

**MEETING AGENDA**  
**ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**April 15-16, 2013**  
**Two White Flint North Building (T2-B3), Rockville, Maryland**

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

**Monday, April 15, 2013**  
**CLOSED SESSION**

8:00 – 8:15	<b>1. HRMS Training</b>	<b>S. Holiday, NRC</b>
8:15 – 8:30	<b>2. eTravel Training</b>	<b>S. Holiday, NRC</b>
8:30 – 9:30	<b>3. Biennial Evaluations and Discussion</b>	<b>S. Holiday, NRC</b>

**OPEN SESSION**

9:30 – 9:45	<b>4. Opening Statements</b>	<b>C. Einberg &amp; B. McDermott, NRC</b>
	Mr. Einberg will formally open the meeting and Mr. McDermott will provide opening comments.	

9:45 – 10:00	<b>5. Special Presentation</b>	<b>Chairman A. Macfarlane, NRC</b>
	Chairman Allison Macfarlane will make a special presentation to Dr. Malmud.	

10:00 – 10:15	<b>6. Old Business</b>	<b>A. Cockerham, NRC</b>
	Ms. Cockerham will review past ACMUI recommendations and provide NRC responses.	

10:15 – 10:30	<b>7. ACMUI Webpage Update</b>	<b>A. Cockerham, NRC</b>
	Ms. Cockerham will discuss the revisions made to the ACMUI webpage.	

10:30 – 11:00 **B R E A K**

11:00 – 12:00	<b>8. Draft Guidance for 10 CFR Part 35 Rulemaking</b>	<b>NRC Staff ACMUI</b>
	Staff from the medical team and the ACMUI will discuss the draft guidance for the expanded 10 CFR Part 35 rulemaking.	

12:00 – 1:30 **L U N C H**

1:30 – 2:30	<b>9. Draft Guidance for 10 CFR Part 35 Rulemaking (cont.)</b>	<b>NRC Staff ACMUI</b>
	Staff from the medical team and the ACMUI will discuss the draft guidance for the expanded 10 CFR Part 35 rulemaking.	

2:30 – 3:00 **B R E A K**

3:00 – 5:00	<b>10. AO Subcommittee Report</b>	<b>S. Langhorst, ACMUI</b>
	Dr. Langhorst will discuss the Abnormal Occurrence Subcommittee Report.	



Opening Remarks

NO HANDOUT

Special Presentation

NO HANDOUT

## 2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

ITEM		DATE	STATUS	
2	NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read "has met the training and experience requirements."	6/12/07	Accepted	Open
3	NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.	6/12/07	Accepted	Open
6	NRC staff should add the words "or equivalent" so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A (35.12(c))	6/13/07	Accepted	Open
7	NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.	6/13/07	Accepted	Open
8	NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or ANP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.	6/13/07	Accepted	Open
10	a) NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. b) NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC's interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment.	6/13/07	a) Accepted Accepted	b) a) Open b) Closed
25	NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.	8/16/07	Accepted	Open
30	The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated under 10 CFR 35.600.	10/22/07	Accepted	Open <i>Delayed</i>
31	NRC staff should require experienced RSOs and AMPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.	10/22/07	Accepted	Open
32	NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.	10/22/07	Accepted	Open
34	NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.	10/22/07	Accepted	Open <i>Delayed</i>
35	NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.	10/22/07	Partially Accepted	Open <i>Delayed</i>
36	NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SDDR.	10/22/07	Accepted	Open
37	NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.	10/22/07	Accepted	Open

## 2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should pursue rulemaking to allow more than one RSO on a medical use license with the indication of one RSO as the individual in charge.	4/28/08	Accepted	Open
5	NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife® Elekta Perfexion™ in future rulemaking.	4/28/08	Accepted	Open <i>Delayed</i>
9	NRC staff should revise the AO criteria to read, "A medical event that results in: 1) death; or 2) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment regimen, as determined by an NRC or Agreement State designated consultant physician."	4/28/08	Accepted	Open
19	NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."	10/27/08	Pending	Open <i>Delayed</i>
22	ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted through the public review process instead of residing in guidance space.	10/27/08	Partially accepted	Open
26	NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs	10/28/08	Accepted	Open <i>Delayed</i>
27	NRC staff should revise 10 CFR 35.40 to clarify that <u>an</u> AU, not <u>the</u> AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open <i>Delayed</i>
28	NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.	10/28/08	Accepted	Open
29	NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo 99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.	10/28/08	Accepted	Open
30	NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.	10/28/08	Accepted	Open

## 2009 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should revise 35.390(b)(1)(ii)(G)(3) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission, or low energy photo-emission, or auger electron; and/or" and revise 35.390(b)(1)(ii)(G)(4) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission"	5/7/09	Accepted	Open
9	Dr. Malmud added three temporary members to the medical events subcommittee: Dr. Welsh (chair), Dr. Langhorst, Mr. Mattmuller. Existing subcommittee members include: Ms. Gilley, Dr. Suleiman, and Dr. Thomadsen.	10/19/09	No NRC action	Open
10	ACMUI recommends NRC staff delete the phrase "at a medical institution" from 10 CFR 35.2, 35.490(b)(1)(ii), 35.491(b)(2) and 35.690(b)(1)(ii).	10/19/09	Accepted	Open

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI endorsed the draft response to NRC comments, as reflected in the meeting handout (ML110600249). ACMUI agreed if NRC believes the release criteria should be changed from a per release criteria to an annual criteria, this change would require new rulemaking, as stated in Regulatory Issue Summary (RIS) 2008-07. ACMUI recommended rulemaking to clarify that the release under 10 CFR 35.75 is per release and not per year	1/5/11	Pending	Open	Langhorst/Gilley	9, 1, 0
6	ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.	1/12/11	ACMUI Action	Open indefinitely	Welsh/Zanzonico	
7	Dr. Malmud will serve as a reviewer to screen I-131 cases for the ACMUI Medical Event Subcommittee	4/11/11	ACMUI Action	Open indefinitely		
11	(1) ACMUI feels ASTRO's approach to Permanent Implant Brachytherapy (handout) is correct approach for patient welfare (2) ACMUI recommends that the NRC require Post-Implant dosimetry following brachytherapy treatment (3) ACMUI believes that prostate brachytherapy is a unique subset of brachytherapy and should therefore require a separate set of rules from non-prostate brachytherapy.	4/11/11	Partially Accepted	Open	Welsh/Mattmuller	11, 0, 0
13	ACMUI recommends to eliminate the written attestation for board certification pathway, regardless of date of certification	4/12/11	Accepted	Open	Zanzonico/Guiberteau	11, 0, 0
14	ACMUI recommends the attestation to be revised to say ... has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee	4/12/11	Accepted	Open	Langhorst/Thomadsen	11, 0, 0
15	ACMUI supports the statement that residency program directors can sign attestation letters, representing consensus of residency program faculties, if at least one member of the faculty is an AU in the same category as that designated by the applicant seeking authorized status, and that AU did not disagree with the approval.	4/12/11	Accepted	Open	Thomadsen/Welsh	11, 0, 0
16	ACMUI continues to assert that the current regulations are based on a per release limit. ACMUI does not recommend any change to the regulation and does not recommend the NRC consider this topic during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit.	4/12/11	Pending	Open	Langhorst/Welsh	11, 0, 0
19	Steve Mattmuller asked that NRC Staff add ACMUI to the organizational chart on the FSME website.	9/22/11	Accepted	Open	Mattmuller	
20	Dr. Langhorst requested that NRC staff 1) place historical documents on the ACMUI website that would give everyone a better understanding of the ACMUI organization and how it got to where it is today and 2) NRC add past ACMUI membership information on the ACMUI Website.	9/22/11	Accepted	Open	Langhorst	
32	ACMUI reaffirms the 2008 AO Criteria as stated in the handout with the amendment that (s) be added to the end of physician, to read "consultant physician(s)"	12/15/11	Accepted	Open	Guiberteau/Mattmuller	11,0,1

2012 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
3	Dr. Thomadsen created a subcommittee to provide a recommendation on licensing for alpha-emitters, including Ra-223. The subcommittee will submit its report by 6/15/12. Subcommittee members include: Dr. Zanzonico (chair), Ms. Bailey, Dr. Langhorst, Mr. Mattmuller, Dr. Palestro, Dr. Suleiman, Dr. Thomadsen, Dr. Welsh. The NRC Staff resource person will be Ms. Ashley Cockerham.	4/17/12	ACMUI Action	Closed		
5	ACMUI approved the Draft Subcommittee Report on Licensing Ra-223 Chloride with minor modifications to be made.	7/9/12	ACMUI Action	Closed		11, 0, 0
6	Dr. Malmud asked NRC staff to find data on events in which the radiopharmacy has dispensed the incorrect amount of a radiopharmaceutical or the incorrect radiopharmaceutical.	9/20/12	NRC Action	Closed		
7	ACMUI recommends licensing of Ra-223 dichloride under 10 CFR 35.300 and recommends (but does not recommend <i>requiring</i> ) direct measurement of activity before/after administration.	9/20/12	ACMUI Recommendation	Closed	Zanzonico/Langhorst	12,0,0
8	ACMUI endorses the subcommittee report submitted on July 16, 2012 with the following changes: 1) recommend licensing of Ra-223 dichloride under 10 CFR 35.300 and recommend (but not require) direct measurement of activity before/after administration; 2) remove statement regarding applicability of report for all future alpha-emitting particles; and 3) remove statement regarding Ra-223 dichloride significantly prolonging survival. ACMUI will submit a report to NRC staff with the aforementioned changes.	9/20/12	ACMUI Action	Closed	Zanzonico/Welsh	12, 0, 0
9	ACMUI requested that reporting structure reviews remain on an annual basis.	9/20/12	NRC Action	Accepted		
10	Dr. Malmud created a subcommittee to review the refined Abnormal Occurrence criteria and provide recommendations to NRC staff. The subcommittee includes: Dr. Langhorst (chair), Ms. Bailey, Ms. Weil, Dr. Palestro, Dr. Welsh, Dr. Thomadsen, and Mr. Mattmuller. NRC staff resource will be Angela McIntosh.	9/21/12	ACMUI Action	Closed		
11	Dr. Langhorst asked NRC staff to provide direction as to whether or not the trigger criteria needs to be a part of the Abnormal Occurrence criteria or if the trigger criteria could be used separately	9/21/12	NRC Action	Closed		
12	ACMUI proposed the next meeting be on April 15-16, 2013 with a backup date of April 29-30, 2013. The ACMUI will meet separately with the Commission, if requested.	9/21/12	NRC Action	Closed		
13						

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI recommended NRC staff allow use of total source strength as a substitute for total dose for determining medical events for permanent implant brachytherapy until the Part 35 rulemaking is complete.	3/5/13	NRC Action	Open		11, 0, 0
2	ACMUI recommended that NRC staff solicit feedback from stakeholders, in Supplementary Information section IV.D, on whether the proposed ME definition for permanent implant brachytherapy would discourage licensees from using this form of therapy. This recommendation was modified the caveat that NRC may utilize the language that they think is appropriate for gaining this type of information from its stakeholders	3/5/13	NRC Action	Open	Zanzonico/Langhorst	
3	ACMUI recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B.	3/5/13 3/12/13	NRC Action	Open		11, 1, 0
4	ACMUI recommended replacing the phrasing in the literature in terms of support for the 5 cubic centimeters of contiguous normal tissue provision of the ME definition, to the specific reference cited as, Nag, et al 2004	3/5/13	NRC Action	Open		
5	ACMUI recommended that licensees approved to use generator systems show specific training on the requirement now listed under 35.290 (c)(1)(ii)(G) for those individuals (Authorized Users and others) who are responsible for proper operation and testing of the generator as part of their license conditions. ACMUI further recommended that Authorized Nuclear Pharmacists who have the adequate training and experience (T&E) are able to provide the supervised work experience for Authorized Users on the elution of generators.	3/5/13	NRC Action	Open		
6	ACMUI endorsed the language in the proposed rule for preceptor attestations that states a candidate is able to independently fulfill the radiation safety related duties for which authorization is being sought.	3/5/13	NRC Action	Open		
7	ACMUI recommended that the work experience for parenteral administrations under Sections 35.390 (b)(1)(2)(g), and 35.396 not be separated between parenteral administrations of a beta gamma emitting radiopharmaceutical versus an alpha emitting radiopharmaceutical, as proposed in the proposed rule.	3/12/13	NRC Action	Open	Zanzonico/Guiberteau	11, 0, 1
8	ACMUI recommended that the date of recognition of a certifying board should not impact individuals seeking to be named as an Authorized User, Authorized Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist through the certification pathway.	3/12/13	NRC Action	Open	Zanzonico/Thomadsen	12, 0, 0
9	ACMUI recommended that the NRC adopt the FDA approved package insert for breakthrough limits for radioisotope generators	3/12/13	NRC Action	Open	Zanzonico/Mattmuller	12, 0, 0
10	ACMUI recommended licensee reporting of out-of-tolerance generator breakthrough results to the NRC	3/12/13	NRC Action	Open	Zanzonico/Weil	5, 7, 0

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
11	ACMUI recommended requiring testing of molybdenum breakthrough on every elution of a molybdenum-technetium generator, rather than after only the first elution.	3/12/13	NRC Action	Open		12, 0, 0
12	ACMUI recommended that the addition of Associate Radiation Safety Officers (ARSOs), and Temporary RSOs also be included in these exemptions in the same manner as AUs, ANPs, and AMPs.	3/12/13	NRC Action	Open	Zanzonico/Langhorst	12, 0, 0
13	In reference to the plain language requirement, the ACMUI suggested that the rule "could be shortened and improved by eliminating redundancies and consolidating related sections and eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed "executive summary"-style section summarizing, perhaps in a bullet format, the key changes introduced in the draft rule."	3/12/13	NRC Action	Open		12, 0, 0
14	ACMUI recommended approval of the Second Draft ACMUI Rulemaking Subcommittee Report (ML13071A690) with the caveat that all modifications discussed during the teleconference would be incorporated before submission to NRC staff.	3/12/13	NRC Action	Closed	Zanzonico/Guiberteau	12, 0, 0
15						
16						
17						
18						
19						
20						

ACMUI Webpage Update

<http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

NO HANDOUT



## Draft Guidance for 2013 Proposed Expanded 10 CFR Part 35 Rulemaking

Pat Zanzonico, PhD  
ACMUI

*With Special thanks to Ms. Sophie Holiday, NRC*



### Introduction

- **Regulatory Guidance (“Reg Guide”)** provides practical instructions on compliant preparation of license applications
- **Regulations define the “what” / Reg Guides describe the “how”**
- **Indexed to applicable regulations (CFR)**
- **Resource used by Licensees for regulatory compliance as well as license applications**

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### Scope of Regulatory Guidance

- **Preparation of License applications**
- **Documentation of T&E for AUs, ANPs, AMPs, and ARSOs**
- **Record-keeping requirements**
- **Model procedures**
- **Sample forms**

*Spongiosa bone Osteoblastic bone  
Often relied upon  
by Licensees*

3



### Draft Guidance for 2013 Proposed Expanded 10 CFR Part 35 Rulemaking

- **Part 1: Draft Supplemental Guidance for NUREG-1556, Volume 9, Revision 2, Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses**
- **Part 2: Draft Supplemental Guidance for NUREG-1556, Volume 13, Revision 1 Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses**
- **Part 3: Questions and Answers**

*• Only sections affected by proposed rule included  
• Red-lined  
Osteoblastic bone*

*Useful information beyond  
License preparation*

4

**Revisions in Draft Guidance = Revisions in Proposed Rule**

- Associate RSOs
- Resolution of Ritenour petition
- Elimination of preceptor attestation requirement for board-certified individuals
- Attestation language: "...able to independently fulfill radiation safety-related duties...."
- 7-year inspection/servicing requirement for gamma stereotactic radiosurgery units

**Revisions in Draft Guidance = Revisions in Proposed Rule**  
*cont*

- Requirement for testing of every generator elution for parent breakthrough
- Requirement for notification of NRC of generator elutions with out-of-tolerance parent breakthrough
- Authorization to use alpha emitters - § 35.300 and § 35.390 (b)(1)(ii)(G)
- New activity-based definition of a medical event for permanent implant brachytherapy - § 35.3045

**Summary Statement**

**Draft Guidance reliably recapitulates Proposed Rulemaking**

- Highlights important changes from current version of 10 CFR 35
- Provides well-structured forms for T&E requirements for authorized professionals
- Includes useful supplemental information in Q&A section

**Abbreviations and Acronyms**

- **ACMUI:** Advisory Committee on Medical Uses of Isotopes
- **AU:** Authorized User
- **ANP:** Authorized Nuclear Pharmacist
- **AMP:** Authorized medical Physicist
- **RSO:** Radiation Safety Officer
- **ARSO:** Associate Radiation Safety Officer
- **CFR:** Code of Federal Regulations
- **NRC:** Nuclear Regulatory Commission
- **Q&A:** Questions and Answers
- **T&E:** Training and Experience

# Draft Guidance for the 2013 Proposed Expanded 10 CFR Part 35 Rulemaking

## **Introduction**

The draft guidance developed to implement the 2013 Proposed Expanded 10 CFR Part 35 rulemaking is provided in three parts. The first two parts consist of revisions to the guidance already provided in the NUREG-1556, "Consolidated Guidance About Materials Licenses" series of volumes for medical uses and commercial nuclear pharmacies. These guidance documents primarily provide guidance that an applicant can use to complete a material license application for a NRC license. These documents also include examples of procedures that an applicant may want to use as models when developing its radiation safety program examples, as well as tools that licensee's may employ when completing the corresponding material license applications. Because the revisions to the regulations are not restricted to elements associated with obtaining a license, the third part of the guidance includes a series of questions and answers that should assist a licensee in understanding and implementing the new regulatory changes.

