	C Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of 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.	”
Item 9: Radiation Monitoring Instruments	A statement that: “Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.” **AND/OR**	”
	A statement that: “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 instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. **AND**	”
	A statement that: “We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.”	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	"
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	"
Item 9: Other Equipment and Facilities	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	"
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	"
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:	
	C Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;	"
	C Area radiation monitoring equipment;	"
	C Viewing and intercom systems (except for LDR units);	"
	C Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;	"
	C Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and	"
	C Emergency response equipment.	"
Item 10. Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610	"
Item 10: Occupational Dose	A statement that: "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, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees." **OR**	"
	A description of an alternative method for demonstrating compliance with the referenced regulations.	"

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Area Surveys	A statement that: "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."	"
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "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 20.1301."	"
Item 10: Spill Procedures	A statement that: "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."	"
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: _____ **AND**	"
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND**	"
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	"
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
Item 11: Waste Management	A statement that: "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 35.92."	"

APPENDIX D

Documentation of Training and Experience To Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Nuclear Pharmacist, or Authorized Medical Physicist

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer to its medical use license only needs to provide evidence that the individual is listed on a medical use license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material broad scope permittee before October 25, 2005 provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced authorized nuclear pharmacist to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacists. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Applicants that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by NRC

Applicants should complete the appropriate sections on NRC Form 313A to show that the individuals meet the appropriate training and experience criteria in 10 CFR Part 35 subparts B, D, E, F, G. H, or J (until October 24, 2005). NRC Form 313A was developed to provide a single location where six different professional groups (physicians, dentist, podiatrist, medical physicist, pharmacist, and radiation safety officer) and ten different medical sub-specialties could document completion of appropriate training and experience requirements. Therefore, some of the sections will not be applicable for each group.

There are two different training and experience routes to qualify an individual as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer. The first is by means of certification by a board recognized by NRC as provided in 10 CFR 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.396, 35.590(a), or 35.690(a), or until October 25, 2005, a board listed in 10 CFR Part 35 Subpart J. Preceptor attestations must also be submitted for individuals to qualify under Subparts B and D through H.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, subparts B, D, E, F, G, and H. Until October 25, 2005 this route also includes the classroom and laboratory training and supervised clinical or work experience requirements in 10 CFR Part 35, Subpart J.

III. Recentness of Training

The required training and experience described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;

- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;

- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization; and

- For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

IV. Instructions and Guidance for Filling Out NRC Form 313A

Note: *If using NRC Form 313A to document training and experience, individuals who have been certified by boards recognized by the NRC need only complete items 1, 2 and 3 of NRC Form 313A. Information for all other individuals to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist or Radiation Safety Officer must be provided in subsequent sections of NRC Form 313A.*

Part I. Training and Experience

Provide information for each individual for whom authorization is sought.

Item 1. Name of individual, proposed authorization, and applicable training requirements.

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name, specify the type authorization being requested (Radiation Safety Officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist), and applicable training requirements.

Note: Do not include personal or private information (e.g., date of birth, social security number) as part of your qualification documentation.

Item 2. State or territory where licensed

NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to

prescribe drugs in the practice of medicine, practice dentistry, practice podiatry, or practice pharmacy, respectively (see definition of "Physician" in 10 CFR 35.2).

Item 3. Certification

The applicant should provide a copy of the board certification or provide the complete name of the specialty board and the category (or subspecialty) if the board recognizes more than one certification specialty. Applicants should provide all of the information noted under Item 3, attending to the requirements for different pathways to approval. Data provided about the month and year certified is used to establish recentness of training, to confirm that NRC recognizes[1] that board's certifications, and to verify that the applicant meets the training requirements.

If an individual to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer cannot meet requirements for board certification pathway, the applicant must fill out the appropriate remaining sections of NRC Form 313A and must submit a written attestation signed by a preceptor (see Part II of NRC Form 313A).

Item 4. Individuals Identified on a License or Permit as Radiation Safety Officers (RSO), Authorized Users (AU), Authorized Medical Physicists (AMP), or Authorized Nuclear Pharmacists (ANP) Seeking Additional Authorizations.

The applicant should provide a copy of the license or broadscope permit listing his or her current authorization, and also complete the items listed under either 4.b or 4.c, depending on the authorization sought.

Item 5. Classroom and Laboratory Training or Didactic Training, 6a. Work or Practical Experience with Radiation, 6b. Supervised Clinical Case Experience, and 6c. Training for Sections 35.50(e), 35.51(c), 35.590(c), or 35.690(c).

Because the applicant is not required to receive the training described in Item 5 at one location or at one time, space is provided to identify each location and date of training. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon the type of approval sought.

While most applicants will only complete Item 6a, those who must document clinical case experiences (e.g., physicians seeking authorization for uses under 10 CFR 35.300 and strontium-90 eye applicator users) should document this in Item 6b.

Item 6c. should be completed by applicants for Radiation Safety Officer, Authorized Medical Physicist, or for use of sealed sources for diagnosis, or remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units as required in 10 CFR 35.690.

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[1] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Note: Classroom and Laboratory Training or Didactic Training may be provided at medical teaching/university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required "structural educational programs" or "training" may be obtained in any number of settings, locations, and educational situations. If the applicant is seeking authorization under the requirements of 10 CFR Part 35 subparts B, D, E, F, G, and H, applicants must submit a written attestation signed by a preceptor, indicating the individual for whom approval is sought meets training requirements of applicable sections and has achieved a level of competency sufficient to function independently. Preceptor statements are also required for ANPs approved under Subpart J (§35.980(a)).

The NRC expects that clinical laboratory hours credited toward meeting the requirements for classroom and laboratory training in Subparts B and D through H will involve training in radiation safety aspects of the medical use of byproduct material. The NRC recognizes, for example, that physicians in training may not dedicate all of their clinical laboratory time specifically to the subject areas covered in these subparts and will be attending to other clinical matters involving the medical use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). However, those hours spent on other duties, not related to radiation safety, should not be counted toward the minimum number of hours of required classroom and laboratory training in radiation safety. This type of supervised work experience, even though not specifically required by the NRC, may be counted toward the supervised work experience to obtain the required total hours of training (e.g., 700 hours for § 35.390). Similarly, the NRC recognizes that clinicians will not dedicate all of their time in training specifically to the subject areas described in Subparts D though H and will be attending to other clinical matters. The NRC will broadly interpret "classroom training" to include various types of instruction received by candidates for approval, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material.

Item 7. Formal Training

This item is completed for individuals qualified to be medical physicists or physicians meeting the requirements in 10 CFR 35.490, 35.690, 35.940, and 35.960.

Item 8. Radiation Safety Officer – One Year Full-Time Work Experience

This item is used to document that the applicant meets the regulatory requirement of one full year of full time work experience in the areas which are listed in Item 6a.

Item 9. Medical Physicist – One-Year Full-Time Training and Experience

This section is used to document that the Medical Physicist has received one full year of full time training and one full year of work experience. Both are required to be under the supervision of an authorized medical physicist but they do not have to be under the same medical physicist.

Item 10. Supervising Individual

Item 10 need only be completed by an applicant seeking to have an individual listed on the license as an AU, RSO, or AMP under Part 35 Subparts B, D, E, F or H. If an applicant is

following the training and experience requirements in Subpart J, it is sufficient to identify the supervising individual and licensed facility in Items 6a and 6b. In addition, the use of Item 10 is also dependent on whether information on the identity, qualifications and location (license number) of the supervising individual has already been provided elsewhere on NRC Form 313A (e.g., in Items 8 or 9).

***Note**: If the individual had more than one supervisor, all supervising individual names must be listed in Items 6a and 6b and Item 10 filled out for each.*

***Note**: The authorized nuclear pharmacist applicant is required to have supervised practical experience in a nuclear pharmacy but the individual(s) providing the supervision are not specified. Therefore the applicant does not need to identify a supervising individual in Item 6a or complete Item 10.*

Part II Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized user, authorized nuclear pharmacist, authorized medical physicist or radiation safety officer (pursuant to 10 CFR Part 35, Subparts B, C, D, E, F, or H and 10 CFR 35.980) and attest that the individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. This preceptor also has to meet specific requirements.

The NRC recognizes supervised work experience, such as that described in 10 CFR 35.290(c), conducted under the supervision of an authorized user in a licensed material use program. A supervisor is an AU who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in 10 CFR 35.490(b)(1), 10 CFR 35.491(b)(2), and 10 CFR 35.690(b)(1) must have been gained at a medical institution. When the supervised work experience is complete, the applicant should provide documentation of it using NRC Form 313A or equivalent, and written attestation from the preceptor using NRC Form 313A or equivalent that indicates that the applicant has obtained all required experience elements. These documents should be submitted as attachments to NRC Form 313, "Application for Material License."

An applicant requesting authorized nuclear pharmacist status for a pharmacist under 10 CFR 35.980(b) is required to provide a different attestation statement than for a pharmacist under Subpart B, 10 CFR 35.55. Information may be provided in Item 11a needed to meet the requirements under 10 CFR Part 35, Subpart J. Space is provided in Items C and D for the preceptor authorized nuclear pharmacist's name and signature.

Item 11

Item 11 has four components: The information in 11a. attests that the applicant has satisfactorily completed the training and supervised work experience requirements; the information in 11b. attests that the applicant meets the requirements in 35.50(e), 35.51(c), 35.390(b)(1)(ii)(G), 35.690(c) for specified types of uses; the information in 11c. attests that the applicant has the competency to function independently; and the information in 11d. attests that the preceptor is an Authorized Nuclear Pharmacist or Radiation Safety Officer or meets the requirements to be a preceptor AU, AMP, and requires the preceptor's signature.