Part 1 consists of the "Draft Supplemental Guidance for NUREG-1556, Volume 9, Revision 2, Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses."

Part 2 consists of the "Draft Supplemental Guidance for NUREG-1556, Volume 13, Revision 1, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses."

In each of these two parts, NRC extracted only those sections and appendices of the NUREG that will contain a change for the proposed draft supplementary guidance document. Within each of these two supplementary documents, an introductory notation was inserted before each section to identify the revised regulation that resulted in the changes and to describe in general terms what was changed. Red line format was used to show where the new text was added and black strikeout format was used to show text that was eliminated. In general, entire sections were included in the proposed draft supplemental documents to put the proposed changes in proper context. If the entire appendix was not included, the page numbers in the NUREG-1556 document where the text including changes started was included in the notation information.

Part 3 includes draft questions and answers that are grouped into common topics.

The public is asked to provide its comments on the proposed changes and to reference the topic of the comment by appropriate part, section, appendix, or question. This will facilitate staff's resolution of the comments. In addition to commenting on the draft questions and answers, please identify additional questions that will provide a better understanding of the proposed rule and its implementation.

## **PART 1**

**Draft Supplemental Guidance for NUREG-1556, Volume 9,  
Revision 2, Consolidated Guidance About Materials Licenses:  
Program - Specific Guidance About Medical Use Licenses.**

**[The following redline addition to the “Abbreviations” section reflects the change to 10 CFR 35.2, adding an Associate Radiation Safety Officer.]**

## **ABBREVIATIONS**

AAPM	American Association of Physicists in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ACR	American College of Radiology
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
<b>ARSO</b>	<b>Associate Radiation Safety Officer</b>
AU	Authorized User
bkg	background
BPR	Business Process Redesign
Bq	bequerel
CFR	Code of Federal Regulations
Ci	curie
cc	centimeter cubed
cm <sup>2</sup>	square centimeter
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DOT	United States Department of Transportation
dpm	disintegrations per minute
EPAct	Energy Policy Act of 2005
F-18	fluorine-18
FDA	United States Food and Drug Administration

GM	Geiger-Mueller
GPO	Government Printing Office
GSR	gamma stereotactic radiosurgery
HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
IP	Inspection Procedure
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
Mo-99	molybdenum-99
mR	milliroentgen
mrem	millirem
mSv	millisievert
N-13	nitrogen-13
NaI(Tl)	sodium iodide (thallium doped)
NARM	Naturally Occurring and Accelerator-Produced Material
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
O-15	oxygen-15
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSL	optically stimulated luminescence dosimeters
PET	Positron Emission Tomography
P-32	phosphorus-32
Pd-103	palladium-103

PDR	pulsed dose-rate
P&GD	Policy and Guidance Directive
QA	quality assurance
Ra-226	radium-226
Ru-82	rubidium-82
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unités)
Sr-82	strontium-82
Sr-85	strontium-85
Sr-90	strontium-90
SSDR	Sealed Source and Device Registry
std	standard
Sv	Sievert
TAR	Technical Assistance Request
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TI	Transport Index
TLD	thermoluminescent dosimeters
U-235	uranium-235
WD	written directive
Xe-133	xenon-133
Y-90	yttrium-90
μCi	microcurie
%	percent

[The following redline additions to Table 1.1 reflect the changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433.]

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.1	License Action Type	•	•	•	•	•	•	•
8.2	Applicant's Name and Mailing Address	•	•	•	•	•	•	•
8.3	Address(es) Where Licensed Material Will Be Used or Possessed	•	•	•	•	•	•	•
8.4	Person to Be Contacted about This Application	•	•	•	•	•	•	•
8.5	Radioactive Material	•	•	•	•	•	•	•
8.6	Sealed Sources and Devices (including Ra-226 Sealed Sources and Devices)				•	•	•	•
8.7	Discrete Source of Ra-226 (other than Sealed Sources)	•	•	•				•
8.8	Recordkeeping for Decommissioning and Financial Assurance	•	•	•	•	•	•	•
8.9	Purpose(s) for which Licensed Material Will Be Used	•	•	•	•	•	•	•
8.10	Individual(s) Responsible for Radiation Safety Program and their Training and Experience	•	•	•	•	•	•	•
8.11	Radiation Safety Officer (RSO) <b>and Associate Radiation Safety Officer</b>	•	•	•	•	•	•	•
8.12	Authorized User (AU)	•	•	•	•	•	•	•
8.13	Authorized Nuclear Pharmacist (ANP)	•	•	•				•
8.14	Authorized Medical Physicist (AMP) <b>and individuals identified in 10 CFR 35.433</b>				•		•	•

**Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review**

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.15	Facilities and Equipment	•	•	•	•	•	•	•
8.16	Facility Diagram	•	•	•	•	•	•	•
8.17	Radiation Monitoring Instruments	•	•	•	•	•	•	•
8.18	Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material	•	•	•				•
8.19	Therapy Unit - Calibration and Use				•		•	•
8.20	Other Equipment and Facilities	•	•	•	•	•	•	•
8.21	Radiation Protection Program	•	•	•	•	•	•	•
8.22	Safety Procedures and Instructions						•	•
8.23	Occupational Dose	•	•	•	•	•	•	•
8.24	Area Surveys	•	•	•	•	•	•	•
8.25	Safe Use of Unsealed Licensed Material	•	•	•				•
8.26	Spill/Contamination Procedures	•	•	•	•	•	•	•
8.27	Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources						•	•
8.28	Minimization of Contamination	•	•	•	•	•	•	•
8.29	Waste Management	•	•	•	•	•	•	•
8.30	Fees	•	•	•	•	•	•	•
8.31	Certification	•	•	•	•	•	•	•
AA	Authorization under 10 CFR 30.32(j) to Prepare PET Radioactive Drugs for Noncommercial Transfer							

**PROGRAM-RELATED GUIDANCE - NO RESPONSE FROM APPLICANTS ON NRC FORM 313**

**Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review**

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.32	Safety Instruction for Individuals Working In or Frequenting Restricted Areas	•	•	•	•	•	•	•
8.33	Public Dose	•	•	•	•	•	•	•
8.34	Opening Packages	•	•	•	•	•	•	•
8.35	Procedures for Administrations When a Written Directive Is Required			•	•		•	•
8.36	Release of Patients or Human Research Subjects			•	•			•
8.37	Mobile Medical Service	•	•	•	•	•	•	•
8.38	Audit Program	•	•	•	•	•	•	•
8.39	Operating and Emergency Procedures	•	•	•	•	•	•	•
8.40	Material Receipt and Accountability	•	•	•	•	•	•	•
8.41	Ordering and Receiving	•	•	•	•	•	•	•
8.42	Sealed Source Inventory	•	•	•	•	•	•	•
8.43	Records of Dosages and Use of Brachytherapy Source	•	•	•	•			•
8.44	Recordkeeping	•	•	•	•	•	•	•
8.45	Reporting	•	•	•	•	•	•	•
8.46	Leak Tests	•	•	•	•	•	•	•
8.47	Safety Procedures for Treatments When Patients Are Hospitalized			•	•		•	•
8.48	Transportation	•	•	•	•	•	•	•

[The following redline additions to Section 3 reflect the changes to 10 CFR 35.2 and 35.24 adding an Associate Radiation Safety Officer.]

### 3 MANAGEMENT RESPONSIBILITY

**Regulations:** 10 CFR 30.9, 10 CFR 35.12, 10 CFR 35.24.

The NRC endorses the philosophy that effective Radiation Protection Program management is vital to safe operations that comply with NRC regulatory requirements (see 10 CFR 35.24).

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

“Management” refers to the chief executive officer or other individual having the authority to **manage, direct, or administer the licensee’s activities** or that person’s delegate or delegates (see 10 CFR 35.2).

To ensure adequate management involvement in accordance with 10 CFR 35.12(a) and 35.24(a), a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management’s commitments to and responsibility for the following:

- Radiation protection, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation protection records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license application;
- Compliance with current NRC and United States Department of Transportation (DOT) regulations and the licensee’s operating and emergency procedures;
- Provision of adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the Radiation Protection Program to ensure that patients, the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- **If applicable, appointment of one or more qualified individuals who have agreed in writing to perform specific duties and tasks as an ARSO;**
- Approval of qualified individual(s) to serve as authorized medical physicists (AMPs), **individuals identified in 10 CFR 35.433**, ANPs, and AUs for licensed activities.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the following:

- The NRC Enforcement Policy which is included on the NRC’s Web site at <http://www.nrc.gov/what-we-do/regulatory/enforcement/enforce-pol.html>

- The NRC Inspection Manual, Chapter 2800, “Materials Inspection Program,” and
- Inspection Procedures:
  - 83822 – “Radiation Protection,”
  - 84850 – “Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61,”
  - 84900 – “Low-Level Radioactive Waste Storage,”
  - 87130 – “Nuclear Medicine Programs — Written Directive Not Required,”
  - 87131 – “Nuclear Medicine Programs — Written Directive Required,”
  - 87132 – “Brachytherapy Programs,”
  - 87133 – “Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs,” and
  - 87134 – “Medical Broad-Scope Programs.”

For availability of these documents, see the Notice of Availability on the inside front cover of this report. In addition, the Inspection Manual and procedures are available at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

**[The following redline/strike out revisions to Section 5.1 reflect a change to 10 CFR 35.12 to require only one copy of a license application.]**

## **5.1 PREPARING AN APPLICATION**

Applicants for an NRC materials license should do the following:

- Use the most recent guidance in preparing an application, including Appendix AA of this document, if appropriate;
- Complete NRC Form 313 (Appendix A), Items 1 through 4, 12, and 13, on the form itself;
- Complete NRC Form 313, Items 5 through 11, on supplementary pages, or use Appendix C;
- Complete the appropriate NRC Form 313A series of forms (Appendix B) to document training and experience, if electing to complete this optional form;
- Provide sufficient detail for NRC to determine that equipment, facilities, training, experience, and the Radiation Safety Program are adequate to protect health and safety and minimize danger to life and property;
- For each separate sheet, other than the NRC Form 313A series of forms or Appendix C, that is submitted with the application, identify and cross-reference it to the item number on the application or the topic to which it refers;
- Submit all documents, typed, on 8-1/2 x 11-inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- If submitted, proprietary information and other sensitive information must be clearly identified (see Section 5.2 below);
- Submit ~~the an~~ original signed application ~~and one copy~~; and.
- Retain one copy of the license application for future reference.

<b>Part 35</b>	<b>Applicability</b>
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Applications must be signed by the applicant's or licensee's management as required by 10 CFR 35.12(a); see Section 8.31, "Certification."
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**[The following redline additions to Section 8 reflect changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433.]**

## **8 CONTENTS OF AN APPLICATION**

This section explains, item by item, the information that medical use applicants must provide on NRC Form 313 (see Appendix A) and should provide on the appropriate NRC Form 313A series of forms if electing to use this optional form (see Appendices B and D). If an application contains security-related sensitive information (see Section 5.2), the cover letter should state that the “attached documents contain security-related sensitive information.” If a cover letter is not used, NRC Form 313 should include this statement. The information needed to complete Items 5 through 11 on Form 313 describes the applicant’s proposed medical use Radiation Safety Program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item. Appendix AA explains additional information the applicant must provide on NRC Form 313 when requesting authorization under 10 CFR 30.32(j) for preparing PET radioactive drugs for noncommercial distribution to medical use licensees within its consortium.

Table 1 in Appendix C is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in this report present sample procedures that applicants may use in developing their procedures. Suggested responses for each block on the NRC Form 313 appear under “Response from Applicant” in this guide.

If a particular part of a section does not apply, simply note “N/A” for “not applicable.” If a particular section applies, but a procedure does not have to be developed, simply note “N” for “no response required.” N/A, N, or short sentence responses to Items 5 through 11 should run consecutively on one or more sheets separate from responses provided on NRC Form 313. Lengthy responses should be appended as attachments.

As indicated on NRC Form 313 (see Appendix A), responses to Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use the appropriate NRC Form 313A series of forms (see Appendix B) to document training and experience for new AUs, medical physicists, **individuals identified in 10 CFR 35.433**, nuclear pharmacists, **ARSOs** and RSOs. The NRC Form 313A series of forms may also be used by experienced individuals seeking additional authorizations. Applicants may use Appendix C to assist with completion of the application.

**[The following redline/strikeout revisions to Item 5 reflect changes to 10 CFR 35.65 to prohibit bundling of single sources or use of calibration, transmission, or reference sources for medical use under the provisions of 10 CFR 35.65; and to clarify that certain calibration, transmission, or reference sources may not have to be listed on the license when used under the provisions of 10 CFR 35.500.]**

## **8.5 ITEM 5: RADIOACTIVE MATERIAL**

**Regulations:** 10 CFR 30.32, 10 CFR 32.210, 10 CFR 35.65, 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000.

**Criteria:** Byproduct material for medical use in 10 CFR Part 35 is divided into seven types of use (10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000).

<b>Part 35</b>	<b>Applicability</b>
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

**Discussion:** The applicant should indicate the byproduct material requested. The amount and type of information necessary will vary according to the type of use and material requested.

Under Section 651c of the EPA Act, the NRC now has regulatory authority over accelerator-produced byproduct material as well as discrete sources of Ra-226. Although sealed Ra-226 sources (e.g., Ra-226 needles) were once used for manual brachytherapy and are no longer believed to be used for medical uses, the medical use of discrete sources of Ra-226 is included in this guidance because its use for this purpose is not prohibited. The guidance also distinguishes between discrete sources of Ra-226 and sealed sources of Ra-226 because not all discrete sources are sealed sources.

The medical uses of the other new byproduct materials are essentially the same as the uses of the previously defined byproduct materials. However, some of the radionuclides now included in the expanded definition of byproduct material have significantly shorter half-lives and higher energy levels (e.g., PET radionuclides) that may result in delivery of the unsealed material by direct transfer tube from the accelerator production facility to the 35.100 and 35.200 medical use areas. This may result in higher potential radiation doses to workers and the public if additional handling and shielding precautions are not implemented, and licensees should consider this in evaluating their equipment, facilities, and programs.

**35.100 and 35.200 Use:** For 10 CFR 35.100 and 35.200 medical uses, the chemical/physical form may be “Any” unsealed byproduct material permitted by 10 CFR 35.100 or 35.200, as appropriate. For 10 CFR 35.100 and 35.200 medical uses, the total amount requested may be “As Needed.”

The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.100	Any	As needed
Any byproduct material permitted by 10 CFR 35.200	Any	As needed <sup>1</sup>

**35.300 Use:** For 10 CFR 35.300 use, the chemical/physical form may be “Any” unsealed byproduct material permitted by 10 CFR 35.300. The total amount requested must be specified. The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.300	Any	300 millicuries

**35.400, 35.500, 35.600, and 35.1000 Use:** For 10 CFR 35.400, ~~35.500~~, 35.600, and 35.1000 use, the radionuclide, the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number), the total amount in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), and the maximum number of sources or activity possessed at any one time must be specified. **For 10 CFR 35.500 use, the sealed source information described above does not need to be provided of calibration, transmission, or reference sources used for this medical use if the individual activity or a bundled activity is not greater than the maximum activity of any single source authorized in 10 CFR 35.65. The sealed source and device information described above has to be provided for all other sources and devices used under 35.500.** Sealed sources of Ra-226 may be used for 10 CFR 35.400, 35.500, and 35.1000 uses. Unsealed Ra-226 can only be used for medical use under 35.1000. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
I-125 (specific radiation therapy system liquid brachytherapy source, 35.1000 use)	Liquid source (Manufacturer Name, Model #DEF)	2 curies total
Ra-226	Sealed source or device (Manufacturer Name, Model #HIJ)	Not to exceed 50 millicuries per source and 250 millicuries total

<sup>1</sup> Applicants that have their own cyclotrons and produce PET radionuclides that they use to produce PET radioactive drugs for their own use under the appropriate provisions of 10 CFR Part 35 may have different shielding or special equipment requirements than most medical use applicants who receive unit doses, multi-dosage vials, or generators from drug manufacturers or commercial nuclear pharmacies that are packaged in self-shielding radiation transport shields. Information needed for the different shielding or special equipment requirements can be found in Section 9.

Cesium 137 (i.e., specific brachytherapy radionuclide, 35.400 use)	Sealed source or device (Manufacturer Name, Model #MNO)	2 curies total
Pd-103 (i.e., specific manual brachytherapy source, 35.400 use)	Sealed source or device (Manufacturer Name, Model #QRS)	Not to exceed 0.5 millicuries per source and 3 curies total
Gadolinium 153 (i.e., specific diagnostic sealed-source radionuclide, 35.500 use)	Sealed source or device (Manufacturer Name, Model #TUV)	Not to exceed 500 millicuries per source and 1 curie total
Cobalt 57 (transmission sources bundled to exceed more than 30 millicuries, in PET scanners, 35.500 use)	Sealed source or device (Manufacturer Name, Model #CTR)	Not to exceed 30 millicuries per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed-source radionuclide, 35.600 use)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total
Iridium 192 (i.e., specific afterloader sealed-source radionuclide, 35.600 use)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed- source radionuclide, 35.600 use)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total

For sealed sources used in devices, an applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registry (SSDR) certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

**Calibration, Transmission, and Reference Sources:** For all calibration, transmission, and reference sources, including those with Ra-226, covered under 10 CFR 35.65, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 10 CFR 35.11 for the medical use of byproduct material. **Although 10 CFR 35.65 does not permit use of the calibration, transmission, and calibration sources for intentional internal or external administration of byproduct material, or the radiation from byproduct material, to patients or human research sources (i.e. medical use), it does permits the use of these sources without listing them on the license for medical use as long as they are being used in accordance**

with the requirements in 10 CFR 35.500. Calibration, transmission, and reference sealed sources with an individual activity or a bundled activity greater than the maximum activity of any single source authorized in 10 CFR 35.65 have to be listed on the license.

**Shielding Material/Depleted Uranium:** Some high-activity radionuclide generators used to produce byproduct materials for 10 CFR 35.200 and 35.300 uses (e.g., Tc-99m generators) may include depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) as shielding material. If a generator has depleted uranium shielding, an applicant should request authorization to possess depleted uranium as shielding material. Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield the therapy sources and devices. This includes identifying depleted uranium used as shielding in linear accelerators because, even though NRC does not regulate the accelerator, it does regulate the depleted uranium in the accelerator. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in U-235) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices. The applicant should review the manufacturer’s specifications for each device specified in the license request to determine: (1) if depleted uranium is used to shield the source(s) within the device; and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult the manufacturer’s specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms). The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Depleted Uranium	Metal	999 kilograms

**Other Material:** The applicant should make a separate entry for other required items (e.g., Ra-226 not previously described, more byproduct material for *in vitro* testing than is allowed under 10 CFR 31.11, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 31.11	Prepackaged kits	50 millicuries
Ra-226	unsealed	1 millicurie

Sources that are authorized by 10 CFR 35.65, “Authorization for calibration, transmission, and reference sources,” should *not* be listed.

Applicants should number each line entry consecutively, following the 10 CFR Part 35 material.

**Blood Irradiators:** If the use of a device to irradiate blood is anticipated, the applicant should review NUREG-1556, Volume 5, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses.”

**Production of Radionuclides by Accelerators:** If the applicant will use an accelerator to produce radionuclides, a separate license application will be needed for the production of the radionuclides. The applicant should review NUREG-1556, Volume 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator.”

**Production of PET Radioactive Drugs for Noncommercial Distribution to Medical Use Licensees Within a Consortium:** If the applicant will use PET radionuclides to produce PET radioactive drugs for its own medical use and noncommercial distribution to other members of its consortium, the applicant, to satisfy 10 CFR 30.33(a)(1), should identify the PET radionuclides, the proposed use of the material, and the maximum activity. The applicant should also review Appendix AA.

The following format may be used for unsealed PET radionuclides used to produce PET radioactive drugs for noncommercial transfer to other members within the consortium.

Byproduct Material	Chemical/Physical Form	Maximum Amount
PET Radionuclides for noncommercial distribution	Any	____ curies

When applying for this authorization, the applicant should also consider applying for authorization to take back potentially contaminated transport shields from other consortium members. Each consortium member should dispose of unused dosages and used syringes and vials at its own facility.

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included (i.e., materials received awaiting use (new teletherapy or brachytherapy sources for exchange), materials in use or possessed, material used for shielding, and materials classified as waste awaiting disposal or held for decay-in-storage).

**Response from Applicant:** The applicant should submit the information as described above. Certain information about quantities of radioactive materials is no longer released to the public and needs to be marked “security-related information – withhold under 10 CFR 2.390.” Therefore, when responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly. Applicants requesting authorization for the medical use of a discrete source of Ra-226 (which includes a sealed source of Ra-226) or other NARM sources or devices containing NARM sources that do not have the information described above (e.g., manufacturer and model number from an SDR certificate), or the information required in 10 CFR 30.32(g)(3), should consult the appropriate NRC Regional Office to discuss the contents of their application.

[The following redline additions to Section 8.6 reflect changes to 10 CFR 35.65 to prohibit bundling of single sources or use of calibration, transmission, or reference sources for medical use under the provisions of 10 CFR 35.65, and to that clarify when used in accordance with the requirements in 35.500 the sources may not have to be listed on the license.]

## 8.6 ITEM 5: SEALED SOURCES AND DEVICES (including Ra-226 sealed sources and devices)

Part 35	Applicability
100	
200	
300	
400	✓
500	✓
600	✓
1000	✓

**Regulations:** 10 CFR 30.32(g), 10 CFR 30.33(a)(2), 10 CFR 32.210, 10 CFR 35.65.

**Criteria:** In accordance with 10 CFR 30.32(g), applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR 35.65, and certain NARM sources for which this information is not available). **The exception for calibration, transmission, or reference sources applies to either medical uses under 10 CFR 35.500 or non-medical uses. (Note: If the single or bundled activity of calibration, transmission, and reference sources exceeds the single source activity limit in 10 CFR 35.65 the manufacturer's name and model number for each requested sealed source and device must be provided.)** Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC, an Agreement State or a non-Agreement State, or certain sources when information required in 10 CFR 30.32(g)(3) is provided.

Under the EPAct, the NRC was given regulatory authority over additional byproduct material including accelerator-produced radionuclides and discrete sources of Ra-226. See 10 CFR 30.4 for a complete definition of byproduct material.

Applicants and licensees should determine whether they possess, or will possess, sealed sources or devices containing this new byproduct material for uses under 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, or 10 CFR 35.1000, as well as check, calibration, transmission, and references sources that are not included in 10 CFR 35.65.

Applicants will need to request authorization for possession of these sealed source(s) or device(s). It should also be noted that NRC's regulatory authority includes the new byproduct material produced prior to August 8, 2005. As a result, neither the NRC, an Agreement State, nor a non-Agreement State, may have performed a safety evaluation of the sealed source or device and it may not have an Sealed Source and Device Registry (SSDR) certificate. Information that must be submitted for all sources is described in 10 CFR 30.32(g).

**Discussion:** The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR certificate. Some non-Agreement

States may also have performed similar safety evaluations for sealed sources and devices containing NARM, and these safety evaluations may be documented in SDDR certificates. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify whether they have been evaluated in an SDDR certificate or specifically approved on a license. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor.

If such a review has not been conducted for the specific source/device model(s), licensees should request a copy of the latest version of NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," from an NRC Regional Office and submit the information requested therein to NRC for review.

If the sealed source or device that has not been reviewed contains NARM material and was produced before the effective date of the rule, November 30, 2007, the information required by 10 CFR 32.210 may not be available. If this is the case, the applicant must provide the information required in 10 CFR 30.32(g)(3).

An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SDDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SDDR certificates without obtaining NRC's prior permission in a license amendment. Licensees providing information in accordance with the provisions of 10 CFR 30.32(g) may not make changes to the sealed sources, device, or source-device combination that would alter the description provided to NRC without obtaining NRC's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the SDDR certificates, applicants may want to review or discuss them with the manufacturer.

**Response from Applicant:** If the possession of a sealed source(s) or device(s) is requested, the applicant shall submit the information described above.

**Reference:** See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," and NUREG-1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

**Note:** To obtain copies of the SDDR certificate, applicants should contact the manufacturer/distributor of the device or the appropriate NRC Regional Office (see Figure 2.1 for addresses and telephone numbers).

[The following redline/strikeout revisions to Section 8.9 reflect changes to: 10 CFR 35.65 to clarify when used under 35.500 calibration, transmission, or references sources may not have to be listed on the license; changes to 10 CFR 35.400, 35.500, and 35.600 requiring sources be used in accordance with the radiation safety conditions and limitations described in the Sealed Source Device Registration not as approved in the Sealed Source Device Registration; and changes in 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses.]

## 8.9 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

**Regulations:** 10 CFR 30.32(j), 10 CFR 30.33(a)(1), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000.

**Criteria:** In 10 CFR Part 35, byproduct material for medical use is divided into seven types of use as follows:

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

10 CFR 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
10 CFR 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
10 CFR 35.300	Use of unsealed byproduct material for which a written directive is required
10 CFR 35.400	Use of sources for manual brachytherapy
10 CFR 35.500	Use of sealed sources for diagnosis
10 CFR 35.600	Use of a sealed source(s) in a device for therapy-teletherapy unit
	Use of a sealed source(s) in a device for therapy-remote afterloader unit
	Use of a sealed source(s) in a device for therapy-gamma stereotactic radiosurgery unit
10 CFR 35.1000	Other medical uses of byproduct material or radiation from byproduct material

Under 10 CFR 30.32(j), medical use licensees within a consortium are authorized to produce PET radioactive drugs for noncommercial distribution to medical use licensees within the consortium. Appendix AA provides additional information on this 10 CFR Part 30 use.

## Discussion:

**10 CFR 35.100, 35.200, and 35.300 Use:** For 10 CFR 35.100, 35.200, and 35.300 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.100) and the description of the applicable modality (e.g., any uptake, dilution, and excretion procedure for which a written directive is not required).

The use of unsealed byproduct material in therapy (10 CFR 35.300) involves administering a byproduct material, either orally or by injection, to treat or palliate a particular disease. The most common form of use of unsealed byproduct material for therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include, for example, ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses.

If an applicant's request is limited to I-131 under 10 CFR 35.300, the license will be limited to that radionuclide.

**35.400 Use:** The applicant should define the purpose of use by stating that the applicable section of 10 CFR Part 35 is 10 CFR 35.400. If a source is to be used in a device, applicants may need to define the purpose of use by including the manufacturer's name and model number of the device. The licensee should relate the sealed sources, including sealed sources of Ra-226, listed in Item 5 to the devices described in this item.

In manual brachytherapy, several types of treatments are available. These may include, for example:

- Interstitial Treatment of Cancer.
- Eye Plaque Implants. This is considered interstitial, not topical, treatment.
- Intracavitary Treatment of Cancer. For purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.
- Topical (Surface) Applications.

**35.500 Use:** For 10 CFR 35.500 use, the applicant should define the purpose of use by stating that the applicable section of 10 CFR 35 is 10 CFR 35.500 and including the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). **If the applicant will use calibration, transmission or reference sources that do not need to be listed on the license for 10 CFR 35.500 medical use then the applicant should state this.** The licensee should correlate the sealed sources, including sealed sources of Ra-226, listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to the manufacturer's radiation safety and handling instructions and must use the sources **in accordance with the radiation safety conditions and limitations described as approved** in the SSDR.

**35.600 Use:** For 10 CFR 35.600 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35.600 (e.g., teletherapy, remote afterloading, GSR) and including the manufacturer's name(s) and model number(s) of the device(s) containing a sealed

source(s) (e.g., for use in a [Manufacturer's Name and Unit Type, Model xxxx] radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that authorization is being requested for an additional source to be stored in its shipping container, incident to source replacement.

**35.1000 Use:** Applicants must apply for authorization to use byproduct material, or radiation therefrom, in medical applications under 10 CFR 35.1000 when the type of use is not covered under 10 CFR 35.100-35.600. This includes the medical use of unsealed Ra-226 or of Ra-226 sealed sources for uses other than those described by 10 CFR 35.400 or 35.500.

When applying for use under the provisions of 10 CFR 35.1000, applicants should describe the purpose of use and submit the information required under Section 35.12(b) through (d).  
Review regulatory requirements in other Subparts of 10 CFR Part 35, and use them as a guide on how to determine what should be included in an application that is required in Section 35.12. Address any additional aspects of the medical use of the material that are applicable to radiation safety but are not addressed in, or differ from those in subparts A through C and M of 10 CFR Part 35. Identify and commit to follow the applicable radiation safety program requirements in subparts D through H of 10 CFR Part 35. Additional information may be needed for additional radiation safety precautions and instructions, to describe methodologies for measurement of dosages or doses to be administered to patients or human research subjects, and clarify calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

It is anticipated that many of the uses of byproduct material under the provisions of Section 35.1000 may involve research or product development; thus, applicants should ensure review and compliance with 10 CFR 35.6, "Provisions for the protection of human research subjects," and 10 CFR 35.7, "FDA, other Federal, and State requirements." Use of byproduct material in a source or device after approval by the U.S. Food and Drug Administration (FDA) (e.g., under an IDE (investigational device exemption) or an IND (investigational new drug exemption)), does not relieve individuals of the responsibility to obtain a license to use the byproduct material in medicine under the provisions of 10 CFR Part 35.

If the source for the type of use sought under 10 CFR 35.1000 is a sealed source, including sealed sources of Ra-226, Section 8.6 of this guide describes the information that must be provided at the time of application. Broad-scope licensees are exempted under 35.15(a) from requirements of 35.12(d) (which relates to the need to put into an application certain information about the radiation safety aspects of medical use under Section 35.1000). However, broad-scope licensees should ensure that the quantity needed for the proposed use is authorized on their license or apply for an increase if not. Applicants should refer to IN 99-024, "Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices" for more information on sealed sources.

Applicants for uses under Section 35.1000 should consult with the appropriate NRC Regional Office to discuss the contents of their application.

**Nonmedical Uses:** Applicants may also describe nonmedical uses (e.g., survey meter calibrations with NIST-traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 5. This would include the nonmedical use of discrete sources of Ra-226.

Authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium for medical use is another nonmedical use. Applicants intending to produce PET radioactive drugs under this provision should include this use under this section, list the applicable radioactive materials under Item 5, and review Appendix AA for additional information.

**Radionuclide Production by an Accelerator:** Production of radionuclides for both medical and nonmedical uses is beyond the scope of this guidance and a medical use license. See NUREG-1556, Volume 21, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator.”

**Response from Applicant:** The applicant must submit information regarding the purpose for which the licensed material will be used. The applicant should consider including the information described above, as applicable to the type of use(s) proposed.

When responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly.

[The following redline/strikeout revisions to Section 8.10 reflect changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005 and changes to 10 CFR 35.24 permitting licensees to name one or more Associate Radiation Safety Officers.]

## 8.10 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAMS AND THEIR TRAINING AND EXPERIENCE

**Regulations:** 10 CFR 30.33(a)(3), 10 CFR 30.34(j), 10 CFR 33.13, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.51, 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

**Criteria:** The RSO, ARSOs, AUs, AMPs, and ANPs must have adequate training and experience.

**Discussion:** “Authorized user (AU)” is not defined for nonmedical use, but for purposes of this discussion, the term AU will be used to also mean individuals who are authorized for such nonmedical uses. The requirements in 10 CFR 35.24 describe the authority and responsibilities for the Radiation Protection Program, including those of the licensee’s management and the RSO appointed by licensee management. Other personnel who have a role in the Radiation Protection Program are AUs, AMPs, ANPs, Associate Radiation Safety Officers (ARSOs), and members of the Radiation Safety Committee (RSC) (if the licensee is required to establish an RSC). In 10 CFR 30.33(a)(3), the NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F, G, and H of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, ARSOs, and AMPs; AUs for nonmedical uses must meet the criteria in 10 CFR 30.33(a)(3).

A résumé or a curriculum vitae is likely to be insufficient because such documents usually do not supply all the information needed to evaluate an individual’s training and experience for NRC purposes. Applicants should ensure that they submit the specific training information required by NRC regulations in 10 CFR Part 35. The NRC Form 313A series of forms provides a convenient format for submitting the information required in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For nonmedical use AUs, the information provided should focus on educational training and radiation safety training and experience specific to the radionuclides and uses requested.

Licensees are responsible for their Radiation Protection Programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee’s management must appoint an RSO, who agrees in writing to be responsible for implementing the Radiation Protection Program, and must provide the RSO

sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions, including: identifying radiation safety problems; initiating, recommending, or providing corrective actions; stopping unsafe operations; and verifying the implementation of corrective actions. Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities.

The licensee's management can name only one RSO, the individual who remains responsible for implementing the entire radiation protection program. The licensee's management may appoint one or more ARSOs to support the RSO. The ARSO is delegated radiation safety duties and tasks.

Licenseses that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H are required under 10 CFR 35.24(f) to establish an RSC to oversee all uses of byproduct material permitted by the license. Membership in the committee must include an AU for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate.

Licenseses may contract for medical use services, including those involving patient services. However, the licensee should not assume that, by hiring a contractor to provide certain services, it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the Radiation Protection Program, including the training of contractor staff, is effectively implemented by the appropriate individuals.

*Training for an experienced RSO, teletherapy or medical physicist, AU or nuclear pharmacist; recency of training.* Under 10 CFR 35.57(a)(1), (a)(2) and (a)(3), experienced individuals, who may be candidates to serve as RSO, AMP, or ANP, are not required to meet the requirements of Sections 35.50, 35.51, or 35.55, respectively (are "grandfathered"), for the same materials and uses performed on or before October 24, 2005, under certain conditions (e.g. the individual is named on an NRC or Agreement State license). Under 10 CFR 35.57(b)(1) and (b)(2), AUs are also not required to meet the requirements in Subparts D-H of 10 CFR Part 35 for the same materials and uses performed on or before October 24, 2005.

Subsequent to the EPAct, RSOs, medical physicists, nuclear pharmacists, physicians, podiatrists, and dentists that only used accelerator-produced radioactive material, discrete sources of Ra-226, or both, are also grandfathered, under NRC regulations in 10 CFR 35.57(a)(4) and (b)(3), for medical uses or the practice of nuclear pharmacy when using materials for the same uses performed before or under NRC's waiver issued August 31, 2005. The requirements in 10 CFR 35.59 (that the training and experience specified in 10 CFR 35, Subparts B, D, E, F, G, and H, must have been obtained within 7 years preceding the date of application or the individual must have related continuing education and experience) do not apply to those individuals "grandfathered" under the regulations implementing the EPAct. Also, 10 CFR 35.57 provides that nuclear pharmacists, medical physicists, physicians, dentists, and podiatrists that meet the criteria in 10 CFR 35.57(a)(4) and (b)(3) qualify as ANPs, AMPs, and AUs for those materials and uses performed before or under NRC's waiver of August 31, 2005.

Resolution to a petition for rulemaking by American Association of Physicists in Medicine allows recognition of certifications issue by boards previously listed in 10 CFR Part 35, Subpart J, which was deleted by rulemaking on March 30, 2005. This recognition permits experienced board certified individuals to be “grandfathered” for modalities they practiced on or before October 24, 2005. The recognized certification boards are provided in 10 CFR 35.57.

**Response from Applicant:** Refer to the subsequent sections specific to the individuals described above.

[The following redline/strikeout revisions to Section 8.11 reflect changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005; changes to 10 CFR 35.24 permitting licensees to name one or more Associate Radiation Safety Officers; and changes to 10 CFR 35.50 training and experience pathways.]

**8.11 ITEM 7: RADIATION SAFETY OFFICER (RSO) AND ASSOCIATE RADIATION SAFETY OFFICERS (ARSOs)**

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

**Regulations:** 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.2024.

**Criteria:** The RSOs and ARSOs must have adequate training and experience. The training and experience requirements for the RSO and ARSOs are described in 10 CFR 35.50 and allow for the following training pathways:

- Certification as provided in 10 CFR 35.50(a) by a specialty board whose certification process has been recognized by the NRC or an Agreement State, ~~plus a written attestation signed by a preceptor RSO as provided in 35.50(d) and~~ **has completed** training as specified in 35.50(d~~e~~); or
- Completion of classroom and laboratory training (200 hours) and 1 year of full-time radiation safety experience as described in 10 CFR 35.50(b)(1) plus a written attestation signed by a preceptor RSO **or ARSO** as provided in 10 CFR 35.50 (b~~d~~)(2) and training as specified in 35.50(d~~e~~); or
- Certification as provided in 10 CFR 35.50(c)(1) as a medical physicist under 35.51(a), and has completed training as specified in 35.50(d); or
- Identification as provided in 10 CFR 35.50(c)(2) ~~on the licensee's~~ **a Commission or Agreement State license, a permit issued by a Commission master materials license, a permit issued by a Commission or Agreement State licensee of broad scope, or a permit issued by a Commission master materials license broad scope permittee** as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of byproduct material use for which the individual has RSO responsibilities **or ARSO duties**, ~~with a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and~~ **has completed** training as specified in 35.50(d~~e~~).
- **Completion of training and experience required to be named as an AU when simultaneously applying to be the AU and RSO on a new medical license as permitted by 10 CFR 35.50(c)(3).**

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by 10 CFR 35.24(e~~b~~).

## Discussion:

### *Radiation Safety Officer*

The RSO is responsible for day-to-day oversight of the Radiation Protection Program. In accordance with 10 CFR 35.24, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 10 CFR 35.24 to ensure that radioactive materials are used in a safe manner. The NRC requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

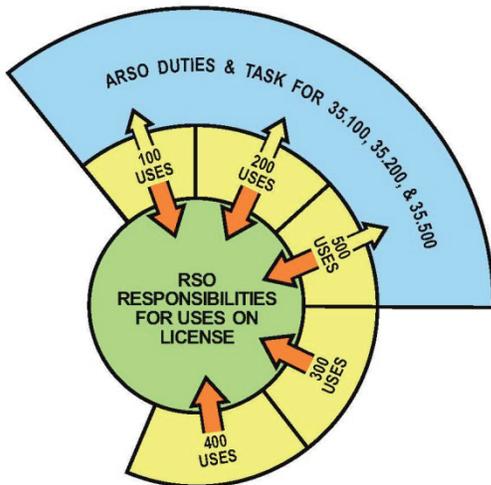
Usually, the RSO is a full-time employee of the licensed facility. The NRC has authorized individuals who are not employed by the licensee, such as a consultant, to fill the role of RSO ~~or to provide support to the facility RSO~~. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 10 CFR 35.24. Appendix I contains a model RSO Delegation of Authority. Appendix B contains NRC Form NRC 313A (RSO), "Medical Use Training and Experience and Preceptor Attestation [35.50]," which can be used to document the RSO's training and experience.

**RSO Responsibilities:** Some of the typical duties and responsibilities of RSOs include ensuring the following:

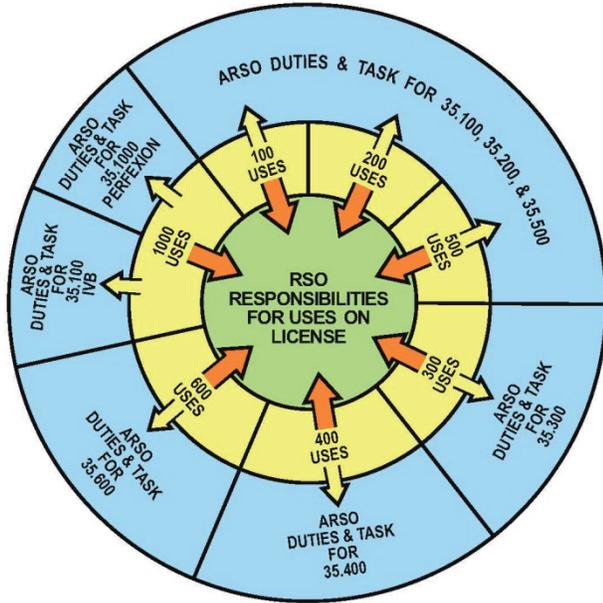
- Unsafe activities involving licensed materials are stopped;
- Radiation exposures are ALARA;
- Material accountability and disposal;
- Interaction with NRC;
- Timely and accurate reporting and maintenance of appropriate records;
- Annual program audits;
- Proper use and routine maintenance;
- Personnel training; and
- Investigation of incidents involving byproduct material (e.g., medical events).
- *Assigning specific duties and tasks to an ARSO, restricted to the types of use for which the ARSO has radiation safety training.*

Appendix I contains a detailed list of typical duties and responsibilities of the RSO.

In implementing the EPAct, the NRC "grandfathered" RSOs that performed as RSOs for medical uses of only accelerator-produced radioactive material, discrete sources of Ra-226, or both. These individuals do not have to meet the requirements in either 10 CFR 35.59 or 10 CFR 35.50; however, the applicant must document that the individual meets the criteria in 10 CFR 35.57 (a)(34).



(a)



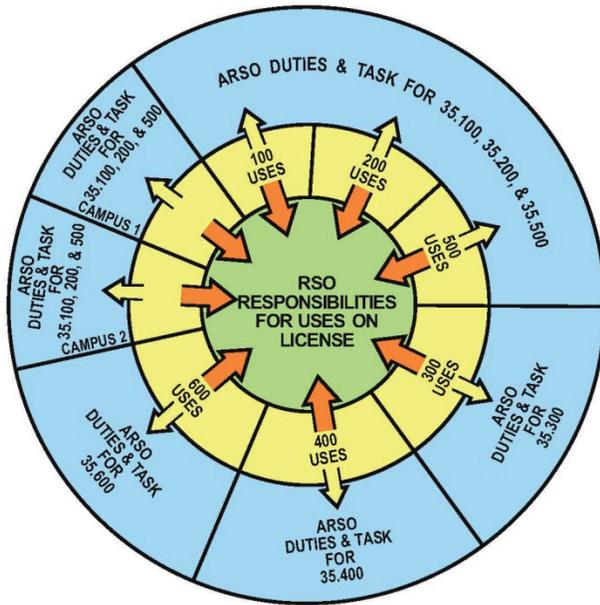
(b)

**Figure 8.a1. Licensing Examples of Potential Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSO) arrangements:**

(a) a moderate sized program – the RSO is responsible for the entire program and has direct oversight over the 35.300 and 35.400 medical uses – a single ARSO has oversight duties and tasks for 35.100, 35.200, and 35.500 medical uses and reports to the RSO.

(b) a larger single campus program – the RSO is responsible for the entire program – there are six ARSOs with oversight duties and tasks over different sections of the program and all report to the RSO.

(c) A large multi-campus program – the RSO is responsible for the entire program – there are six ARSOs with oversight duties and tasks over either the two smaller campuses or different types of medical use at the main campus. All ARSOs report to the RSO.



(c)

### *Associate Radiation Safety Officer*

A licensee may identify one or more individuals as ARSOs to support the RSO, if they choose. The ARSOs could be assigned to oversee the radiation safety operations of designated sections of the licensed program, but the RSO retains responsibility for all sections of the program.

The ARSOs are required to complete the same training and experience requirements as the named RSO for their assigned sections of the radiation safety program. The RSO, with written agreement from licensee management, may assign duties and tasks to each ARSO that are limited to the types of use for which the ARSO has radiation safety training. The ARSOs would oversee the radiation safety operations of their assigned sections of the program, while reporting to the named RSO. The regulations would continue to allow a licensee to name only one RSO on a license. Licensees with multiple operating locations or multiple types of uses can appoint a qualified ARSO at each location or for each type of byproduct material use. These individuals will be listed on the license as ARSOs. Their assigned sections of the program will also be listed.

The ARSO must agree in writing to the specific duties and tasks assigned by the RSO. Before the ARSO can be assigned to oversee the radiation safety operations of a different section of the program, the licensee needs to amend the license and provide documentation that the individual meets the training and experience requirements for the new duties and tasks.

Because the ARSOs have the same training and experience requirements as an RSO, the ARSOs will qualify to be named as the RSO on other licenses for the types of uses for which they are listed.

### *Requirements applicable to both RSO and ARSO*

An AU, AMP, or ANP listed on any license or permit may serve as an RSO or ARSO, allowing an increase in the number of qualified individuals available to serve as RSOs and ARSOs on NRC medical licenses. Additionally, both RSOs and ARSO's could serve as preceptors for individuals seeking to be named as the RSO or ARSO on a license.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, RSO **and ARSO** applicants must have successfully completed the applicable training and experience described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, RSO **and ARSO** applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other pathways to meeting requirements for training and experience.

**Response from Applicant:** Provide the following:

- Name of the **individual**~~proposed~~ RSO.

**AND**

- Identify if applying for RSO or ARSO.

**AND**

- For a proposed ARSO, identify the section(s) of the licensee's program for which the individual will oversee radiation safety operations.

**AND**

*For an individual previously identified as an RSO or ARSO on an NRC 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 an NRC master materials licensee on which the individual was named as the RSO or ARSO if requesting the same materials and medical uses;

**AND**

- After **[DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, documentation of the training requirements in § 35.50(d) for any new materials or new medical uses requested.

*For an individual qualifying under 10 CFR 35.57 (a)(4):*

**(Note:** This is only for a new medical use license requesting use of only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for the same uses authorized under NRC's waiver of August 31, 2005.)

- Documentation that this individual functioned as an RSO for only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, **at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 7, 2005;**

**AND**

- Documentation that the individual performed as the RSO for the same medical uses requested.