APPENDIX E

Sample License Application

NRC FORM **313** **U.S. NUCLEAR REGULATORY COMMISSION**
(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 10/31/2005**

Estimated burden per response to comply with this mandatory information collection request, 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:
CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8084

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

[X] A. NEW LICENSE

[ ] B. AMENDMENT TO LICENSE NUMBER _____

[ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

Dr. Noe Directive
Suite 112
2 Physician Circle Parkway
Anytown, PA 02201

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Suite 112
2 Physician Circle Parkway
Anytown, PA 02201

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Noe Directive, MD

TELEPHONE NUMBER

(123) 456-7890

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time. **See Attachment 1**

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
See Attachment 1

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE
See Attachment 2

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
See Attachment 2

9. FACILITIES AND EQUIPMENT.
See Attachment 2

10. RADIATION SAFETY PROGRAM.
See Attachment 2

11. WASTE MANAGEMENT.
See Attachment 2

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY	7C	AMOUNT ENCLOSED $D, DDD.CC

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, , 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Noe Directive, MD - President	Noe Directive	**April 11, 2003**

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

NRC FORM 313 (8-1999) PRINTED ON RECYCLED PAPER

NRC FORM 313A
(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2005

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35).

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Noe Directive, MD **Authorized user, 10 CFR 35.190, 10 CFR 35.290**

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Pennsylvania Medical License PA-MD-XXYYY

3. CERTIFICATION

a. Provide a copy of the board certification. *(Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)*

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(B)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	**Radiation 200 for Diagnostic Physicians Sample Medical School Anytown, PA**	**50**	**July 1 to August 15, 2002**
Radiation Protection	"	**50**	"
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	**50**	"
Radiation Biology	"	**50**	"
Chemistry of Byproduct Material for Medical Use	"	**50**	"
OTHER			

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(04-2005)

U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ordering, receiving, and unpacking radioactive material safely and performing the related radiation	**Thomas Group, D.O.**	**See item 9**	**August 2002 to March 2003 100**
Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.	"	"	**100**
Calculating, measuring, and safely preparing patient or human research subject dosages	"	"	**100**
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	**50**
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	"	"	**50**
Administering dosages of radioactive drugs to patients or human research subjects	"	"	**100**
Eluting generators, measuring and testing the eluate, and processing the eluate with reagent kits to prepare labeled radioactive drugs	**Jane Jones, MD**	**See item 12**	**50**
			Total > 700 hours

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
N/A					

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U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
N/A		

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

☐ YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision. of _____ the RSO for License No.

: N/A .

9. MEDICAL PHYSICIST -- ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics

: N/A (35.961) or medical physics (35.51) under the supervision of _____

and

☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described

: N/A and for topics identified in item 6a) for (specify use or device)

_____ under the supervision of

_____ who is a medical physicist (35.961) or meets requirements for

Authorized Medical Physicists (35.51) (specify use or device) _____.

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U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of *(if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):*

A. Name of Supervisor

Thomas Group, D.O.

B. Supervisor is:

: Authorized User ☐ Authorized Medical Physicist

☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) **35.290**.
for medical uses in Part 35, Section(s) **35.100 and 35.200**.

D. Address

Sample Medical-Institution Limited
1234 Main Street
Anytown, PA 02120

E. Materials License Number

99-02120-01

PART II -- PRECEPTOR ATTESTATION

Note: *This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 35.590 OR Part 35, Subpart J (except 35.980).*

I attest the individual named in Item 1:

11a.
: has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____, as documented in section(s)_____ of this form.

11b. Select one

☐ meets the requirements in 35.50(e), 35.51(c), 35.390(b)(1)(ii)(G), 35.690(c) for _____ types of use, as documented in section(s) _____ of this form.

: N/A

11c.
: has achieved a level of competency sufficient to function independently as an authorized **User** for **10 CFR 35.100 and 200** uses (or units); **or**

☐ N/A

☐ has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

: N/A

11d.
☐ I am an Authorized Nuclear Pharmacist; **or** ☐ I am a Radiation Safety Officer; **or**

: I meet the requirements of **35.290** section(s) of 10 CFR Part 35 or equivalent Agreement State requirements to be a preceptor : AU or ☐ AMP for the following byproduct material uses (or units): **35.100 and 35.200**

A. Address

Sample Medical Institution Limited
1234 Main Street
Anytown, PA 02120

B. Materials License Number

99-02120-01

C. NAME OF PRECEPTOR (*print clearly*)	D. SIGNATURE -- PRECEPTOR	E. DATE
Jane Diagnostic, MD	Jane Jones	**4-11-03**

Noe Directive, M.D. Attachment 1 of 2

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	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 permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	Any byproduct material permitted by 10 CFR 35.300	Any	___ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Strontium-90	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.

Noe Directive, M.D. Attachment 2 of 2

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: Noe Directive, M.D.	*For an individual previously identified as an RSO on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the a license or a permit (if issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope) that authorized the uses requested and on which the individual was named as the RSO.	”
	For an individual qualifying under 10 CFR 35.50(a):	
	Copy of certification by a speciality board whose certification process has been recognized[1] by the NRC or an Agreement State under 35.50(a). **AND**	”
	Written attestation, signed by a preceptor RSO, that the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	”
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	”
	For an individual qualifying under 10 CFR 35.50(b):	
	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 the applicant seeks approval of an individual to serve as RSO. **AND**	:
	Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	:

[1] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	⋮

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	For an individual qualifying under 10 CFR 35.50(c):	
	Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized[2] by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 35.50(c)(1) demonstrating that the proposed RSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **AND**	”
	Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval; has satisfactorily completed and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	”
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **OR**	”
	Copy of the licensee’s license indicating that the individual is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee’s license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO. **AND**	”
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”

[2] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, copy of the certification(s) by a board whose certification process has been listed by the NRC in 10 CFR 35.900(a). **OR**	”
	Until October 24, 2005, a description of the classroom and laboratory training and experience specified in 10 CFR 35.900(b)(1), and the full-time experience specified in 10 CFR 35.900(b)(2). **OR**	”
	Until October 24, 2005, a copy of the identification as an authorized user on the licensee's license as specified in 10 CFR 35.900(c). **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
7: Authorized Users Name(s), and, Requested Uses for Each Individual Noe Directive, M.D. 35.100, 35.200	*For an individual previously identified as an AU on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	”
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board certified:	
	Copy of the certification(s) by a specialty board(s) whose certification process has been recognized[3] by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested. **AND**	:
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought. **AND**	”

[3] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. **AND**	⋮
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board certified:	
	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**	”
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought. **AND**	”
	Written attestation, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Authorized Nuclear Pharmacists Name(s): N/A	*For an individual previously identified as an ANP on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the license or permit (if issued by an Agreement State or by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope on which the individual was specifically named ANP.	"
	For an individual qualifying under 10 CFR 35.55:	
	Copy of the certification(s) of the specialty board whose certification process has been recognized[4] under 10 CFR 35.55(a). **AND**	"
	Written attestation, signed by a preceptor ANP, that training and experience required for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved. **OR**	"
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience. **AND**	"
	Written attestation, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved. **AND**	"
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	"
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, copy of certification as a nuclear pharmacist by the Board of Pharmaceutical Specialities. **OR**	"

[4] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Until October 24, 2005, description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed ANP is qualified by training and experience for the use requested. **AND**	”
	Written attestation, signed by a preceptor ANP, that training and experience required for certification has been satisfactorily completed and that a level of competency sufficient to independently operate a nuclear pharmacy has been achieved. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”
Item 7: Authorized Medical Physicists Name(s): N/A	*For an individual previously identified as an AMP on a Commission or Agreement State license or permit:*	
	Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on which the individual was specifically named an AMP for the uses requested.	”
	For an individual qualifying under 10 CFR 35.51:	
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized[5] under 10 CFR 35.51(a). **AND**	”
	Written attestation, signed by a preceptor AMP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved. **AND**	”
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system. **OR**	”

[5] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC’s web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested. **AND**	”
	Written attestation, signed by a preceptor AMP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved. **AND**	”
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.	”
	For an individual qualifying under 10 CFR Part 35, Subpart J:	
	Until October 24, 2005, copy of the certification(s) by a board whose certification process has been listed in 10 CFR 35.961(a) or (b). **OR**	”
	Until October 24, 2005, a description of the training and experience specified in 10 CFR 35.961(c), demonstrating that the proposed AMP is qualified by training and experience to serve as an AMP. **AND**	”
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 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:	:
	C Drawings should be to scale, and indicate the scale used.	:
	C Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion";	:
	C 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 a restricted or unrestricted area as defined in 10 CFR 20.1003; and	:
	C Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of 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.	"
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations." **AND/OR**	:
	A statement that: "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 instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. **AND**	:
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	:
Item 9: Dose Calibrator and Other Dosage Measuring Equipment **N/A**	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	"

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 9:Therapy Unit - Calibration and Use__**N/A**__	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	”
Item 9: Other Equipment and Facilities__**N/A**__	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	”
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	”
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:	
	C Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;	”
	C Area radiation monitoring equipment;	”
	C Viewing and intercom systems (except for LDR units);	”
	C Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;	”
	C Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and	”
	C Emergency response equipment.	”
Item 10. Safety Procedures and Instructions__**N/A**__	Attached procedures required by 10 CFR 35.610	”
Item 10: Occupational Dose	A statement that: “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, Rev. 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.” **OR**	”
	A description of an alternative method for demonstrating compliance with the referenced regulations.	”
Item 10: Area Surveys	A statement that: “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.”	”

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "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 20.1301."	:
Item 10: Spill Procedures	A statement that: "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."	:
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources **N/A**	Name of the proposed employee and types of activities requested: _____ **AND**	"
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND**	"
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	"
Item 10: Minimization of Contamination **N/A**	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
Item 11: Waste Management	A statement that: "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 35.92."	:

Dr. Noe Directive

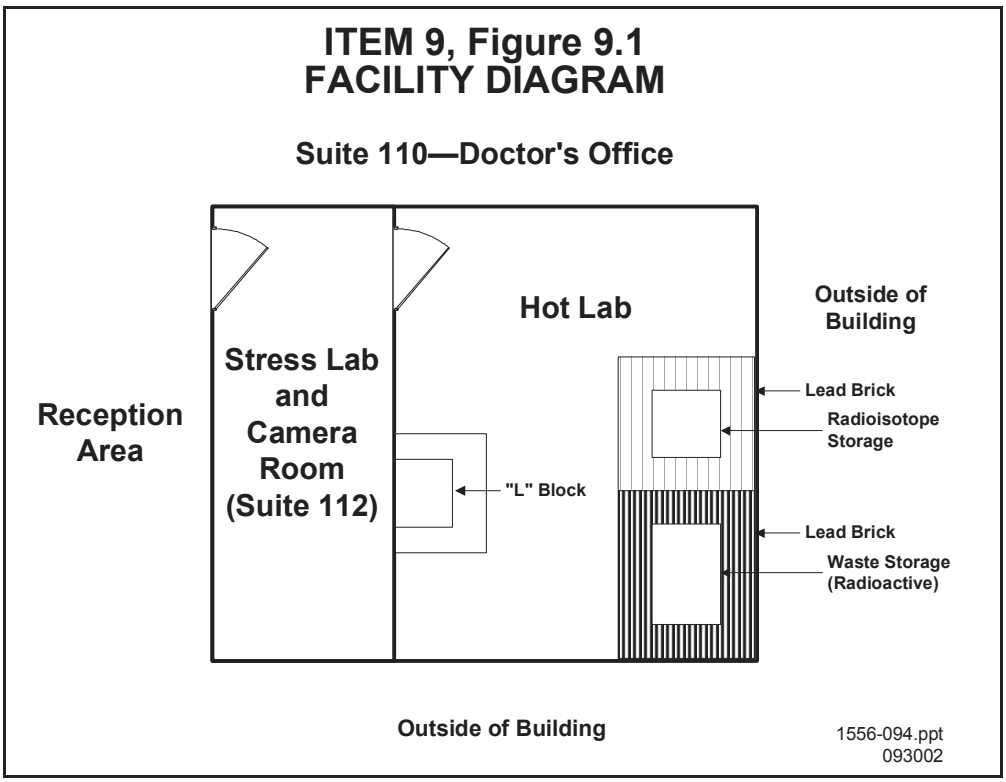

Figure E.1 Sample License Application: Facility Diagram

Notes:

1) *Radioactive material delivered to hot lab.*

2) *Counter surfaces are stainless steel and floors are seamless vinyl to facilitate cleanup and minimize permanent contamination.*

3) *Unoccupied basement located underneath facility and Suite 212 (a doctor's office) located above facility.*

APPENDIX F

Sample Licenses

Sample Licenses

The license conditions listed in the example licenses come from the standard conditions in NUREG 1556 Volume 20, "Guidance About Administrative Licensing Procedures," with some modifications to reflect provisions of 10 CFR Part 35. The modified conditions are as follows:

- Standard tie-down condition (standard condition 38) modified to reflect 10 CFR 35.26

- Decay-in-storage condition (standard condition 140) modified to reflect 10 CFR 35.92

- Sealed sources leak test condition (standard condition 165) modified to reflect 10 CFR 35.67

When preparing licenses, please refer to the latest revision of NUREG 1556, Volume 20 for the most current versions of the license conditions.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Norma L. Vision, M.D.	3. License number 52-02210-01
2. Suite 201 1234 Bright Sun Drive Sun City, Puerto Rico 02210	4. Expiration date March 31, 2015 5. Docket No. 030-02210 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Strontium 90 permitted by 10 CFR 35.400	A. Sealed Source (DuPont Merck Pharmaceutical Co. Model NB-1)	A. 120 millicuries

9. Authorized use:
A. Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Suite 201, 1234 Bright Sun Drive, Sun City, Puerto Rico.

11. The Radiation Safety Officer for this license is Cecil Source, Ph.D.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

    B. Authorized user and use: Norma L. Vision, M.D. - Strontium 90 for ophthalmic radiotherapy.

    C. Authorized medical physicist: Cecil Source, Ph.D.

SAMPLE

License Number
52-02210-01

Docket or Reference Number
030-02210

MATERIALS LICENSE
SUPPLEMENTARY SHEET

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated March 15, 2005

SAMPLE

For the U.S. Nuclear Regulatory Commission

Date _____ By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Medical Institution Limited	3. License number 99-02120-01
2. 1234 Main Street Anytown, Pennsylvania 02120	4. Expiration date October 31, 2012
	5. Docket No. 030-02120 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 900 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources (US Atomic Models Ir-192L, Cs-137V, and I-125M)	D. 2 curies
E. Any byproduct material permitted by 10 CFR 35.500	E. Sealed Sources (US Atomic Model I-125P and GD-153A)	E. 0.3 curie per source and 2 curies total
F. Any byproduct material permitted by 10 CFR 31.11	F. Prepackaged Kits	F. 5 millicuries
G. Strontium-90 permitted by 10 CFR 35.1000	G. Sealed Sources (BEBIG Model Sr0.S03 or AEAT SICW.2 series)	G. 5 millicuries per source and 800 millicuries total
H. Iodine-125 permitted by 10 CFR 35.1000	H. Liquid brachytherapy source Proxima I-125 Iotrex	H. 2 curies
I. Yttrium-90 permitted by 10 CFR 35.1000	I. Sealed sources MDS Nordion Therasphere microspheres	I. 2.5 curies

SAMPLE

License Number
99-02210-01

Docket or Reference Number
030-02210

MATERIALS LICENSE
SUPPLEMENTARY SHEET

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
J. Iridium 192 permitted by 10 CFR 35.600	J. Sealed Sources (US Atomic Model IR-192HDR2)	J. 10 curies per source and 20 curies total
K. Cesium 137	K. Sealed Source (US Atomic Model CS-137C)	K. 200 millicuries
L. Depleted Uranium	L. Metal	L. 999 kilograms

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.
C. Any use permitted by 10 CFR 35.300.
D. Any manual brachytherapy use permitted by 10 CFR 35.400.
E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
F. In vitro studies.
G. One source assembly for medical use in each Novoste A1000 series models for intravascular brachytherapy permitted by 10 CFR 35.1000.
H. For temporary manual brachytherapy in Proxima Therapeutics Gliasite RTS system permitted by 10 CFR 35.1000.
I. For permanent manual brachytherapy using MDS Nordion Therasphere Y-90 microspheres and delivery system permitted by 10 CFR 35.1000.
J. One source for medical use described in 10 CFR 35.600, in a US Atomic Model IR-192THER remote afterloader unit. The source activity may not exceed 10 curies at the time of medical use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
K. For use in a US Atomic Model CS-137SC for calibrations and checking of licensee's survey instruments.
L. For shielding in a linear accelerator.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1234 Main Street, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Melba Physicist, M.S.

SAMPLE

License Number
99-02210-01

Docket or Reference Number
030-02210

MATERIALS LICENSE
SUPPLEMENTARY SHEET

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

B. The following individuals are authorized users for the material and medical uses indicated:

	Material and Use
Jane Jones, M.D.	35.100; 35.200; 35.300; 35.500; *In vitro* studies
Thomas Group, D.O.	35.100; 35.200; 35.300 except Iodine-131
Gilbert Lawrence, M.D.	35.100; 35.200; 35.300 sodium iodide I-131 in quantities less than or equal to 33 millicuries only for oral administration for imaging and localization studies‡; 35.500

‡The example condition of use for Dr. Lawrence in this sample license illustrates the authorization of a physician who is permitted, under 10 CFR 35.57, to continue use of I-131 for uses for which he was previously authorized but would not qualify because of new requirements for training and experience (in 10 CFR 35.390) for authorized medical use of byproduct material for which a written directive is now required.

See the discussion in Section 8 of this guide under "8.9 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE," and in "8.11 ITEM 7: AUTHORIZED USERS (AUs)."

John Therapy, M.D.	35.400; 35.600 only iridium-192 for uses in a High Dose Rate Remote Afterloader Unit; 35.1000 only for strontium-90 for intravascular brachytherapy; Depleted Uranium
Mary Innovative, MD	35.1000 only Yttrium-90 microspheres
Newton Technology, MD	35.1000 only Iodine-125 Gliasite RTS system

C. The following individuals are authorized users for non-medical uses:

	Material and Use
James Pathology	*In vitro* studies
Cecil Source, Ph.D.	Cesium-137 for calibration of instruments

SAMPLE

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-02210-01

Docket or Reference Number
030-02210

D. The following individual is an authorized medical physicist:

	Material and Use
Melba Physicist, M.S.	Iridium-192 for use in a High Dose Rate Remote Afterloader Unit

E. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.

15. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie

SAMPLE

License Number
99-02210-01

Docket or Reference Number
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SUPPLEMENTARY SHEET

(185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated June 10, 2002
B. Letter dated September 30, 2002

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

SAMPLE

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Thomas I. Royed, M.D.	3. License number 99-02200-01
2. Suite 301 2 Physician Circle Parkway Anytown, Pennsylvania 02200	4. Expiration date December 31, 2012 5. Docket No. 030-02200 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Iodine-131 permitted by 10 CFR 35.300	A. Any	A. 500 millicuries

9. Authorized use:
A. Any iodine-131 procedure permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Suite 301, 2 Physician Circle Parkway, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Roger O. Blation, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

SAMPLE

License Number
99-02200-01

Docket or Reference Number
030-02200

MATERIALS LICENSE
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B. The following individuals are authorized users for the materials and medical use indicated:

Authorized Users	Material and Use
Roger O. Blation, M.D.	Oral administration of sodium iodide I-131
Thomas I. Royed, M.D.	Oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated October 30, 2002

SAMPLE

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Manuel U. Seeds, M.D.	3. License number 99-02200-01
2. Suite 106 3 Physician Circle Parkway Anytown, Pennsylvania 02200	4. Expiration date September 30, 2014 5. Docket No. 030-02200 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.400	A. Sealed Sources (US Atomic Model US-I-125-10L)	A. 500 millicuries

9. Authorized use:

A. Any manual brachytherapy use permitted by 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.

SAMPLE

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Suite 106, 3 Physician Circle Parkway, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Manuel U. Seeds, M.D.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

    B. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Use
Manuel U. Seeds, M.D.	35.400

License Number
99-02200-01

Docket or Reference Number
030-02200

MATERIALS LICENSE
SUPPLEMENTARY SHEET

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated July 20, 2004

SAMPLE

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Noe Directive, M.D.	3. License number 99-02201-01
2. Suite 112 2 Physician Circle Parkway Anytown, Pennsylvania 02201	4. Expiration date June 30, 2013 5. Docket No. 030-02201 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any, except generators	B. As needed

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at Suite 112, 2 Physician Circle Parkway, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Noe Directive, MD.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

SAMPLE

License Number
99-02201-01

Docket or Reference Number
030-02201

MATERIALS LICENSE
SUPPLEMENTARY SHEET

B. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Use
Noe Directive, M.D.	35.100; 35.200

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated April 11, 2003

SAMPLE

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Mobile Nuclear Medicine	3. License number 99-02220-01
2. Suite 214 2 Physician Circle Parkway Anytown, Pennsylvania 02220	4. Expiration date December 31, 2012 5. Docket No. 030-02220 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any, except generators	B. As needed

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at Suite 214, 2 Physician Circle Parkway, Anytown, Pennsylvania and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

    If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

SAMPLE

License Number
99-02220-01

Docket or Reference Number
030-02220

MATERIALS LICENSE
SUPPLEMENTARY SHEET

11. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

    B. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Use
Thomas Group, D.O.	35.100; 35.200

12. The Radiation Safety Officer for this license is Thomas Group, D.O.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated November 15, 2002

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

SAMPLE

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Teletherapy	3. License number 99-02300-01
2. 200 Cobalt Street Anytown, Pennsylvania 02300	4. Expiration date June 30, 2013
	5. Docket No. 030-02300 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60 permitted by 10 CFR 35.600	A. Sealed Sources (US Atomic Model US-CO-60TELE)	A. 5,500 curies per source and 11,000 curies total
B. Depleted Uranium	B. Metal	B. 999 kilograms

9. Authorized use:

A. One source for medical use permitted by 10 CFR 35.600, in a US Atomic Model TELE teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.

B. Shielding in a teletherapy unit.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 200 Cobalt Street, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Sarah Smith, M.S.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

SAMPLE

License Number
99-02300-01

Docket or Reference Number
030-02300

MATERIALS LICENSE
SUPPLEMENTARY SHEET

B. The following individual is an authorized user for the material and medical uses indicated:

	Material and Use
David Jones, M.D.	Cobalt-60 for medical uses in a Teletherapy Unit; Depleted Uranium

C. The following individual is an authorized medical physicist:

	Material and Use
Sarah Smith, M.S.	Cobalt-60 in a Teletherapy Unit for calibrations, spot-checks, and training

13. The licensee is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated March 19, 2003

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

SAMPLE

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Gamma Stereotactic	3. License number 99-02310-01
2. 100 Main Street Anytown, Pennsylvania 02310	4. Expiration date March 31, 2013 5. Docket No. 030-02310 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60 permitted by 10 CFR 35.600	A. Sealed Sources (US Atomic Model US-CO-60STER)	A. 33 curies per source and 10,000 curies total

9. Authorized use:

A. For medical use permitted by 10 CFR 35.600, in a US Atomic Model STEREO gamma stereotactic radiosurgery unit. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery unit.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 100 Main Street, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Kimberly Therapy, Ph.D.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

SAMPLE

License Number
99-02310-01

Docket or Reference Number
030-02310

MATERIALS LICENSE
SUPPLEMENTARY SHEET

B. The following individuals are authorized users for the material and medical uses indicated:

	Material and Use
John Smith, M.D.	35.600 only Cobalt-60 for medical use in a Gamma Stereotactic Radiosurgery Unit
Jessica Water, M.D.	35.600 only Cobalt-60 for medical use in a Gamma Stereotactic Radiosurgery Unit

C. The following individuals are authorized medical physicists for the material and uses indicated:

	Material and Use
Kimberly Therapy, Ph.D.	Cobalt-60 for use in a Gamma Stereotactic Radiosurgery Unit
Ronald Stereo, M.S.	Cobalt-60 for use in a Gamma Stereotactic Radiosurgery Unit

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 15, 2002
B. Letter dated March 4, 2003

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

SAMPLE

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Pacemaker License	3. License number SNM-22160
2. 100 Medical Center Drive Anytown, Pennsylvania 22160	4. Expiration date October 31, 2012
	5. Docket No. 070-22160 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Plutonium (principal radionuclide Pu-238)	A. Sealed Sources (US Atomic Model US-PU-238)	A. 5 curies per source and 50 curies total

9. Authorized use:

A. As a component of US Atomic Model PACE nuclear-powered pacemakers for clinical evaluation in accordance with manufacturer's protocol dated March 25, 1974. This authorization includes: follow-up, explantation, recovery, and disposal, but not implantation.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 100 Medical Center Drive, Anytown, Pennsylvania.

11. The Radiation Safety Officer for this license is Chief Radiologist, M.D.

12. The physicians responsible for follow-up, explantation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are Chief Cardiosurgeon, M.D.

13. The specified possession limit for nuclear-powered pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.

14. The licensee shall continue patient follow-up and replacement procedures for the nuclear-powered pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear-powered pacemaker by return to the manufacturer shall be followed upon the death of the patient.

SAMPLE

License Number
SNM-22160

Docket or Reference Number
070-22160

MATERIALS LICENSE
SUPPLEMENTARY SHEET

15. The licensee shall report to the U.S. Nuclear Regulatory Commission's Regional Office referenced in Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.

16. The licensee shall report to the U.S. Nuclear Regulatory Commission 's Regional Office referenced in Appendix D of 10 CFR Part 20, within 24 hours of occurrence, the death of any nuclear pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within 30 days.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated September 30, 2002
    B. Letter dated October 15, 2002

SAMPLE

For the U.S. Nuclear Regulatory Commission

Date _____ By _____
Division of Nuclear Materials Safety

APPENDIX G

Information Needed for Transfer of Control

Information Needed for Transfer of Control

The following information is taken from NUREG 1556, Volume 15, "Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses."

Definitions

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom NRC may contact if more information is needed.

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.

3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

APPENDIX H

NRC Form 314

“Certificate of Disposition of Materials”

NRC FORM 314 **U.S. NUCLEAR REGULATORY COMMISSION**
(06-2004)
10 CFR 30.36(j)(1); 40.42(j)(1);
70.38(j)(1); and 72.54(j)(1)

APPROVED BY OMB: NO. 3150-0028 **EXPIRES 06/30/2007**

Estimated burden per response to comply with this mandatory collection request: 30 minutes This is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0028), Office of Management and Budget, Washington DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

CERTIFICATE OF DISPOSITION OF MATERIALS

LICENSEE NAME AND ADDRESS	LICENSE NUMBER	DOCKET NUMBER
	LICENSE EXPIRATION DATE	

A. LICENSE STATUS *(Check the appropriate box)*

☐ This license has expired. ☐ This license has not yet expired; please terminate it.

B. DISPOSAL OF RADIOACTIVE MATERIAL

(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

☐ 1 No radioactive materials have ever been procured or possessed by the licensee under this license.

☐ 2 All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner.

☐ a. Transfer of radioactive materials to the licensee listed below:

☐ b. Disposal of radioactive materials:

☐ 1 Directly by the licensee:

☐ 2 By licensed disposal site:

☐ 3 By waste contractor:

☐ c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

☐ 1 A radiation survey was conducted by the licensee. The survey confirms:

☐ a. the absence of licensed radioactive materials

☐ b. that any remaining residual radioactivity is within the limits of 10 CFR 20 , Subpart E, and is ALARA.

☐ 2 A copy of the radiation survey results:

☐ a. is attached; or ☐ b. is not attached (Provide explanation); or ☐ c. was forwarded to NRC on: _____ Date

☐ 3 A radiation survey is not required as only sealed sources were ever possessed under this license, and

☐ a. The results of the latest leak test are attached; and/or ☐ c. No leaking sources have ever been identified.

The person to be contacted regarding the information provided on this form:

NAME	TITLE	TELEPHONE *(Include Area Code)*	E-MAIL ADDRESS

Mail all future correspondence regarding this license to:

C. CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

NRC FORM 314 (6-2004)

PRINTED ON RECYCLED PAPER

CERTIFICATE OF DISPOSITION OF MATERIALS

PLEASE READ THESE INSTRUCTIONS BEFORE COMPLETING NRC FORM 314.

Subpart E of 10 CFR Part 20 establishes the radiological criteria for license terminations/decommissioning of facilities licensed under 10 CFR Parts 30, 40, 50, 60, 61, 70, and 72, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

INSTRUCTIONS

Section B, Item 2.
Licensees should describe the specific radioactive material transfer actions. If radioactive wastes were generated in terminating this license, the licensee should describe the disposal actions taken, including the disposition of low-level radioactive waste, mixed waste, greater-than-Class-C waste, and sealed sources.