*For an individual qualifying under 10 CFR 35.50(a):*

- Copy of certification by a specialty board whose certification process has been recognized<sup>1</sup> by the NRC or an Agreement State under 10 CFR 35.50(a);

**AND**

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in the radiation safety, regulatory

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

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 ARSO**;

**AND**

- ~~Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as Completed the required training and experience in 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**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

*For an individual qualifying under 10 CFR 35.50(c)(1):*

- Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized<sup>2</sup> 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 **or ARSO** is qualified by experience applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO **or ARSO** ;

**AND**

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO **or ARSO** is qualified by training in 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 ARSO**;

**AND**

- ~~Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as Completed the required training and experience in 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**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

*For an individual qualifying under 10 CFR 35.57(a)(2):*

- **Copy of certification by a specialty board whose certification listed in 10 CFR 35.57(a)(2);**

**AND**

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

- Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

**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 35.50(c)(2):*

- Copy of the ~~Commission or Agreement State licensee's license, permit issued by a Commission master material license, permit issued by a Commission or Agreement State licensee of broad scope, or permit issued by a Commission master material license broad scope permittee~~ indicating that the individual is an AU, AMP or ANP ~~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 ~~or ARSO~~ ;

**AND**

- ~~Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures 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 successfully completed the training and experience specified for certification, as well as Completed the required training and experience in 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**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

*For an individual qualifying under 10 CFR 35.50(c)(3):*

- Documentation of training and experience required to be named as an AU when simultaneously applying to be the AU and RSO on a new medical license;

**AND**

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO is qualified by training in 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)(1) demonstrating that the proposed RSO ~~or ARSO~~ 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 or ARSO;

**AND**

- Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in 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 ARSO;

**AND**

- Written attestation, signed by a preceptor RSO or ARSO, that the individual has successfully completed the training and experience in 10 CFR 35.50(b)(1), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and is able to ~~achieve a level of radiation safety knowledge sufficient to function independently~~ fulfill the radiation safety-related duties as an RSO or as an ARSO for a medical use licensee;

**AND**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

**Notes:**

- NRC Form 313A (RSO), "Radiation Safety Officer and Associate Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.50.
- The licensee must notify the NRC within 30 days if, under 10 CFR 35.14, an RSO or ARSO permanently discontinues his or her duties under the license or has a name change; licensees must also request an amendment to change an RSO and the ARSO under 10 CFR 35.13.
- An AU for medical uses, AMP, or ANP may be designated as the RSO or ARSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities or ARSO duties and tasks (see 10 CFR 35.50(c)(2)) and the RSO, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.
- The training and experience for the RSO of a medical use broad-scope license will be reviewed using the above criteria as well as criteria in 10 CFR Part 33.

[The following redline/strikeout revisions to Section 8.12 reflect changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005 and changes to 10 CFR 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, and 35.690 revising the preceptor attestation requirements. The revisions to preceptor attestation requirements include rewording the attestation statement, removing the attestation requirement for most board certified individuals, and allowing residency program directors to provide attestation statements.]

## 8.12 ITEM 7: AUTHORIZED USERS (AUs)

**Regulations:** 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.11, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

**Criteria:** Training and experience requirements for AUs for medical uses are described in 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, or 10 CFR 35.690.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

**Discussion:** Although NRC does not define “AU” for nonmedical uses, for purposes of this discussion the term AU will be used to also mean individuals authorized for such nonmedical uses.

**AU for Medical Uses:** The responsibilities of AUs involved in medical use include the following:

- Radiation safety commensurate with use of byproduct material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the AU’s supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material;
- Preparation of written directives (WD), if required.

Applicants must meet recentness of training requirements described in 10 CFR 35.59. The AU applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways.

Section 35.57 of 10 CFR Part 35 provides that experienced AUs who are named on a license or permit are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before the effective date

of changes to the regulations in Section 35.57 (check the regulations to determine this date). For example, a physician who was authorized to use sodium iodine-131 for imaging and localization, involving greater than 30 microcuries (a quantity for which a written directive is required under 10 CFR 35.40), would continue to be authorized for this use.

In implementing the EPAct, the NRC “grandfathered” physicians, podiatrists, and dentists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical use, for the same uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements in 10 CFR 35.59, 35.190, 35.290, 35.390, 35.396, or 35.490. However, the applicant must document that the individual meets the criteria in 10 CFR 35.57(b)(3). This Section also states that physicians, dentists, and podiatrists who met certain criteria will qualify as AUs for those materials and uses performed before NRC’s waiver was terminated for them.

Technologists, therapists, or other personnel may use byproduct material for medical use under an AU’s supervision in accordance with 10 CFR 35.27, “Supervision,” and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7). Examples include FDA requirements for the conduct of certain types of clinical research after the submission of applications for Investigational New Drugs (IND) and under the auspices of a Radioactive Drug Research Committee (21 CFR 361.1).

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

An individual, who is qualified to be an AU but has not been named as an AU on a medical use license or permit may apply for and be authorized simultaneously as the RSO and the AU on the same *new* medical use license.

A licensee may request an AU on any medical use license or permit to be named as the RSO for the same byproduct material for which the AU is authorized.

**AU for Nonmedical Uses:** For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include the individuals who will actually be responsible for the safe use of the byproduct material for the requested use. This includes the individuals responsible for the production of PET radioactive drugs for noncommercial transfer to other medical users within a consortium (see Appendix AA).

An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing information about the user’s training and experience.

Authorized nonmedical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

#### **Response from Applicant:**

**AU for Medical Uses:** Provide the following:

- Name of the proposed AU and uses requested;

**AND**

- Medical, podiatry, or dental license number and issuing entity;

**AND**

*For an individual previously identified as an AU on an NRC 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 an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested;

**AND**

- For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c)). A preceptor attestation may also be required. (For example, a preceptor attestation is needed **for all individuals** to meet the requirements of 10 CFR 35.396 and **for individuals coming through the alternate training and experience pathway for 35.390 and 35.690.**)

*For an individual qualifying under 10 CFR 35.57(b)(3):*

- Documentation that the physician, dentist, or podiatrist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses **performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005;**

**AND**

- Documentation that the physician, dentist, or podiatrist used these materials for the same medical uses requested;

**AND**

- For an AU requesting a medical use for which he or she is not currently authorized on a license or permit, a description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (**e.g., training and experience needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c).**) A preceptor attestation may also be required. (For example, **a preceptor attestation is needed for all individuals to meet the requirements of 10 CFR 35.396 and for individuals coming through the alternate training and experience pathway for 35.390 and 35.690**~~training, experience, and attestations are needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c).~~)

*For an individual who was certified before October 24, 2005 by a board listed in 10 CFR 35.57(b)(2):*

- Copy of certification issued before October 24, 2005 by a specialty board whose certification is listed in 10 CFR 35.57(b)(2);

**AND**

- Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

**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 board-certified:*

- A copy of the certification(s) by a specialty board(s) whose certification process has been recognized<sup>3</sup> by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested;

**AND**

- For a physician with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;

**AND**

- For a physician with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating that the proposed AU is also qualified for imaging and localization medical uses;

**AND**

- For a physician with a board certification recognized under 10 CFR 35.490 or 10 CFR 35.690 for medical uses described in 10 CFR 35.396, a description of the training and supervised work experience and a copy of the attestation required in 10 CFR 35.396(e) to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;

**AND**

- For an individual seeking authorization under 10 CFR Part 35, Subpart H, a 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;

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

**AND**

- ~~· A written attestation, signed by a preceptor physician AU, that the training and experience specified for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. For individuals seeking authorization under 10 CFR 35.390, 10 CFR 35.396, and 10 CFR 35.690, the attestation must also include successful completion of the clinical case work in 10 CFR 35.390(b)(1)(ii)(G), or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, as appropriate;~~

**AND**

- If applicable, a 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(s) requested;

**AND**

- For an individual seeking authorization under 10 CFR Part 35, Subpart H, a 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**

- A written attestation, signed by a preceptor physician AU, that the above training and experience have been satisfactorily completed and **the individual is able to fulfill the radiation safety-related duties** as an AU for the **requested** medical uses ~~authorized has been achieved;~~

**AND**

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

**Notes:**

- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"; or NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"; or NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]" may be used as appropriate to document training and experience for those individuals qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H.
- Licensees must notify the NRC within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.

- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet the 10 CFR Part 35 criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

**Note to reviewers:** Licenses will reflect any limitations on use for listed AUs (e.g., whether administrations in excess of 33 mCi of iodine-131 are allowed and specific uses under 10 CFR 35.600).

**AU for Nonmedical Uses:** Provide the following:

- Name of the proposed nonmedical use AU,
- Description of types, quantities, and proposed nonmedical uses for which the individual is responsible, and
- Description of individual's educational and radiation safety training and experience with the types of materials and uses requested. This may include:
  - A copy of the NRC or Agreement State License listing the individual as an AU for the same types, quantities, and uses requested.
  - A permit issued by a Master Materials License licensee or broad-scope licensee or broad-scope permittee identifying the individual as an AU for the types, quantities, and uses requested.

**Note:** Authorized nonmedical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

[The following redline/strikeout revisions to Section 8.13 reflect changes to 10 CFR 35.55 revising the wording of the attestation statement and removing the attestation requirement for board certified individuals.]

**8.13 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST (ANP)**

**Regulations:** 10 CFR 30.33(a)(3), 10 CFR 32.72(b)(2), 10 CFR 35.2, 10 CFR 35.11, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59.

**Criteria:** Training and experience requirements for ANPs are described in 10 CFR 35.55.

Part 35	Applicability
100	✓
200	✓
300	✓
400	
500	
600	
1000	✓

**Discussion:** At many licensed medical facilities, an ANP is directly involved with the preparation of radiopharmaceuticals under the provisions of 10 CFR 35.100(b), 35.200(b), or 35.300(b). This may include the production of PET radioactive drugs under the provisions of 10 CFR 30.32(j).

Technologists, or other personnel, may prepare byproduct material for medical use under an ANP’s supervision in accordance with 10 CFR 35.27, “Supervision,” and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7). (Preparation of byproduct material for medical use may also be performed under the supervision of a physician who is an AU.)

Applicants are reminded that the recentness of training requirements described in 10 CFR 35.59 also apply to training and experience requirements in 10 CFR Part 35, Subpart B. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

In implementing the EPAAct, the NRC “grandfathered” nuclear pharmacists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, in the practice of nuclear pharmacy for the uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 35.59 or 10 CFR 35.55. The applicant must, however, document that the individual meets the criteria in 10 CFR 35.57(a)(43). Section 35.57 also provides that nuclear pharmacists who met certain criteria will qualify as ANPs for those materials and uses performed before or under NRC’s waiver of August 31, 2005.

**Response from Applicant:** Provide the following:

- Name of the proposed ANP;

**AND**

- Pharmacist's license number and issuing entity;

**AND**

*For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs:*

- 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 an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

**OR**

*For an individual qualifying under 10 CFR 35.57(a)(43):*

- Documentation that the nuclear pharmacist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, in the practice of pharmacy **at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005;**

**AND**

- Documentation that the nuclear pharmacist used these materials for the same uses as requested.

**OR**

*For an individual qualifying under 10 CFR 35.55(a):*

- Copy of the certification of the specialty board whose certification process has been recognized<sup>1</sup> under 10 CFR 35.55(a);

**AND**

- ~~· Written attestation, signed by a preceptor ANP, that training and experience required for certification have 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.

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

**OR**

*For an individual qualifying under 10 CFR 35.55(b):*

- 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 have been satisfactorily completed and that **the individual is able** ~~competency sufficient to function~~ **independently fulfill the radiation safety-related duties** as an ANP ~~has been~~ **achieved**;

**AND**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

**Notes:**

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55.
- Under 10 CFR 35.14, licensees must notify the NRC within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

[The following redline/strikeout revisions to Section 8.14 reflect changes to 10 CFR 35.51 revising the attestation statement and removing the attestation requirement for board certified individuals. They also reflect the addition of training requirements for an individual identified in 35.433.]

**8.14 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP) AND INDIVIDUALS IDENTIFIED IN 10 CFR 35.433**

**Regulations:** 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.51, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.433.

**Criteria:** Training and experience requirements for AMPs are described in 10 CFR 35.51 and for individuals identified in 10 CFR 35.433 are described in 10 CFR 35.433.

Part 35	Applicability
100	
200	
300	
400	✓
500	
600	✓
1000	✓

**Discussion:** While the AMP or an individual identified in 10 CFR 35.433 may not administer the dose, at licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and other tasks associated with the administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

Section 35.57 of 10 CFR Part 35 provides that experienced AMPs who were named on a license or permit are not required to comply with the training requirements in 10 CFR 35.51 to continue performing those uses for which they were authorized on or before October 24, 2005. Section 35.57 also provides that physicists holding certain board certifications on or before October 24, 2005 are not required to comply with the training requirements in 10 CFR 35.51 for those materials and uses that they performed on or before October 24, 2005. All AMPs are required to meet the requirements of 10 CFR 35.51(c) after (date that is 90 days after publication in the Federal Register) if they are seeking authorizations for new materials and medical uses.

In implementing the EAct, the NRC “grandfathered” medical physicists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 35.59 or 10 CFR 35.51. The applicant must, however, document that the individual meets the criteria in 10 CFR 35.57(a)(43). Section 35.57 also provides that medical physicists who met certain criteria will qualify as AMPs for those materials and uses performed before or under NRC’s waiver of August 31, 2005. **Note:** Although there may be a number of medical physicists working with manual brachytherapy sources during the waiver, the NRC only requires AMPs for the medical use of strontium-90 eye applicators, teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units. Because none of these devices are known to contain only NARM material, the NRC expects few, if any, medical physicists to meet the criteria in 10 CFR 35.57 of an AMP.

**Response from Applicant:** Provide the following:

***Proposed Authorized Medical Physicist***

- Name of the proposed AMP.

**AND**

*For an individual previously identified as an AMP on an NRC 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 an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.

**OR**

*For an individual qualifying under 10 CFR 35.57(a)(43):*

- Documentation that the medical physicist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses **at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC** ~~before or during the effective period of NRC’s waiver of August 31, 2005;~~

**AND**

- Documentation that the medical physicist used these materials for the same medical uses as requested.

**OR**

*For an individual qualifying under 10 CFR 35.51(a):*

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized<sup>2</sup> under 10 CFR 35.51(a);

**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;

**AND**

- ~~· *Written attestation*, signed by a preceptor AMP, that the required training and experience required for certification, as well as the required training in 10 CFR 35.51(c) for the types of uses specified, have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved;~~

**AND**

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

**OR**

*For an individual qualifying under 10 CFR 35.57(a)(3):*

- Copy of the certification issued by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005;

**AND**

- Documentation that the medical physicist performed the same medical uses as requested on or before October 24, 2005.

**AND**

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

**OR**

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

*For an individual qualifying under 10 CFR 35.51(b):*

- 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**

- 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 the licensee seeks approval of an individual as AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system;

**AND**

- Written attestation, signed by a preceptor AMP, that the **proposed AMP has satisfactorily completed** the training and experience required in 10 CFR 35.51(b)(1), as well as the training in 10 CFR 35.51(c) for the types of use specified, ~~have been satisfactorily completed~~ and is able ~~that a level of competency sufficient to function independently~~ **fulfill the radiation safety-related duties** as an AMP **for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status** ~~has been achieved~~;

**AND**

- If applicable, a description of recent related continuing education and experience as required by 10 CFR 35.59.

***Proposed Individual Identified Under 10 CFR 35.433.***

- **Name of the proposed individual identified in 10 CFR 35.433.**

**AND**

**Documentation that the individual is an authorized medical physicist**

**OR**

- **Documentation of a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;**

**AND**

- **Documentation of successful completion of 2 years of full time practical training and/or supervised experience in medical physics.**

**AND**

- **Documentation of training in:**

- **The creating, modifying, and completing of written directives;**
- **Procedures for administrations requiring a written directive; and**
- **Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.**

**Notes:**

- NRC Form 313A (AMP), “Authorized Medical Physicist **and Individuals Identified in 10 CFR 35.433** Training and Experience and Preceptor Attestation [10 CFR 35.51],” may be used to document training and experience for those individuals qualifying under 10 CFR 35.51.
- NRC Form 313A (AMP), “Authorized Medical Physicist **and Individuals Identified in 10 CFR 35.433** Training and Experience and Preceptor Attestation [10 CFR 35.51],” may be used to document training and experience for those individuals identified in 10 CFR 35.433.
- Under 10 CFR 35.14, licensees must notify NRC within 30 days if an AMP **or individual identified in 10 CFR 35.433** permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B **or 10 CFR 35.433**, are met. If the training and experience do not appear to meet the criteria in Subpart B **or 10 CFR 35.433**, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

[The following redline additions to Section 8.19 address the addition of individuals identified in 10 CFR 35.433, changes made to 10 CFR 35.12 to clarify information needed for 10 CFR 35.1000 medical uses, and reminds applicant that there are calibration and use provisions similar to those for therapy units in 10 CFR 35.400 and 35.600 for certain 10 CFR 35.1000 medical uses.]

## 8.19 ITEM 9: THERAPY UNIT — CALIBRATION AND USE

**Regulations:** 10 CFR 30.33(a)(2), 10 CFR 35.12, 10 CFR 35.27, 10 CFR 35.432, 10 CFR 35.630, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645, 10 CFR 35.2432, 10 CFR 35.2630, 10 CFR 35.2632, 10 CFR 35.2642, 10 CFR 35.2643, 10 CFR 35.2645.

**Criteria:** The above regulations contain NRC requirements, including recordkeeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For manual brachytherapy sources and low dose-rate (LDR) remote afterloader sources, licensees may use source activity or output determined by the manufacturer, provided that the manufacturer's measurements meet applicable requirements. Similar provisions are included in licensing guidance for certain 35.1000 medical uses. See NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for specific information.

**Discussion:** Except for manual brachytherapy sources and LDR remote afterloader sources, where the source output or activity is determined by the manufacturer in accordance with 10 CFR Part 35, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 10 CFR 35.630. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, ACR, ANSI). (Note: Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of strontium-90 sources.) The licensee's AMP or other individual identified in 10 CFR 35.433 must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645). If the licensee seeks authorization for a medical use under 35.1000, the licensing guidance on NRC's website

Part 35	Applicability
100	
200	
300	✓*
400	
500	
600	✓*
1000	✓

\*Special requirements re: brachytherapy and LDR afterloader sources and Sr-90 sources.

(<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) should be reviewed to determine if calibration and use procedures need to be submitted for that 35.1000 medical use. Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used.

The calibration procedures should address, in part, the method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an “in air” measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

Full calibrations must be performed before first medical use<sup>1</sup>, whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in 10 CFR 35.632, 10 CFR 35.633, and 10 CFR 35.635. Manual brachytherapy sources must be calibrated only initially, prior to use.

For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source. Contact a licensing specialist at an NRC Regional Office for additional assistance.

**Response from Applicant:** Provide the following:

- The applicant must provide the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.
- The applicant for a medical use under 35.1000 must provide the procedures described in the licensing guidance posted for that 35.1000 medical use on NRC’s website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>), or explain why the procedure is not provided.

**References:**

- AAPM Task Group No. 21, “A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams”;
- AAPM Task Group No. 40, “Comprehensive QA for Radiation Oncology,” AAPM Report No. 54, “Stereotactic Radiosurgery”;
- AAPM Task Group No. 56, “Code of Practice for Brachytherapy Physics.”

Copies of these documents and many other documents from AAPM referenced in this guide may be obtained from Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from <http://www.medicalphysics.org>.

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<sup>1</sup> For brachytherapy sources, “first medical use” is defined as the first use following the effective date of the revised 10 CFR Part 35, October 24, 2002.

[The following redline additions to Section 8.20 reflect clarifications made to 10 CFR 35.12 for information needed for 10 CFR 35.1000 medical uses, and remind applicants that there are equipment and facility descriptions similar to those for medical uses in 10 CFR 35.300, 35.400, and 35.600 for certain 10 CFR 35.1000 medical uses.]

## 8.20 ITEM 9: OTHER EQUIPMENT AND FACILITIES

**Regulations:** 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 30.33(a)(2), 10 CFR 30.34, 10 CFR 35.12, 10 CFR 35.315, 10 CFR 35.415, 10 CFR 35.457, 10 CFR 35.615, 10 CFR 35.647, 10 CFR 35.657.

**Criteria:** Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

**Discussion:** The applicant should describe, in Item 9 of the application, other equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application. This description should be identified as Attachment 9.4.

The applicant must describe additional facilities and equipment for PET radionuclide and radiopharmaceutical therapy programs to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (e.g., private room with private bath). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., a fume hood). Also note there are hazards associated with volatile iodine in pill form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

For **PET radionuclide use** and **PET radioactive drug production areas**, the applicant should focus on the need for (1) additional shielding, (2) hot cells containing remote handling devices, (3) other remote handling devices that may be needed when handling and storing the higher energy emissions of these materials, and (4) special delivery systems if the applicant prepares its own PET radionuclides or has them delivered by a direct transfer tube or system from a PET radionuclide producer. Applicants synthesizing PET radioactive drugs should also focus on volatility issues and releases.

For **teletherapy**, **GSR**, and **high dose-rate (HDR) facilities**, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. One method of meeting the requirements of 10 CFR 35.615(c) is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication

(e.g., flashing light) of an exposed or partially exposed source. Applicants may propose an alternative to a permanently mounted monitor.

Section 10 CFR 35.615(d) requires that, except for LDR units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communications system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations require adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. Section 10 CFR 35.615(b), in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the on-off control for the source(s) is reset at the console.

Due to the unique characteristics of **pulsed dose-rate (PDR) remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment.
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected.
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
  - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position.
  - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or the appropriate internal error condition(s) exists.
  - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment.

- The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times.
- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees should prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where **LDR remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Similar equipment and facility provisions are included in licensing guidance for certain 35.1000 medical uses. See NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for specific information.

**Response from Applicant:** Follow the guidance in Section 5.2 to determine if the response to this section includes security-related sensitive information and needs to be marked accordingly.

For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, describe the additional facilities and equipment for these uses.

For manual brachytherapy facilities, provide a description of the emergency response equipment.

For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- 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) is in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and

- Emergency response equipment.

For 35.1000 medical uses, review the licensing guidance posted for that 35.1000 medical use on NRC's website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>), and provide the appropriate descriptions of other equipment and facilities, or explain why the descriptions are not provided.

[The following redline additions to Section 8.21 remind applicants that there are minor radiation safety program change provisions similar to those in 10 CFR 35.26 for certain 10 CFR 35.1000 medical uses.]

**8.21 ITEM 10: RADIATION PROTECTION PROGRAM**

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

**Regulations:** 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR 30.33, 10 CFR 30.34(e), 10 CFR 35.24, 10 CFR 35.26, 10 CFR 35.610, 10 CFR 35.2024, 10 CFR 35.2026.

**Criteria:** The regulations in 10 CFR 20.1101 state that each licensee must develop, document, and implement a Radiation Protection Program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of 10 CFR Part 20 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. Under 10 CFR 30.34(e), the NRC may incorporate into byproduct materials licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to protect health or to minimize danger to life and property. Licensee management’s authorities and responsibilities for the Radiation Protection Program are described in 10 CFR 35.24, while 10 CFR 35.26 sets forth four circumstances in which the licensee may revise its Radiation Protection Program without NRC approval. For example, no NRC approval is required when the revision does not require a license amendment. **Applicants for 35.1000 medical uses may apply for license conditions that permit the licensee to revise its radiation safety program for that 35.1000 medical use to conform with revised licensing guidance posted on NRC’s on its web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) without additional NRC approvals. The circumstances for this approval are similar to those in 10 CFR 35.26.**

**Discussion:** Applicants/licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed Radiation Protection Program during the licensing process. Tables C.1 and C.2 in Appendix C may be helpful in determining what information should be provided when requesting a license. If the licensee has authority for the production of PET radioactive drugs under 10 CFR 30.32(j), the radiation production program must include radiation safety issues associated with this nonmedical use.

**Response from Applicant:** Respond to subsequent sections of this document regarding Item 10 of the application.

**Applicants for 35.1000 medical uses may apply for approval to revise, without further NRC approval, the radiation safety program for that 35.1000 medical use to conform with revised licensing guidance posted on NRC’s on its web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>).**

[The following redline additions to Section 8.22 remind applicants that safety and emergency procedures required in 10 CFR 35.12 may be required for 10 CFR 35.1000 medical uses.]

## 8.22 ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

**Regulations:** 10 CFR 30.34(j), 10 CFR 35.12(c)(2), 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645.

**Criteria:** When applying for authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium, the applicant must develop, document, and implement certain procedures. See Appendix AA for discussion and response from applicant.

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

Before using materials under 10 CFR 35.600, the applicant must develop, document, submit, and implement written safety procedures for emergency response. Section 10 CFR 35.610 requires, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures needed to meet 10 CFR 35.610 must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions,
- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure, and
- The names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

Before using materials under certain 35.1000 medical uses, the applicant must develop, document, submit, and implement written safety procedures for emergency response. The licensing guidance on NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for 35.1000 medical uses provides specific information for each 35.1000 medical use.

**Discussion:** The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency

procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice may also be important for adequate emergency coordination for such maneuvers as removing a patient from a malfunctioning GSR unit and manual movement of the patient treatment table. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.
- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing the safety of the patient.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.
- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.
- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). **Note:** If the first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.
- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

**Response from Applicant:**

Provide procedures required by 10 CFR 35.610.

See Appendix AA for responses required by 10 CFR 30.32(j).

If appropriate, review 35.1000 medical use licensing guidance on NRC's website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>), and provide safety and emergency procedures requested for the particular 35.1000 medical use, or describe why the procedures are not needed.

[The following redline/strikeout revisions to Section 8.27 reflect changes to 35.655 that extend the time for full-inspection servicing for gamma stereotactic radiosurgery units to 7 years and reminds applicants that similar inspection and servicing requirements may apply to certain 10 CFR 35.1000 medical uses.]

**8.27 ITEM 10: INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES**

**Regulations:** 10 CFR 20.1101, 10 CFR 30.32, 10 CFR 30.34, 10 CFR 35.605, 10 CFR 35.655, 10 CFR 35.2605, 10 CFR 35.2655.

**Criteria:** In accordance with 10 CFR 35.605 and 10 CFR 35.655, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, 10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years for teletherapy units and 7 years for gamma stereotactic radiosurgery units, whichever comes first, to ensure that the source exposure mechanism and other safety components functions properly. Maintenance is necessary to ensure that the device functions as designed, and source integrity, and safety components are is not compromised. Similar provisions are included in licensing guidance for certain 35.1000 medical uses. See NRC's web site (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) for specific information.

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

**Discussion:** Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

The NRC requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 10 CFR 35.605 before responding to this item. Section 10 CFR 35.605 allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

**Response from Applicant:** No response is necessary if the licensee contracts with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair, and inspect

the specific therapy device possessed by the licensee. However, if the applicant requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the applicant must provide sufficient information to allow the NRC to evaluate and approve such authorization (see CFR 35.605 and 10 CFR 35.655). This should include the following:

- 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.

**Note:** The applicant should specify only those installation, maintenance, inspection, adjustment, and repair functions, as described in a certificate or letter from the manufacturer of the device, that document the employee's training in the requested function(s).

**[The following redline addition to Section 9 reflects changes to 10 CFR 35.13 requiring a licensee to amend the license before permitting an individual to work as an ARSO or before assigning a current ARSO to oversee a new section of the radiation protection program.]**

## **9 AMENDMENTS AND RENEWALS TO A LICENSE**

**Regulations:** 10 CFR 30.37, 10 CFR 30.38, 10 CFR 35.13.

The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226, under the new definition of byproduct material resulting from the EPA Act.

Licensees may need license amendments for such purposes as to authorize use of these materials, to revise their Radiation Safety Programs to meet new requirements, or to provide new facility diagrams. The NRC issued a waiver on August 31, 2005, that permitted licensees to continue to use the newly defined byproduct material until the waiver was terminated on August 8, 2009. Licensees in Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana who possess and use accelerator-produced radioactive material or discrete sources of Ra-226, or both, may continue to use these materials for medical use or prepare PET radioactive drugs for noncommercial distribution to other consortium members until the date of NRC's final licensing determination, provided the licensee submits an amendment application within 6 months after November 30, 2007. Other licensees should check with the appropriate NRC Regional Office to determine when they have to submit their license amendments.

<b>Part 35</b>	<b>Applicability</b>
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Licensees are responsible for applying for amendments to licenses and for keeping them up-to-date. Furthermore, to continue a license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Under 10 CFR 35.13, a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- Receipt or use of byproduct material for a type of use permitted by 10 CFR Part 35, but not authorized on the licensee's current Part 35 license;
- Permitting anyone to work as an AU for medical uses, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b) (information required to document training and experience may be provided on the appropriate NRC Form 313A series of forms for change or addition of AU for medical uses, AMP, ANP, ~~or~~ RSO, or ARSOs);
- Changing the RSO;
- **Prior to permitting an individual to work as an ARSO or before the RSO assigns a current ARSO to oversee a new section of the radiation protection program.**

- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than, currently authorized on the NRC license;
- Changing an area or address of use identified in the application or on the license. This includes additions and relocations of areas where PET radionuclides are produced or additions or relocations of a radionuclide delivery line from the PET radionuclide production area to a 10 CFR 35.100 or 10 CFR 35.200 medical use area. However, other changes and additions to the 10 CFR 35.100 and 10 CFR 35.200 medical use area do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes, and
- Revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the materials licensing staff at the appropriate NRC Regional Office.

For both renewal and amendment requests, applicants should do the following:

- Use the most recent guidance in preparing an amendment or renewal request,
- Submit in duplicate either an NRC Form 313 or a letter requesting an amendment or renewal, and
- Provide the license number.

## **APPENDIX B**

### **NRC Form 313A Series**

**“Medical Use Training and Experience and Preceptor Attestation”**



**RADIATION SAFETY OFFICER OR  
ASSOCIATE RADIATION SAFETY OFFICER  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION  
[10 CFR 35.50]**

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (MM/DD/YYYY)

Name of Individual  RSO  ARSO

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100     35.200     35.300     35.400     35.500     35.600 (remote afterloader)
- 35.600 (teletherapy)     35.600 (gamma stereotactic radiosurgery)     35.1000 ( \_\_\_\_\_ )

**PART I – TRAINING AND EXPERIENCE**  
*(Select one of the five methods below)*

\*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

**1. Board Certification**

- a. Provide a copy of the board certification.
- b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.50;
  - (i) Go to the table in 5c and describe training provider and dates of training for each type of use for which authorization is sought.
  - (ii) Stop here
- c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57 (a)(2);
  - (i) Provide documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;

**OR**

**2. Current Radiation Safety Officer or Associate Radiation Safety Officer Seeking Authorization to Be Recognized as a RSO or ARSO for the Additional Medical Uses Checked Above**

- a. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO or ARSO is sought.
- b. Stop here

**OR**

**3. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on a license or permit identified in 10 CFR 35.50 (c)(2)**

- a. Provide license number.
- b. Use the table in section 5.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Stop here

**OR**

**RADIATION SAFETY OFFICER OR  
ASSOCIATE RADIATION SAFETY OFFICER  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

**4. Individuals applying simultaneously to be the RSO and AU on a new license**

- a. Documentation of training and experience to be a new AU is attached
- b. The new license application is attached.
- c. Stop here.