Section B, Item 2.a.
The information provided concerning the transfer of radioactive material to another licensee should specify the date of the transfer, the name of the licensee recipient, an individual contact name and telephone number for the licensee recipient, and the recipient's NRC or Agreement State license number.

Section B, Item 2.b.
For disposal of radioactive materials, licensees should describe the specific disposal method or procedure (e.g., decay-in-storage). For those cases when radioactive materials are disposed of by a licensed disposal site or by a waste contractor, the licensee should specify the name, address, and telephone number of the licensed disposal site operator or waste contractor.

Section B, Item 2.c.
"Residual radioactivity," as defined in 10 CFR 20.1003, means radioactivity in ‘areas' (structures, materials, soils, etc.) remaining as a result of activities (licensed and unlicensed) under the licensee's control from sources used by the licensee, excluding background radiation. ALARA is defined in 10 CFR 20.1003.

FILE CERTIFICATES AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND CERTIFICATES TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND CERTIFICATES TO:

NUCLEAR MATERIALS SAFETY SECTION
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
SAM NUNN ATLANTA FEDERAL CENTER
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND CERTIFICATES TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND CERTIFICATES TO:

MATERIAL RADIATION PROTECTION SECTION
U. S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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.

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 RSO Duties and Responsibilities

The RSO's duties and responsibilities 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. Typically, these duties and responsibilities include ensuring the following:

- Stopping unsafe activities involving licensed material;
- 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 is 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 one 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, and 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 by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

_____	_____
Signature of Management Representative	Signature of Radiation Safety Officer
_____	_____
Date	Date

cc: Affected department heads

APPENDIX J

Model Training Program

Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen from 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 requires 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 who engage in certain specialized practices is also included.

Model Training Program for Medical 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 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 in the following topics, *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).

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 microcurie of I-131), or Therapeutic Treatment Planning

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) in the following topics, *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 of determining each trainee's competency to use the device for each type of proposed use, such as practical examinations.

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 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 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 35.490, 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 system, 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 who perform 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

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

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 (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%

Model Procedure for Calibrating Survey Instruments

This model provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your 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 which 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 radioactive sealed source(s) that:

  - Approximates a point source;

  - Is 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;

  - Emit the type of radiation measured;

  - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed; and

  - Provide 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 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).

C 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.

C 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 is 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.

C 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.

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 Appendix B to Part 20 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 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 efficiency of the instrument.

  For example:

$$Eff_a = \frac{(cpm_{std} - cpm_{bkg})}{(activity\ standard\ microCi)}$$

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:

[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 has much less of a dependence on the counting geometry.

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

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 efficiency of the instrument.

  For example,

$$Eff = \frac{(cpm_{std} - cpm_{bkg})}{(activity_{std}\ in\ microci}$$

  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 date of the next efficiency due 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

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 which 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.

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

Next Audit Date: _____

Auditor: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

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 license amended [35.13]?
   2. Does new RSO meet NRC training requirements [35.50, 35.57, 35.59]?
   3. Is RSO fulfilling all duties [35.24]?
   4. 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?

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

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

F. Licensed Material:

   1. Isotope, chemical form, quantity and use as authorized?
   2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is 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 millicurie 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 millicurie [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 microcurie 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 35.100, 200, and 300 are:

   a. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

OR

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

OR

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

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [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 the actual uses of medical devices consistent with the authorized uses listed on the license?

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

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

Radiation Safety Program

A. Minor changes to program [35.26]?

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]?

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/licensed by FDA/State Agency as a Drug Manufacturer with distribution regulated under Part 32):

_____ 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. 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. 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. Listed on facility license

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

E. Dosage measuring instruments checked for proper function before used 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 used 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]?

Notifications Since Last Audit [35.14]

A. Any Notifications since last audit [35.14]?

B. Appropriate documentation provided to NRC for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work [35.14(a)]?

C. NRC notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 35.100 or 35.200 use [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. Is the individual's understanding of current procedures and regulations adequate?

C. 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 [10 CFR 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:

D. Additional therapy device instructions/training:

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

E. Part 20 – 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]?

F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist 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. Safety instruction to personnel provided include [10 CFR 35.310, 10 CFR 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 in emergency or death?
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 [10 CFR 35.60]:

1. List type of equipment used:
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 [10 CFR 35.2060]?

B. Determination of dosages of unsealed byproduct material [35.63]?

1. Each dosage determined and recorded prior to medical use [35.63(a)]?
2. Measurement of unit dosages made either by direct measurement or by decay correction [35.63(b)]?
3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or 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 FCi per mCi of Tc-99m [35.204(a)]?
3. 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 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

A. Use of radiopharmaceuticals:

1. Protective clothing worn?

2. Personnel routinely monitor their hands?
3. No eating/drinking in use/storage areas?
4. No food, drink, or personal effects kept in use/storage areas?
5. Proper dosimetry worn?
6. Radioactive waste disposed of in proper receptacles?
7. Syringe shields and vial shields used?

B. Leak tests and Inventories:

1. Leak test performed on sealed sources and brachytherapy sources [35.67(b)(1)]?
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 Part 20 and 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]?

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 is stored?
3. Weekly 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 does 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

A. Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year [10 CFR 20.1301(a)(1)]?

B. Has a survey or evaluation been performed per 10 CFR 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 one hour [10 CFR 20.1301(a)(2)]?

E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [10 CFR 20.1801 and 20.1802]?

F. Records maintained [10 CFR 20.2103, 10 CFR 20.2107]?

Patient Release

A. Individuals released when TEDE 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

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 died or had a medical emergency [35.315(b)]?

Brachytherapy

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 died or had a medical emergency [35.415(c)]?

E. Records maintained [35.2404]?

Radioactive Waste

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 App. 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]?
   a. Within unrestricted limits [10 CFR Part 20 App. B, Table 2]?
3. Waste incinerated?
   a. License authorizes [20.2004(a)(3)]?
   b. Directly monitor exhaust?
   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)
   a. Air effluent less than 10 mrem constraint limit [20.1101]?
   b. If no, reported appropriate information to NRC.
      i. Corrective actions implemented and on schedule?
   c. Description of effluent program:
      i. Monitoring system hardware adequate?
      ii. Equipment calibrated, as appropriate?

iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) 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 are maintained [20.2103, 20.2108, 35.2092]?

Receipt And Transfer of Radioactive Material

A. Describe 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)]?

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

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

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

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

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

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

A. Shipments are:

1. delivered to common carriers;
2. transported in own private vehicle;
3. both;
4. no shipments since last audit.

B. Return radiopharmacy doses or sealed sources?

1. Licensee assumes shipping responsibility?

2. 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 TI, Nuclide, Activity, and Hazard Class?
4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee)?
5. Closed and sealed during transport?

D. Shipping Papers:

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

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, etc.)?

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 one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding one 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 authorized medical physicist [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 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 are 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 authorized users, the authorized medical physicist, 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. Authorized medical physicist and authorized user:

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 authorized user may be physically present instead of the authorized user) [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

A. Exposure evaluation performed [20.1501]?

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

C. External Dosimetry:

1. Monitors workers per [20.1502(a)]?

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?

2. Briefly describe program for monitoring and controlling internal exposures [20.1701, 20.1702]?

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. Were 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, then was the dose in compliance [20.1208] and were the records maintained [20.2106(e)]?

F. Who performed any planned special exposures at this facility (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 [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]:
   a. Submitted to Region within 15 days?

Notification and Reports

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

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

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

D. In compliance with 20.2203, 30.50 (overexposures and high radiation levels)?

E. Aware of NRC Ops Center phone number?

F. In compliance with 20.2203 (Constraint on air emissions)?

Posting and Labeling

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

B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to 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 20.1902, 1904 and not exempted by 20.1903, 20.1905?

Recordkeeping for Decommissioning

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:

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

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 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). 10 CFR 20.1201 provides the occupational dose limits for adults. 10 CFR 20.1502 provides in part that adults likely to receive in one 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 (see10 CFR 20.2106) and individuals must be informed on at least an annual basis of their doses (see 10 CFR 19.13(b)).

If an individual is likely to receive more than 10% of the annual dose limits, 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

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 activitiesÿ" 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.

10 CFR 20.1502(a) requires the use of individual monitoring devices for the following:

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent 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
  - 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, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, 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: Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;

- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable ‘accident’ scenarios should also be evaluated);

- 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 (OSLs), 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 non-uniform, 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.

10 CFR 20.2106 requires that the recording for individual monitoring be done on NRC Form 5 or equivalent. NRC 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.

In order to demonstrate compliance with occupational dose limits of 10 CFR 20.1201, 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, if an individual's dosimeter is lost. 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 non-routine 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

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 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 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; knee; leg 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 whose dose 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 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. A consideration of actions should be taken by the RSO 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.

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

Declared Pregnancy and Dose to Embryo/Fetus

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). 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 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). 10 CFR Part 20 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in FCi/ml that, if an occupational worker were to be continuously exposed to 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 10 CFR Part 20, Appendix B.

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 10 CFR Part 20 ALI and DAC numbers 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 non-stochastic 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:

i. adequate equipment to perform bioassay measurements,

ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,

iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),

iv. the interval between bioassays,

v. action levels, and

vi. 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."

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 <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/>.

APPENDIX N

Model Emergency Procedures

Model Spill, Emergency Surgery, and Autopsy Procedures

Model Spill Procedures – Low and High Dose Unsealed Sources

This model provides acceptable procedures for responding to emergencies. Applicants may either adopt this model or develop alternative procedures to meet the requirements of 10 CFR 20.1101.

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. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "caution radioactive material" labeled 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 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

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 "caution radioactive material" labeled absorbent paper, 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 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 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 procedure may be restricted access pending complete decay.

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

Use Table P.1 as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor.

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

Spill Kit

Assemble a spill 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

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

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

Model Procedures for Ordering and Receiving Packages

This model provides acceptable procedures for ordering and receiving packages containing licensed material. Applicants may either adopt this model or develop alternative procedures.

Model Guidance

- Authorize, through a designee (e.g., RSO), each order of radioactive materials 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.

- For deliveries during normal working hours, inform carriers to deliver radioactive packages directly to a specified area.

- For deliveries during off-duty hours, inform 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

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 (e.g., 13.5 curies of Mo-99 [20 curies for domestic use], Cs-137, Ir-192; 54.1 curies of I-125; 541 curies of Xe-133, or 216 curies of Tc-99m). Such packages must be received expeditiously when the carrier offers it 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). 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 notify the RSO or the designee of the RSO if the RSO is not present immediately.
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.
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.

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

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(T1) 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.

APPENDIX Q

Model Leak Test Program

Model Leak Test Program

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 sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 FCi) of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

- 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.
- 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.

- Calculate efficiency of the instrument.

  For example,

$$Eff = \frac{(cpm_{std} - cpm_{bkg})}{(activity_{std} \text{ in microcurie})}$$

  where:

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

- Analyze each wipe sample to determine net count rate.

- For each sample, calculate the activity in microcurie and record.

- The activity on the wipe sample is given by:

$$activity_{wipe\ sample} \text{ in microcurie} = \frac{(cpm_{wipe\ sample} - cpm_{bkg})}{(Eff \text{ in cpm/microcurie})}$$

- Leak test records will be retained in accordance with 10 CFR 35.2067 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 microcurie;
  – 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 (0.005 FCi) or greater:

  – Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in 10 CFR Parts 20 and 30 [10 CFR 35.67].
  – File a report within 5 days of the leak test in accordance with 10 CFR 35.3067.

APPENDIX R

Model Procedure for Area Surveys

Model Procedure for Area Surveys

This model provides acceptable procedures for area surveys. 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. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

Ambient Radiation Level Surveys

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).

- 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 one hour. Appropriate surveys will be conducted to assure that the requirements of 10 CFR 20.1301 are met.

- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:

  - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 FCi).

  - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 FCi 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. Example 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

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 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;
  - 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 (i.e., bone scan injections, Tc-99m heart agents, etc.), 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.

C A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.

C The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

C If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example 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	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	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

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 contaminant 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 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 occupation doses ALARA;
- 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

An example alternate survey frequency is described below. 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 Grouping of Radioisotopes for Alternate Survey Frequency

Group 1	Group 1, excerpted from IAEA Safety Series 115, does not include radioisotopes traditionally used in medicine.
Group 2	Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 T1-204
Group 3	C-14 F-18 Na-24 P-32 S-35 Cr-51 Fe-59 Co-57 Co-58 Se-75 Sr-85 Y-90 Mo-99 Tc-99 Rh-105 Pd-103 In-115m Sn-113 Sm-153 Eu-152 Eu-155 Gd-153 Dy-165 Yb-175 Lu-177 Au-198 Hg-197 Tl-201
Group 4	H-3 0-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

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 non-occupational 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;
- 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

This model provides acceptable procedures for administrations that require written directives. You may either adopt this model procedure or develop your 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 written directives (WD). This model does not restrict your 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 FCi), 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 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 written directive (as defined in 10 CFR 35.2), the licensee should develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of 10 CFR 35.40, 35.41, and 10 CFR 35.63, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in 10 CFR 35.40(b), including the patient or human research subject's name;

- Verify the patient's or human research subject's identity prior to each administration;

- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;

- 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 or Any Dosage of Quantities Greater than 30 Microcurie of Sodium Iodide I-131

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 patient's or human research subject's identity 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

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

H. 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.

I. 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 non-radioactive 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 arithmetic 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 written directive 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 written directive 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 non-recastable 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., arithmetic 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

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

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 NRC Operations Center is (301) 951-0550. The Center will accept collect calls.

APPENDIX T

Model Procedures for Safe Use of Unsealed Licensed Material

Model Procedures for Safe Use of Unsealed Licensed Material

This model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your own procedure. (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 your 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, 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 authorized user.

- 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. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (10 CFR 35.41).

- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

- Secure all licensed material 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

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)."

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

Release Equation

The activities at which patients could be released were 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."

NCRP Report No. 37 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, $(1-e^{-0.693t/Tp})$ 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 to 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:

$$D(A) = \frac{3.41 \, \Gamma_p \, (0.25)}{(100 \, cm)^2}$$

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:

$$D(A) = \frac{3.41 \, \Gamma_p \, (1)}{(100 \, cm)^2}$$

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.

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, 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. You may either adopt these model instructions or develop your 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 that 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 to permit

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

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.

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
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2

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)
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.

*** These radionuclides are not byproduct material and are not regulated by the NRC. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the NRC and state requirements for non-NRC regulated material.

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.

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.

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	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	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

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 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.

** These radionuclides are not byproduct material and are not regulated by the NRC. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the NRC and state requirements for non-NRC regulated material.

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.

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.2.3.1 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 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, 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 specifying the 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, 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
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	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

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.

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 A

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

Radionuclide[1]	Physical Half-Life (days)[2]	Exposure Rate Constant[3] (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	60.14	1.114
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.594
P-32	14.29	N/A[6]
Pd-103 implant	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
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A[6]
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A[6]
Yb-169	32.01	1.83

Footnotes for Table U.5

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

2 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.

[3] 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, pp. 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.

[4] 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.

[5] 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.

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

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:

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

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 one day but is greater than one 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 = 4) 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.)

$$D(4) = \frac{34.01\ C_0\ T_P\ E}{r^2}$$

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.

$$D(4) = \frac{34.01\ (2220\ MBq)\ (8.04\ d)\ (0.125)}{(100\ cm)^2}$$

D (4) = 4.59 millisieverts (0.459 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:

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

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 megabecquerel (150 millicurie) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will calculate the dose 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	0.201	0.322	0.801	5.21
Post Thyroidectomy for Thyroid Cancer	0.953	0.322	0.053	7.32

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:

$$D(4) = \frac{(5550)(22)(1.5)}{(100\,cm)^2}\{(0.75)(8.04)(0.8)(1-e^{-0.693(6.33)/8.04})$$
$$+e^{-0.693(6.33)/8.04}(0.25)(0.95)(0.32)$$
$$+e^{-0.693(6.33)/8.04}(0.25)(0.05)(7.3)\}$$

D(4) = 3.40 mSv (0.340 rem)

Therefore, thyroid cancer patients to whom 5550 megabecquerel (150 millicurie) of iodine-131 or less has 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 has been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose 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:

$$D(4) = \frac{(5550)(22)(1.5)}{(100\,cm)^2}\{(0.75)(8.04)(0.8)(1-e^{-0.693(6.33)/8.04})$$
$$+e^{-0.693(6.33)/8.04}(0.25)(0.20)(0.32)$$
$$+e^{-0.693(6.33)/8.04}(0.25)(0.80)(5.2)\}$$

D(4) = 4.86 mSv (0.486 rem)

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 has 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 millicurie 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 has 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 has been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will again calculate the dose 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

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).

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 their 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 location 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, non-institutional medical practice, commercial facility, or mobile van. You should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital). As required by 10 CFR 30.33 and 10 CFR 35.12, you 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, 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."

- You 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 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 one hour nor 100 mrem per year.

Client Site

This section applies only to therapeutic uses of byproduct material. 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) you should provide the following additional facility information:

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

- 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. You should 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, you must ensure the following:

- Each client is properly licensed for medical use of byproduct material. If applicable, you 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 you will instruct supervised individuals in your written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of byproduct material. Additionally, as required by 10 CFR 35.27, you will require the supervised individual to:

- Follow the instructions of the supervising authorized user for medical uses of byproduct material;

- Follow the instructions of the supervising authorized nuclear pharmacists or supervising authorized user 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, you will check instruments for proper operation before use at each address of use. You will check dosage measurement instruments 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

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, you 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 your radiation protection program required by 10 CFR 20.1101. You should 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-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 phone contact for minor spills to prompt on-site 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 is secured during transport and use at the client's facilities.

- Radioactive waste is handled properly during transport. You will 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

If waste will be stored in vans, the vans will be properly secured and posted as byproduct material storage locations. You will 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 sewerage 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 sewerage 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, you will develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted 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.

- You must maintain records, as described in 10 CFR 35.2647 and 10 CFR 35.2643, showing the results of the above safety checks 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 HDR 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

This model provides acceptable procedures for waste disposal. 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

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 disposed of 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

Used Mo/Tc-99m 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;
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.

Model Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material 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.