**OR**

**5. Structured Educational Program for Proposed RSO or ARSO**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Radiation dosimetry			
<b>Total Hours of Training:</b>			<input type="text"/>

**RADIATION SAFETY OFFICER OR  
ASSOCIATE RADIATION SAFETY OFFICER  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

**5. Structured Educational Program for Proposed RSO or ARSO (continued)**

**b. Supervised Radiation Safety Experience**

*(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)*

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ <div style="border: 1px solid black; height: 30px; width: 100%; margin-top: 5px;"></div>		

\* Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

**RADIATION SAFETY OFFICER OR  
ASSOCIATE RADIATION SAFETY OFFICER  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

**5. Structured Educational Program for Proposed RSO or ARSO (continued)**

**b. Supervised Radiation Safety Experience (continued)**

*(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)*

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer or Associate Radiation Safety Officer
The supervising individual is authorized as the for the following medical uses:  <input type="checkbox"/> 35.100 <input type="checkbox"/> 35.200 <input type="checkbox"/> 35.300 <input type="checkbox"/> 35.500 <input type="checkbox"/> 35.600 (remote afterloader) <input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> Radiation Safety Officer or the <input type="checkbox"/> Associate Radiation Safety Officer  <input type="checkbox"/> 35.400 <input type="checkbox"/> 35.600 (teletherapy) <input type="checkbox"/> 35.1000 ( _____ )

**c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.**

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

**RADIATION SAFETY OFFICER OR  
ASSOCIATE RADIATION SAFETY OFFICER  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50] (continued)**

**5. Structured Educational Program for Proposed RSO or ARSO (continued)**

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual <i>If training was provided by supervising RSO, ARSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</i>	License/Permit Number listing supervising individual
---	--

License/Permit lists supervising individual as:

- Radiation Safety Officer       Associate Radiation Safety Officer  
 Authorized User                 Authorized Nuclear Pharmacist       Authorized Medical Physicist

Authorized as RSO, ARSO, AU, ANP, or AMP for the following medical uses:

- 35.100       35.200       35.300       35.400  
 35.500       35.600 (remote afterloader)       35.600 (teletherapy)  
 35.600 (gamma stereotactic radiosurgery)       35.1000 ( \_\_\_\_\_ )

d. Skip to and complete Part II Preceptor Attestation.

**PART II – PRECEPTOR ATTESTATION**

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

**First Section**

**Structured Educational Program for Proposed RSO or ARSO**

I attest that \_\_\_\_\_ has satisfactorily completed  
Name of Proposed RSO/ARSO  
 a structural educational program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

**AND**

**Second Section**

I attest that \_\_\_\_\_ has training in  
Name of Proposed RSO/ARSO  
 radiation safety, regulatory issues, and emergency procedures for the following types of use:

**Complete for all (check all that apply):**

- 35.100       35.200  
 35.300      oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required  
 35.300      oral administration of greater than 33 millicuries of sodium iodide I-131  
 35.300      parental administration of any radionuclide that is primarily used for its beta radiation characteristics, or its photon energy, less than 150 keV for which a written directive is required

**PART II – PRECEPTOR ATTESTATION (continued)**

Complete for all (check all that apply):

- 35.300      parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required
  
- 35.400
- 35.500
- 35.600      remote afterloader units
- 35.600      teletherapy units
- 35.600      gamma stereotactic radiosurgery units
- 35.1000     emerging technologies, including:

**Third Section**

**AND**

I attest that

\_\_\_\_\_  
Name of Proposed Radiation Safety Officer or Associate Radiation Safety Officer

is able to independently fulfill the radiation safety-related duties as:

A Radiation Safety Officer for a medical use licensee.

**OR**

An Associate Radiation Safety Officer for a medical use licensee.

**Fourth Section**

**Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for

I am the Associate Radiation Safety Officer for

Name of Facility: \_\_\_\_\_

License/Permit Number: \_\_\_\_\_

Name of Preceptor (Typed or printed)

Telephone Number

Date

Signature



**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION  
[10 CFR 35.51, 35.57(a)(3), and 35.433]**

Name of Individual \_\_\_\_\_

Authorized Medical Physicist  
 Individual Identified in 10 CFR 35.433 (go to Page 4)

**Requested Authorization(s) (check all that apply)**

35.400 Ophthalmic use of strontium-90     35.600 Teletherapy unit(s)  
 35.600 Remote afterloader unit(s)     35.600 Gamma stereotactic radiosurgery unit(s)

**PART I – TRAINING AND EXPERIENCE (Select one of the three methods below)**

\*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- AUTHORIZED MEDICAL PHYSICIST**
- 1. Board Certification**
- a. Provide a copy of the board certification.
- b. If the board certification process has been recognized by the Commission or an Agreement State under 10 CFR 35.51:
- (i) Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.
- (ii) Stop here.
- c. If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57(a)(3), attach:
- (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
- (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
- (iii) Stop here.
- 2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**
- a. Go to the table in section 3.c. to document training for new device.
- b. If not board certified skip to and complete Part II Preceptor Attestation.
- c. If board certified, stop here.
- 3. Education, Training, and Experience for Proposed Authorized Medical Physicist**
- a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
College or University	

- b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.
- Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of \_\_\_\_\_ who meets the requirements for an Authorized Medical Physicist.
- AND**
- Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of \_\_\_\_\_ who meets the requirements for an Authorized Medical Physicist.

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION  
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

**3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)**

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)  
*If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.*

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics			
Performing sealed source leak tests and inventories			
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual\*\* \_\_\_\_\_ License/Permit Number listing supervising individual as an  
authorized Medical Physicist \_\_\_\_\_

for the following types of use:

- Remote afterloader unit(s)       Teletherapy unit(s)       Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

\* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

\*\* If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION  
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

**3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)**

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation			
Safety procedures for the device use			
Clinical use of the device			
Treatment planning system operation			

Supervising Individual  
*If training is provided by Supervising Medical Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*

License/Permit Number listing supervising individual as an authorized Medical Physicist

for the following types of use:

Remote afterloader unit(s)       Teletherapy unit(s)       Gamma stereotactic radiosurgery unit(s)

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION  
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

**Individual Identified Under 10 CFR 35.433.**

1. Complete the table below to document education;

Degree	Major Field
College or University	

2. Supervised Full-Time practical training and supervised work experience in medical physics

Yes. Completed 2 years of full-time practical training and/or work experience in medical physics (including areas identified below) at

\_\_\_\_\_ under the supervision of \_\_\_\_\_ medical physicist.

*If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.*

3. Complete the table below to document training and supervised work experience.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility	Dates of Training*	Dates of Work Experience*
The creating, modifying, and completing of written directives.			
Procedures for administrations requiring a written directive			
Performing the calibration measurements of brachytherapy sources as detailed in 10 CFR 35.432			
Supervising Individual		License/Permit Number	

4. Stop here

**AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUAL IDENTIFIED IN 10 CFR 35.433,  
TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION  
[10 CFR 35.51, 35.57(a)(3), and 35.433] (continued)**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

**First Section  
Complete the following:**

I attest that \_\_\_\_\_ has satisfactorily completed the 1-year of full-time  
Name of Proposed Authorized Medical Physicist  
 training in medical physics and an additional year of full-time work experience as required by 10 CFR  
 35.51(b)(1).

**AND**

**Second Section  
Complete the following:**

I attest that \_\_\_\_\_ has training for the types of use for which authorization  
Name of Proposed Authorized Medical Physicist  
 is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a  
 treatment planning system.

**AND**

**Third Section  
Complete the following:**

I attest that \_\_\_\_\_ is able to independently fulfill the radiation safety-related  
Name of Proposed Authorized Medical Physicist  
 duties as an Authorized Medical Physicist for the following:

35.400 Ophthalmic use of strontium-90       35.600 Teletherapy unit(s)  
 35.600 Remote afterloader unit(s)       35.600 Gamma stereotactic radiosurgery unit(s)

**AND**

**Fourth Section  
Complete the following for preceptor attestation and signature:**

I meet the requirements in 10 CFR 35.51, 35.57, or equivalent Agreement State requirements for  
 Authorized Medical Physicist for the following:

35.400 Ophthalmic use of strontium-90       35.600 Teletherapy unit(s)  
 35.600 Remote afterloader unit(s)       35.600 Gamma stereotactic radiosurgery unit(s)

Name of Facility:		License/Permit Number:	
Name of Preceptor (Typed or Printed)		Telephone Number	Date
Signature			



**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION**  
[10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized Nuclear Pharmacist

State or Territory Where Licensed

**PART I – TRAINING AND EXPERIENCE**  
*(Select one of the two methods below)*

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

**1. Board Certification**

a. Provide a copy of the board certification.

**2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			

**Total Hours of Training:**

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION (continued)**

**2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)**

**b. Supervised Practical Experience in a Nuclear Pharmacy.**

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys			
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides			
Calculating, assaying, and safely preparing dosages for patients or human research subjects			
Using administrative controls to avoid medical events in administration of byproduct material			
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures			

**Total Hours of Experience:**

Supervising Individual

**c. Go to and complete Part II Preceptor Attestation.**

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION (continued)**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

**First Section**

**Complete the following:**

**Structured Educational Program**

I attest that \_\_\_\_\_ has satisfactorily completed a 700-hour structured  
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

**Second Section**

**Complete the following for preceptor attestation and signature:**

I am an Authorized Nuclear Pharmacist for \_\_\_\_\_  
Nuclear Pharmacy or Medical Facility

\_\_\_\_\_  
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
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**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.100, 35.200, and 35.500)  
[10 CFR 35.190, 35.290, 35.57 and 35.590]

Name of Proposed Authorized User	State or Territory Where Licensed
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Requested Authorization(s) (check all that apply)

35.100 Uptake, dilution, and excretion studies       35.200 Imaging and localization studies

35.500 Sealed sources for diagnosis (specify device) \_\_\_\_\_

**PART I -- TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
- b. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(i), provide the following:
- (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
  - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
  - (iii) Stop here.
- 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**
- a. Authorized user on Materials License \_\_\_\_\_ meeting 10 CFR 35.390, 10 CFR 35.57 for 35.300 uses, or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.  
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

**Total Hours of Experience:**

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290       35.390 + generator experience in 32.290(c)(1)(ii)(G)       35.57 for 35.200 uses

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.100, 35.200, and 35.500)  
[10 CFR 35.190, 35.290, 35.57 and 35.590](continued)

**3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			

**Total Hours of Training:**

b. Supervised Work Experience (completion of this table is not required for 35.590).  
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

**Supervised Work Experience**

**Total Hours of Experience:**

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
**(for uses defined under 35.100, 35.200, and 35.500)**  
**[10 CFR 35.190, 35.290, 35.57 and 35.590](continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

**b. Supervised Work Experience. (continued)**

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual

License/Permit Number listing supervising individual as an authorized user or an authorized nuclear pharmacist

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190     35.290     35.390     35.390 + generator experience in 35.290(c)(1)(ii)(G)  
 35.55     35.57 for 35.200 uses

**c. For 35.590 only, provide documentation of training on use of the device.**

Device	Type of Training	Location and Dates

**d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.**

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
**(for uses defined under 35.100, 35.200, and 35.500)**  
**[10 CFR 35.190, 35.290, 35.57 and 35.590](continued)**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

**First Section**

**Check one of the following for each use requested:**

For 35.190

I attest that \_\_\_\_\_ has satisfactorily completed the 60 hours of training and  
Name of Proposed Authorized User  
experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User  
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290 (c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses under 10 CFR 35.100 and 35.200.

**Second Section**

**Complete one of the following for attestation and signature:**

- Authorized User:
  - I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:
    - 35.190     35.290     35.390     35.390 + generator experience     35.57 for 35.200 uses
- OR**
- Residency Program Director:
  - I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:
    - 35.190     35.290     35.390     35.390 + generator experience     35.57 for 35.200 uses
  - I affirm that this facility member concurs with the attestation I am providing as program director.
  - I affirm that the residency training program is approved by the:
    - Residency Review Committee of the Accreditation Council for Graduate Medical Education
    - Royal College of Physicians and Surgeons of Canada
    - Committee on Post-Graduate Training of the American Osteopathic Association
  - I affirm that the residency training program includes training and experience specified in:
    - 35.190     35.290

Name of Facility:		License/Permit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)		Telephone Number	Date
Signature			



**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.300)  
[10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized User	State or Territory Where Licensed
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Requested Authorization(s) (check all that apply):

35.300 Use of unsealed byproduct material for which a written directive is required

**OR**

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

35.300 Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required

35.300 Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

**PART I -- TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
  - b. For 35.390, provide documentation on supervised case experience. The table in section 3.c. may be used to document this experience.
  - c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Skip to and complete Part II Preceptor Attestation.
  - d. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(ii), provide the following:
    - (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
    - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
  - e. Stop here.
- 2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**
- a. Authorized User on Materials License \_\_\_\_\_ under the requirements below or equivalent Agreement State requirements (check all that apply):
    - 35.390       35.392       35.394       35.490       35.690
  - b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. If board certified stop here. If not board certified, provide completed Part II Preceptor Attestation.

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

**3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training  35.390  35.392  35.394  35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
<b>Total Hours of Training:</b> <input type="text"/>			

b. Supervised Work Experience  35.390  35.392  35.394  35.396

*(If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

**b. Supervised Work Experience (continued)**

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)\*\*:

<input type="checkbox"/> 35.390	With experience administering dosages of:	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.392		<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394		<input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
<input type="checkbox"/> 35.396		<input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required
<input type="checkbox"/> 35.57		

\*\* Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

**c. Supervised Clinical Case Experience**

*If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.*

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required			
Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required			

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**3. Training and Experience for Proposed Authorized User (continued)**

**c. Supervised Clinical Case Experience (continued)**

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)\*\*:

- |                                 |   |  |
|---------------------------------|---|--|
| <input type="checkbox"/> 35.390 | With experience administering dosages of: | <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)   |
| <input type="checkbox"/> 35.392 |   | <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)  |
| <input type="checkbox"/> 35.394 |   | <input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required |
| <input type="checkbox"/> 35.396 |   | <input type="checkbox"/> Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required   |
| <input type="checkbox"/> 35.57  |   |  |

\*\* Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

**d. Provide completed Part II Preceptor Attestation.**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

**First Section**

**Check one of the following for the requested authorization:**

**For 35.390:**

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User  
 and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

**For 35.392:**

I attest that \_\_\_\_\_ has satisfactorily completed the 80 hours of classroom  
Name of Proposed Authorized User  
 and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

**For 35.394:**

I attest that \_\_\_\_\_ has satisfactorily completed the 80 hours of classroom  
Name of Proposed Authorized User  
 and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**Second Section**

- I attest that \_\_\_\_\_ has satisfactorily completed the required clinical case experience required in 35.390(b)(1)(ii)G listed below:
- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
  - Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
  - Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy less than 150 keV, for which a written directive is required
  - Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

**Third Section**

- I attest that \_\_\_\_\_ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.300 for:
- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
  - Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
  - Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
  - Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

**Fourth Section**  
**For 35.396:**

**Current 35.490 or 35.690 authorized user:**

- I attest that \_\_\_\_\_ is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (e)(1), and the supervised work and clinical case experience required by 35.396(e)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:
- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
  - Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

**OR**

**Board Certification:**

- I attest that \_\_\_\_\_ has satisfactorily completed the board certification requirements of 35.396(d), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (e)(1) and the supervised work and clinical case experience required by 35.396(e)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user under 10 CFR 35.300 for:

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**Fourth Section (continued)**

**For 35.396:**

**Current 35.490 or 35.690 authorized user:**

- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

**Fifth Section**

Complete one of the following for the attestation and signature:

**Authorized User**

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.390       35.392       35.394       35.396       35.57 for 35.300 uses

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of any radionuclide that is primarily used for its beta radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required
- Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required

**OR**

**Residency Program Director:**

I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements:

- 35.390       35.392       35.394       35.396       35.57 for 35.300 uses

I affirm that this facility member has experience in administering dosages in the same dosage category or categories for which the individual is requesting authorized user status and concurs with the attestation I am providing as program director.