APPENDICES X-BB

RECORDKEEPING AND REPORTING REQUIREMENTS

DOT RULES FOR SHIPPING

REFERENCES

PUBLIC COMMENTS ON DRAFTS AND NRC RESPONSES

APPENDIX X

Recordkeeping Requirements

Recordkeeping Requirements

Table X.1 Typical Records and Retention Times			
Record	**Survey Requirement**	**Recordkeeping Requirement**	**Retention Period**
Results of surveys and calibrations	20.1501; 20.1906(b)	20.2103(a)	3 years
Results of surveys to determine dose from external sources		20.2103(b)(1)	duration of license
Results of measurements and calculations used to determine individual intakes		20.2103(b)(2)	duration of license
Results of air samplings, surveys, and bioassays	20.1703(c)(1); 20.1703(c)(2)	20.2103(b)(3)	duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		20.2103(b)(4)	duration of license
Determination of prior occupational dose		20.2104	duration of license
Planned special exposure	20.1206	20.2105	duration of license
Individual monitoring results	20.1502	20.2106	duration of license
Dose to individual members of the public	20.1301	20.2107	duration of license
Waste disposal	20.2002; 20.2003; 20.2004; 20.2005	20.2108	duration of license
Records of receipt of byproduct material		30.51(a)(1)	duration of possession and 3 years after transfer
Records of transfer of byproduct material		30.51(a)(2)	3 years after transfer
Records of disposal of byproduct material		30.51(a)(3)	duration of license
Authority and responsibilities of radiation protection program	35.24(a)	35.2024	5 years
Radiation protection program changes	35.26(a)	35.2026	5 years
Written directives	35.40	35.2040	3 years
Procedures for administrations requiring a written directive	35.41(a)	35.2041	duration of license
Calibrations of instruments used to measure activity of unsealed byproduct material	35.60	35.2060	3 years
Radiation survey instrument calibrations	35.61	35.2061	3 years

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Dosages of unsealed byproduct material for medical use	35.63	35.2063	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	35.67(b)	35.2067	3 years
Surveys for ambient radiation exposure rate	35.70	35.2070	3 years
Release of individuals containing unsealed byproduct material or implants containing byproduct material	35.75	35.2075	3 years
Mobile medical services	35.80(a)(1)	35.2080	3 years
Decay-in-storage	35.92	35.2092	3 years
Molybdenum-99 concentrations	35.204(b)	35.2204	3 years
Safety instruction	35.310; 35.410; 35.610	35.2310	3 years
Surveys after source implant and removal	35.404; 35.604	35.2404	3 years
Brachytherapy source accountability	35.406	35.2406	3 years
Calibration measurements of brachytherapy sources	35.432	35.2432	3 years
Decay of strontium-90 sources for ophthalmic treatments	35.433	35.2433	life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.604	35.2605	3 years
Safety procedures	35.610(a)(4); 35.610(d)(2)	35.2610	duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.630	35.2630	duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	35.632; 35.633; 35.635	35.2632	3 years
Periodic spot-checks of teletherapy units	35.642	35.2642	3 years
Periodic spot-checks of remote afterloader units	35.643	35.6243	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	35.645	35.6245	3 years

Table X.1 Typical Records and Retention Times			
Record	**Survey Requirement**	**Recordkeeping Requirement**	**Retention Period**
Additional technical requirements for mobile remote afterloader units	35.647	35.6247	3 years
Surveys of therapeutic treatment units	35.652	35.2652	duration of use of unit
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit

APPENDIX Y

Reporting Requirements

Reporting Requirements

Table Y.1 Typical NRC Notifications and/or Reports			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Reports to individual workers	none	annually	10 CFR 19.13(b)
Reports to former individual workers	none	upon request	10 CFR 19.13(c)
Notification of special circumstances to individuals	none	30 days	10 CFR 19.13(d)
Reports to worker terminating employment	none	upon request	10 CFR 19.13(e)
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i); 10 CFR 20.2203 (a)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii); 10 CFR 20.2203 (a)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i); 10 CFR 20.2203 (a)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii); 10 CFR 20.2203(a)
Doses in excess of specified criteria	none	30 days	10 CFR 20.2203(a)(2)
Levels of radiation or concentrations of radioactive material in excess of specified criteria	none	30 days	10 CFR 20.2203(a)(3)
Planned special exposures	none	30 days	10 CFR 20.2204
Report to individuals of exceeding dose limits	none	30 days	10 CFR 20.2205
Report of individual monitoring	none	annually	10 CFR 20.2206
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)
Licensee permits individual to work as AU, ANP, or AMP	none	30 days	10 CFR 35.14(a)
AU, ANP, or AMP discontinues performance of duties under license or has a name change	none	30 days	10 CFR 35.14(b)(1)
Licensee's mailing address changes	none	30 days	10 CFR 35.14(b)(2)
Licensee's name changes without constituting a transfer of control	none	30 days	10 CFR 35.14(b)(3)
Licensee adds or changes areas of 35.100 or 35.200 use of byproduct material identified in application or license	none	30 days	10 CFR 35.14(b)(4)
Medical event	1 day	15 days	10 CFR 35.3045
Dose to embryo or nursing child	1 day	15 days	10 CFR 35.3047
Leaking source	none	5 days	10 CFR 35.3067

Note: Telephone notifications shall be made to the NRC Operations Center at 301-951-0550, except as noted.

APPENDIX Z

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

Licensed material must be transported in accordance with DOT regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;

- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;

- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;

- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;

- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;

- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;

- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;

- Shippers – General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for U.S. NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and

- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials" or contact the DOT at <http://www.dot.gov>.

APPENDIX AA

List of Documents Considered in Development of this NUREG

List of Documents Considered in Development of this NUREG

This report incorporates and updates the guidance previously found in the Regulatory Guides (RG), Policy and Guidance Directives (P&GD), and Information Notices (IN) listed in the table below. When this report is issued in final form, the documents in the table will be considered superseded and should not be used. Other references were also used in this report and are listed in "References."

Some sections of the guidance include references to other documents that may be useful to the applicant. Appendix AA provides a complete list of documents referenced in the guidance. While specific availability information is included for some reference documents, the documents also may be accessed at the NRC Public Document Room, which is located at NRC Headquarters in Rockville, Maryland, or the NRC Electronic Reading Room at <www.nrc.gov>. See the Notice of Availability on the inside front cover of this report for more information.

Document Identification	Title	Date
RG 10.8, Revision 2	Guide for the Preparation of Applications for Medical Use Programs.	8/87
Appendix X to RG 10.8, Revision 2	Guidance on Complying With New Part 20 Requirements.	6/92
Draft RG DG-0009	Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.	3/97
Draft RG FC 414-4	Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs.	12/85
P&GD FC 87-2	Standard Review Plan (SRP) for License Applications for the Medical Use of Byproduct Material.	12/87
Supplement 1 to P&GD FC 86-4; Revision 1	Mobile Remote Afterloading Brachytherapy Licensing Module.	5/97
P&GD FC 86-4, Revision 1	Information Required for Licensing Remote Afterloading Devices.	9/93
Addendum to Revision 1 to P&GD FC 86-4	Information Required for Licensing Remote Afterloading Devices – Increased Source Possession Limits.	7/95
P&GD 3-15	Standard Review Plan for Review of Quality Management Programs.	6/95
RG 8.39	Release of Patients Administered Radioactive Materials.	4/97
RG 8.33	Quality Management Program.	10/91
P&GD 3-17 (previously 16)	Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants.	
RG 8.23	Radiation Safety Surveys at Medical Institutions, Revision 1.	1/81

The additional references listed below were used.

References

Title 10, Code of Federal Regulations

1. Part 2 – Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.

2. Part 19 – Notices, Instructions, and Reports to Workers; Inspections and Investigations.

3. Part 20 – Standards for Protection Against Radiation.

4. Part 21 – Reporting of Defects and Noncompliance.

5. Part 30 – Rules of General Applicability to Domestic Licensing of Byproduct Material.

6. Part 31 – General Domestic Licenses for Byproduct Material.

7. Part 32 – Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.

8. Part 33 – Specific Domestic Licenses of Broad Scope for Byproduct Material.

9. Part 35 – Medical Use of Byproduct Material.

10. Part 40 – Domestic Licensing of Source Material.

11. Part 70 – Domestic Licensing of Special Nuclear Material.

12. Part 71 – Packaging and Transportation of Radioactive Material.

13. Part 150 – Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274.

14. Part 170 – Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended.

15. Part 171 – Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

Title 49, Code of Federal Regulations

1. Part 172 – Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, and Training Requirements.

2. Part 173 – Shippers – General Requirements for Shipments and Packagings.

3. Part 177 – Carriage by Public Highway.

4. Part 178 – Specifications for Packagings.

NRC Regulatory Guides (RG)

1. RG 1.86 – Termination of Operating Licenses for Nuclear Reactors, June 1974.

2. RG 3.66 – Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72, June 1990.

3. RG 7.10 -, Revision 1 - Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, June 1986. (Superceded by NUREG 1556, Volume 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Radiography Licenses," August 1998.)

4. RG 8.4 – Direct-Reading and Indirect-Reading Pocket Dosimeters, February 1973.

5. RG 8.7 – Instructions for Recording and Reporting Occupational Radiation Exposure Data, Revision 1, June 1992.

6. RG 8.9 – Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program, Revision 1, June 1993.

7. RG 8.10 – Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable, Revision 1-B, September 1975.

8. RG 8.13 (Final) - Instruction Concerning Prenatal Radiation Exposure, June 1999.

9. RG 8.18 - Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable, Revision 1, October 1982. (Superceded by NUREG 1736, "Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation," October 2001.)

10. RG 8.21 – Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants.

11. RG 8.25 – Air Sampling in the Workplace, Revision 1, June 1992.

12. RG 8.29 – Instruction Concerning Risks from Occupational Radiation Exposure, Revision 1, February 1996.

13. RG 8.34 – Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, July 1992.

14. RG 8.36 – Radiation Dose to the Embryo/Fetus, July 1992.

15. RG 10.2 - Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope, Revision 1, December 1976. (Superceded by NUREG 1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," December 1999.)

16. RG 10.5 (Draft) – Applications for Type A Licenses of Broad Scope, October 1994.

17. RG 10.8 – Revision (Draft NUREG-1569 - never published), Program-Specific Guidance for Medical Use Licensees, 1997.

18. RG FC 412-4 (Draft) – Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985.

19. RG FC 413-4 (Draft) – Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985.

NRC Information Notices (IN) and Regulatory Issue Summaries (RIS)

1. IN 89-25, Revision 1 – Unauthorized Transfer of Ownership or Control of Licensed Activities.

2. IN 94-09 – Release of Patients with Residual Radioactivity.

3. IN 94-70 – Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals.

4. IN 96-28 – Suggested Guidance Relating to Development and Implementation of Corrective Action.

5. IN 97-30 – Control of Licensed Material During Reorganizations, Employee-Management Disagreements, and Financial Crises.

6. IN 99-24 - Broad-Scope Licenses' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices.

7. IN 99-33 – Management of Wastes Contaminated with Radioactive Materials.

8. RIS 2002-06 - Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays, April 2002.

9. RIS 2002-10 - Revision of the Skin Dose Limit in 10 CFR Part 20, July 2002.

NRC Policy and Guidance Directives (P&GD)

1. FC 412-4 (Draft) - Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985. (Superceded by NUREG 1556, Volume 18,

"Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," November 2000.)

2. FC 413-4 (Draft) - Guide for the Preparation of Applications of Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985. (Superceded by NUREG 1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," November 2000.)

3. P&GD 1-23 - Guidance for Multi-Site Licenses, April 1996. (Superceded by NUREG 1556, Volume 20, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Administrative Licensing Procedures," December 2000.)

4. P&GD FC 90-2, Revision 1 - Standard Review Plan for Evaluating Compliance with Decommissioning Requirements, April 1991. (Superceded by NUREG 1757, Vol. 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," September 2003.

5. P&GD 8-11 - NMSS Procedures for Reviewing Declarations of Bankruptcy, August 1996. (Superceded by NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," November 2000.)

NRC NUREGs

1. NUREG-0267, Revision 1 – Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable, October 1982.

2. NUREG-1134 – Radiation Protection Training for Personnel Employed in Medical Facilities, May 1985.

3. NUREG-1400 – Air Sampling in the Workplace, September, 1993.

4. NUREG-1492 – Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, February 1997.

5. NUREG-1539 – Methodology and Findings of the NRC's Materials Licensing Process Redesign, April 1996.

6. NUREG-1541 (Draft) – Process and Design for Consolidating and Updating Materials Licensing Guidance, April 1996.

7. NUREG-1556, Volume 3 (July 1998) – Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration, September 1997.

8. NUREG-1556, Volume 11 - Program-Specific Guidance About Licenses of Broad Scope.

9. NUREG-1556, Volume 15 - Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses, November, 2000.

10. NUREG-1556, Volume 18 – Program Specific Guidance about Service Provider Licenses, November 2000.

11. NUREG-1556, Volume 20 – Guidance about Administrative Licensing Procedures, December 2000.

12. NUREG-1600 – General Statement of Policy and Procedures for NRC Enforcement Actions, June 1995 and Compilation of NRC Enforcement Policy as of September 10, 1997.

13. NUREG/CR-4444 – Radiation Safety Issues Related to Radiolabeled Antibodies, 1991.

14. NUREG/CR-4884 – Interpretation of Bioassay Measurement, July 1987.

15. NUREG-CR-5631, PNL-7445, Rev. 2 – Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses, 1996.

16. NUREG-CR-6276 – Quality Management in Remote Afteloading Brachytherapy, October 1994.

17. NUREG/CR-6323 – Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices: A Preliminary Application, September 1995.

18. NUREG/CR-6324 – Quality Assurance for Gamma Knives, September 1995.

19. NUREG-1736 – Consolidated Guidance: 10 CFR Part 20 – Standards for Protection Against Radiation, 2001.

20. NUREG 1757 – Consolidated NMSS Decommissioning Guidance, September 2003.

National Council on Radiation Protection and Measurements (NCRP) Publications
(Available from NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095, or ordered electronically from <http://www.ncrp.com>)

1. NCRP Report No. 30 – Safe Handling of Radioactive Materials, 1964.

2. NCRP Report No. 37 – Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides, 1970.

3. NCRP Report No. 40 – Protection Against Radiation from Brachytherapy Sources, 1972.

4. NCRP Report No. 49 – Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV, 1976.

5. NCRP Report No. 57 – Instrumentation and Monitoring Methods for Radiation Protection, 1978.

6. NCRP Report No. 58 – A Handbook of Radioactivity Measurement Procedures, Second Edition, 1985.

7. NCRP Report No. 69 – Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, 1981.

8. NCRP Report No. 71 – Operational Radiation Safety – Training, 1983.

9. NCRP Report No. 87 – Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, February 1987.

10. NCRP Report No. 88 - Radiation Alarms and Access Control Systems, 1986.

11. NCRP Report No. 102 – Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use), 1989.

12. NCRP Report No. 105 – Radiation Protection for Medical and Allied Health Personnel, 1989.

13. NCRP Report No. 107 – Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, 1990.

14. NCRP Report No. 111 - Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities, 1991.

15. NCRP Report No. 112 - Calibration of Survey Instruments Used in Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination, 1991.

16. NCRP Commentary No. 11 – Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, February 1995.

International Commission on Radiological Protection (ICRP) Publications
(Published by Elsevier Science: <www.elsevierhealth.com/journals/icrp>.)

1. ICRP Report No. 26 – Recommendations of the International Commission on Radiological Protection, 1977.

2. ICRP Report No. 30 – Limits for Intakes of Radionuclides by Workers, 1978.

3. ICRP Report No. 35 – General Principles of Monitoring for Radiation Protection of Workers, 1982.

4. ICRP Publication No. 53 – Radiation Dose to Patients from Radiopharmaceuticals, 1987.

5. ICRP Publication 54 – Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation, 1987.

ANSI Standards (Available from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036 or ordered electronically from <http://www.ansi.org>)

1. ANSI N13.4-1971 (R1983) – Specification of Portable X- or Gamma Radiation Survey Instruments.

2. ANSI N13.5-1972 (R1989) – Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation.

3. ANSI N13.6-1966 (R1989) – Practice for Occupational Radiation Exposure Records Systems.

4. ANSI N14.5-1987 – Leakage Tests on Packages for Shipment of Radioactive Materials.

5. ANSI N42.12-1994 – Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides.

6. ANSI N42.13-1986 (R1993) – Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides.

7. ANSI N42.15-1990 – Performance Verification of Liquid Scintillation Counting Systems.

8. ANSI N42.17A-1989 – Performance Specifications for Health Physics Instrumentation-Portable Instrumentation for Use in Normal Environmental Conditions.

9. ANSI N322 – Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters.

10. ANSI N323A-1997 – Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.

11. ANSI N449.1-1978 (R1984) – Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment.

American Association of Physicists in Medicine (AAPM) Reports
(Available from Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from <http:.//www.medicalphysics.org>. Readers may wish to contact AAPM to determine if more recent documents or reports on these topics have been issued by AAPM. Such documents should be reviewed by applicants for compliance with 10 CFR Part 35 prior to use.)

1. AAPM Task Group No. 21 – A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams, 1984.

2. AAPM Report No. 41 – Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41), 1993.

3. AAPM Report No. 46 – Comprehensive QA for Radiation Oncology, (Radiation Therapy Committee Task Group No. 40), 1994.

4. AAPM Report No. 51, Dosimetry of Interstitial Brachytherapy Sources, (Radiation Therapy Committee Task Group No. 43), 1995.

5. AAPM Report No. 54 – Stereotactic Radiosurgery, (Radiation Therapy Committee Task Group No. 42), 1995.

6. AAPM Report No. 59 – Code of Practice for Brachytherapy Physics, (Radiation Therapy Committee Task Group No. 56), 1997.

7. AAPM Report No. 61 – High Dose Rate Brachytherapy Treatment Delivery, (Radiation Therapy Committee Task Group No. 59) 1998.

8. AAPM Report No. 67 – Protocol for Clinical Dosimetry of High Energy Photon and Electron Beams, Medical Physics 26(9), pp. 1847-1870, (Radiation Therapy Committee Task Group No. 51) September, 1999.

Other Technical Publications

1. International Commission on Radiation Units and Measurements (ICRU), "Certification of Standardized Radioactive Sources," Report No. 12, 1968.

2. U.S. Department of Health, Education, and Welfare, "Radiological Health Handbook," 1970.

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

4. International Atomic Energy Agency (IAEA), "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970.

5. IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments," Technical Report Series No. 133, 1971.

6. 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.

7. 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.

8. Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981.

9. Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984.

10. S. R. Jones, "Derivation and Validation of a Urinary Excretion Function for Plutonium Applicable over Ten Years Post Intake," *Radiation Protection Dosimetry*, Volume 11, No. 1, 1985.

11. "Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987.

12. J. R. Johnson and D. W. Dunford, "GENMOD – A Program for Internal Dosimetry Calculations," AECL-9434, Chalk River Nuclear Laboratories, Chalk River, Ontario, 1987.

13. 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, 1988.

14. K. W. Skrable et al., "Intake Retention Functions and Their Applications to Bioassay and the Estimation of Internal Radiation Doses," *Health Physics Journal*, Volume 55, No. 6, 1988.

15. A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990.

16. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990.

17. 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.

18. P. Early, D. B. Sodee, "Principles and Practice of Nuclear Medicine," 2nd ed., 1995.

19. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," *Pediatric Nuclear Medicine*, 1995.

20. "Intravascular Brachytherapy – Guidance for Data to be Submitted to the Food and Drug Administration In Support of Investigational Device Exemption (IDE) Applications," Draft Version 1.3, 1996.

21. R.O. Dunkelberger, II, "Which Probe Should I Use," *Baltimore-Washington Health Physics Society Newsletter.*

APPENDIX BB

Summary of Public Comments on Drafts and NRC Responses

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The initial draft of NUREG-1556 Vol. 9 was published for public comment in August 1998. A revised draft was published in March 2002. Appendix Z of the March 2002 draft included a summary of comments on the 1998 draft and NRC responses. The NRC held two public workshops, on April 25 and April 30, 2002, to receive stakeholder comments on the March 2002 draft. The NRC also received written public comments during a 60-day comment period (April 5 to June 4, 2002). A summary and analysis of both sets of comments was published as a separate document, Appendix BB to NUREG-1556, Vol. 9 (January 2003). This document is also available on the NRC's web site <http://www.nrc.gov> in the Electronic Reading Room; interested parties may also check the NRC's web page on the Medical Use of Byproduct Material <http://www.nrc.gov/miau/med-use-toolkit.html>.