I affirm that the residency training program is approved by the:

- Residency Review Committee of the Accreditation Council for Graduate Medical Education
- Royal College of Physicians and Surgeons of Canada
- Committee on Post-Graduate Training of the American Osteopathic Association

I affirm that the residency training program includes training and experience specified in:

- 35.390       35.392       35.394       35.396

Name of Facility:	License/Permit Number:
-------------------	------------------------

Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
--	------------------	------

Signature
-----------



**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690]

Name of Proposed Authorized User \_\_\_\_\_ State or Territory Where Licensed \_\_\_\_\_

Requested Authorization(s) (check all that apply)

35.400 Manual brachytherapy sources     35.600 Teletherapy unit(s)

35.400 Ophthalmic use of strontium-90     35.600 Gamma stereotactic radiosurgery unit(s)

35.600 Remote afterloader unit(s)

**PART I – TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

\*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
  - b. For 35.690, go to the table in 3 e. and describe training provider and dates of training for each type of use for which authorization is sought.
  - c. For a board certification issued on or before October 24, 2005, that is listed in 10 CFR 35.57(b)(2)(iii), provide the following:
    - (i) Documentation that the individual performed each use checked above on or before October 24, 2005.
    - (ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.
    - (iii) Stop here.
- 2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**
- a. Go to the table in section 3.e. to document training for new device.
  - b. If board certified stop here. If not board certified, provide completed Part II Preceptor Attestation.
- 3. Training and Experience for Proposed Authorized User**
- a. Classroom and Laboratory Training     35.490     35.491     35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690] (continued)

**3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690] (continued)

**3. Training and Experience for Proposed Authorized User (continued)**

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader unit(s)       Teletherapy unit(s)       Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690] (continued)

**3. Training and Experience for Proposed Authorized User (continued)**

**d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)**

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

**e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.**

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Supervising Individual. (If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)		License/Permit Number listing supervising individual as an Authorized User	
<b>Authorized for the following types of use:</b> <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

**f. Provide completed Part II Preceptor Attestation.**

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
**(for uses defined under 35.400 and 35.600)**  
**[10 CFR 35.490, 35.491, and 35.690] (continued)**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**

Check one of the following for each requested authorization:

**For 35.490:**

I attest that \_\_\_\_\_ has satisfactorily completed the 200 hours of  
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

**For 35.491:**

I attest that \_\_\_\_\_ has satisfactorily completed the 24 hours of  
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

**Second Section**

**For 35.690:**

I attest that \_\_\_\_\_ has satisfactorily completed 200 hours of classroom  
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

**AND**

**Third Section**

**For 35.690: (continued)**

I attest that \_\_\_\_\_ has received training required in 35.690(c) for device  
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s)     Teletherapy unit(s)     Gamma stereotactic radiosurgery unit(s)

**AND**

**AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.400 and 35.600)  
[10 CFR 35.490, 35.491, and 35.690] (continued)

**Fourth Section**

I attest that \_\_\_\_\_ is able to independently fulfill the radiation safety-related duties as an authorized user for:

Name of Proposed Authorized User

Remote afterloader unit(s)     Teletherapy unit(s)     Gamma stereotactic radiosurgery unit(s)

**Fifth Section**

Complete one of the following for attestation and signature:

**Authorized User:**

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

- |  |   |
|--|---|
| <input type="checkbox"/> 35.400 Manual brachytherapy sources   | <input type="checkbox"/> 35.600 Teletherapy unit(s)                         |
| <input type="checkbox"/> 35.400 Ophthalmic use of strontium-90 | <input type="checkbox"/> 35.600 Gamma stereotactic radiosurgery unit(s)     |
| <input type="checkbox"/> 35.600 Remote afterloader unit(s)     | <input type="checkbox"/> 35.57 for 35.400 and/or 35.600 uses, as applicable |

**OR**

**Residency Program Director (for 35.490 and/or 35.690 only):**

I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:

- |   |  |
|---|--|
| <input type="checkbox"/> 35.400 Manual brachytherapy sources            | <input type="checkbox"/> 35.57 for 35.400 uses                         |
| <input type="checkbox"/> 35.600 Teletherapy unit(s)                     | <input type="checkbox"/> 35.57 for teletherapy unit(s)                 |
| <input type="checkbox"/> 35.600 Remote afterloader unit(s)              | <input type="checkbox"/> 35.57 for remote afterloader unit(s)          |
| <input type="checkbox"/> 35.600 gamma stereotactic radiosurgery unit(s) | <input type="checkbox"/> 35.57 gamma stereotactic radiosurgery unit(s) |

I affirm that this faculty member concurs with the attestation I am providing as program director.

I affirm that the residency training program is approved by the:

- Residency Review Committee of the Accreditation Council for Graduate Medical Education
- Royal College of Physicians and Surgeons of Canada
- Committee on Postdoctoral Training of the American Osteopathic Association

I affirm that the residency training program includes training and experience specified in:

- 35.490     35.690

Name of Facility: \_\_\_\_\_

License/Permit Number: \_\_\_\_\_

Name of Preceptor or Residency Program Director (Typed or printed)	Telephone Number	Date
--	------------------	------

Signature \_\_\_\_\_

**[The following redline/strikeout revisions to Appendix C reflect the changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and individual identified in 10 CFR 35.433; the change to 10 CFR 35.65 to prohibit bundling of single sources; changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards listed in NRC regulations prior to March 30, 2005; changes to 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, and 35.690 revising the preceptor attestation requirements and the preceptor attestation statement; changes to 10 CFR 35.50 training and experience pathways; and the change to 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses.]**

## **APPENDIX C**

### **License Application Checklists**

#### **License Application Checklists**

This Appendix contains checklists that may be used to assist in organizing an application. It addresses information a medical use licensee needs to provide for authorization to produce PET radioactive drugs for noncommercial transfer to consortium members. See Appendix AA for additional information.

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 applicants must respond, “highlight” the columns under the categories of materials requested in Item 5 (e.g., 10 CFR 35.300, 35.400). If any “Y” beside an item is highlighted, applicants must provide detailed information in response to that item. If the letters “N/A” are highlighted, applicants may respond “N/A” on their applications. 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 that type of license. If any “P” beside an item is highlighted, applicants 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								
Section #	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	Discrete Source of Ra-226 (Other than sealed sources)	Y	Y	N	N	N	Y	
8.8	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.9	Purpose(s) for Which Licensed Material Will Be Used	Y	Y	Y	Y	Y	Y	
8.10	Training and Experience	G	G	G	G	G	G	
8.11	Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)	Y	Y	Y	Y	Y	Y	I, D
8.12	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D

Table C.1 Applicability Table								
Section #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.13	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.14	Authorized Medical Physicist (AMP) and Individuals Identified in 10 CFR 35.433	N/A	N/A	Y*	N/A	Y	Y	D
8.15	Facilities and Equipment	G	G	G	G	G	G	
8.16	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.18	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.19	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.20	Other Equipment and Facilities	N	N	N	N	Y	N	
8.21	Radiation Protection Program	G	G	G	G	G	G	
8.22	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.23	Occupational Dose	P	P	P	P	P	P	M
8.24	Area Surveys	P	P	P	P	P	P	R
8.25	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.26	Spill/Contamination Procedures	P	P	P	N/A	N/A	P	N
8.27	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.28	Minimization of Contamination	N	N	N	N	N	N	
8.29	Waste Management	P	P	P	P	P	P	W
8.30	Fees	Y	Y	Y	Y	Y	Y	

<b>Table C.1 Applicability Table</b>								
<b>Section #</b>	<b>Topic</b>	<b>35.100/200</b>	<b>35.300</b>	<b>35.400</b>	<b>35.500</b>	<b>35.600</b>	<b>35.1000</b>	<b>APP</b>
8.31	Certification	Y	Y	Y	Y	Y	Y	
8.32	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	J
8.33	Public Dose	N	N	N	N	N	N	
8.34	Opening Packages	N	N	N	N	N	N	
8.35	Written Directive Procedures	N/A	N	N	N/A	N	N	S
8.36	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	U
8.37	Mobile Medical Service	N	N	N	N	N	N	V
8.38	Audit Program	N	N	N	N	N	N	L
8.39	Operating and Emergency Procedures	N	N	N	N	N	N	N
8.40	Material Receipt and Accountability	N	N	N	N	N	N	
8.41	Ordering and Receiving	N	N	N	N	N	N	O
8.42	Sealed Source Inventory	N	N	N	N	N	N	
8.43	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.44	Recordkeeping	N	N	N	N	N	N	X
8.45	Reporting	N	N	N	N	N	N	Y
8.46	Leak Tests	N	N	N	N	N	N	Q
8.47	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
8.48	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 the type of radioactive material requested and the 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.

The applicant should review the guidance in Section 5.2 and mark security-related information appropriately.

**Note:** The NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226, as a result of the EPAct. Uses of these materials are added to Table C.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 This response includes security-related sensitive information (see Section 5.2) which is included in Attachment \_\_\_\_\_ and marked "Security-related information – withhold under 10 CFR 2.390"

No

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 material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	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.

**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.)*

	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.

**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
	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:  <input type="checkbox"/> Gd-153;  <input type="checkbox"/> I-125;  <input checked="" type="checkbox"/> Radionuclide (transmission sources bundled and exceeding single source limits in 35.65)  <input type="checkbox"/> 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).

	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	<i>In vitro</i> studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	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 of the 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.

<b>Table C.3 Items 7 through 11 on NRC Form 313: Training &amp; Experience, Facilities &amp; Equipment, Radiation Protection Program, and Waste Disposal</b> <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: <input type="checkbox"/> Radiation Safety Officer or <input type="checkbox"/> Associate Radiation Safety Officer  Name:	<i>For an individual previously identified as an RSO or ARSO on an NRC or Agreement State license or permit:</i>  Previous license number (if issued by the NRC), or a copy of a license (if issued by an Agreement State), or a copy of a permit (if issued by an NRC master materials licensee) on which the individual was specifically named as the RSO or ARSO.  After <b>[DATE THAT IS 90 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]</b> , documentation of the training requirements in § 35.50(d) for any new materials or new medical uses requested.	<input type="checkbox"/>

<b>Table C.3 Items 7 through 11 on NRC Form 313: Training &amp; Experience, Facilities &amp; Equipment, Radiation Protection Program, and Waste Disposal</b> <i>(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)</i>		
Item Number and Title	Suggested Response	Check box to indicate material included in application
	<p><i>For an individual qualifying under 10 CFR 35.57(a)(3):</i></p> <p>Documentation that the individual was:</p> <ul style="list-style-type: none"> <li>- the RSO for only the medical uses of accelerator-produced radioactive material, <del>or</del> discrete sources of Ra-226, <b>or both included in the definition of byproduct material as a result of the EPA Act;</b></li> <li>- the RSO for the medical uses of these materials <b>at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC during the effective period of NRC's waiver of August 31, 2005.</b></li> </ul>	
	<p><i>For an individual qualifying under 10 CFR 35.50(a):</i></p> <p>Copy of certification by a specialty board whose certification process has been recognized<sup>1</sup> by NRC or an Agreement State under 10 CFR 35.50(a).</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>

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

	<p>Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO <b>or ARSO</b> is qualified by training in 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 <b>or ARSO</b>.</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p><del>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed training in and experience required for certification, as well as training in 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.</del></p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>

<i>For an individual qualifying under 10 CFR 35.50(c)(1):</i>	
Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized <sup>2</sup> by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO <b>or ARSO</b> is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO <b>or ARSO</b> .	<input type="checkbox"/>
<b>AND</b>	
Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO <b>or ARSO</b> is qualified by training in 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 <b>or ARSO</b> .	<input type="checkbox"/>
<b>AND</b>	
<del>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified for certification, as well as training in 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.</del>	<input type="checkbox"/>
<del><b>AND</b></del>	
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
<i>For an individual qualifying under 10 CFR 35.57 (a)(2):</i>	
Copy of certification by a specialty board whose certification listed in <b>10 CFR 35.57 (a)(2)</b>	<input type="checkbox"/>

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

Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;	<input type="checkbox"/>
<b>AND</b>	
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
<b>AND</b>	
<i>For an individual qualifying under 10 CFR 35.50(c)(2):</i>	
Copy of the <b>Commission or Agreement State license, permit issued by a Commission master material license, permit issued by a Commission or Agreement State licensee of broad scope, or permit issued by a Commission master material license broad scope permittee licensee's license</b> indicating that the individual is an AU, AMP, or ANP identified on the <b>license or permit</b> and has experience with radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO <b>or ARSO</b> .	<input type="checkbox"/>
<b>AND</b>	
<del>Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in 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.</del>	<input type="checkbox"/>
<del><b>AND</b></del>	
<del>Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 10 CFR 35.50(c)(2), as well as training in 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.</del>	<input type="checkbox"/>
<del><b>AND</b></del>	
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>

	<p><u>For an individual applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50 (c)(3).</u></p>	
	<p>Documentation of training and experience to be a new AU is attached.</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>The new license application is attached.</p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.50(b):</i></p>	
	<p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO <b>or ARSO</b> 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 <b>or ARSO</b>.</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO <b>or ARSO</b> is qualified by training in 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 <b>or ARSO</b>.</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>Written attestation, signed by a preceptor RSO <b>or ARSO</b>, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b)(1), as well as the training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and <b>is able</b> <del>has achieved a level of radiation safety knowledge sufficient to function independently</del> <b>fulfill the radiation safety-related duties</b> as an RSO <b>or ARSO for a medical use license</b>.</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>

Item 7: Authorized Users for medical uses:	<i>For an individual previously identified as an AU on an NRC or Agreement State license or permit:</i>	
Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual	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 an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	<input type="checkbox"/>
	<p><i>For an AU requesting authorization for an additional medical use:</i></p> <p>Description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290 (b), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)).</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	A preceptor attestation, if required (e.g., attestation is required for all individuals to meet the requirements in 10 CFR 35.396 and for individuals coming through the alternate training and experience pathway for <del>35.390(b)(1)(ii)(G), or</del> and 35.690(e)).	
	<i>For an individual qualifying under 10 CFR 35.57(b)(3):</i>	

	<p>Documentation that the physician, podiatrist, or dentist:</p> <ul style="list-style-type: none"> <li>used only accelerator-produced radioactive materials, <del>or</del> discrete sources of Ra-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC <del>before or during the effective period of NRC's waiver of August 31, 2005;</del> and</li> <li>used these materials for the same medical uses requested.</li> </ul>	
	<p><i>For an individual who was certified before October 24, 2005 by a board listed in 10 CFR 35.57(b)(2):</i></p> <p>Copy of the board certification.</p> <p style="text-align: center;"><b>AND</b></p> <p>Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005;</p> <p style="text-align: center;"><b>AND</b></p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:</i></p> <p>Copy of the certification(s) by a specialty board(s) whose certification process has been recognized<sup>3</sup> by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested.</p> <p style="text-align: center;"><b>AND</b></p>	<p style="text-align: center;"><input type="checkbox"/></p>

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

	<p>For an individual with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>For an individual with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating the proposed AU is also qualified for imaging and localization medical uses;</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>For an individual with a board certification recognized under 10 CFR 35.490 or 35.690 seeking authorization under 10 CFR 35.396(c), a description of the classroom and laboratory training and supervised work experience required to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>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;</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>

	<p>Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification, as well as the clinical casework, or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, if appropriate, have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved;</p> <p style="text-align: center;"><b>AND</b></p>	☐
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	☐
	<p><i>For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:</i></p> <hr/> <p>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(s) requested.</p> <p style="text-align: center;"><b>AND</b></p>	☐
	<p>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.</p> <p style="text-align: center;"><b>AND</b></p>	☐
	<p>Written attestation, signed by a preceptor physician AU, that the above training and experience have been satisfactorily completed and <b>the individual is able</b> <del>that a level of competency sufficient to function independently</del> <b>fulfill the radiation safety-related duties</b> as an AU for the <b>requested</b> medical uses <del>authorized</del> <b>has been achieved.</b></p> <p style="text-align: center;"><b>AND</b></p>	☐
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	☐

Item 7: Authorized Nuclear Pharmacists	<i>For an individual previously identified as an ANP on an NRC or Agreement State license or permit:</i>	
Name(s) and license to practice pharmacy:	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 an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named ANP.	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.57(a)(43):</i></p> <p>Documentation that the nuclear pharmacist:</p> <ul style="list-style-type: none"> <li>• used only accelerator-produced radioactive materials or discrete sources of Ra-226, or both, in the practice of nuclear pharmacy <b>at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005; and</b></li> <li>• used these materials for the same uses requested.</li> </ul>	
	<p><i>For an individual qualifying under 10 CFR 35.55(a):</i></p> <p>Copy of the certification(s) of the specialty board whose certification process has been recognized<sup>4</sup> under 10 CFR 35.55(a).</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p><del>Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.</del></p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>

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

	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
	<i>For an individual qualifying under 10 CFR 35.55(b):</i>	
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience.  <b>AND</b>	<input type="checkbox"/>
	Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and <b>the individual is able</b> that a level of competency sufficient to function independently <b>fulfill the radiation safety-related duties</b> as an ANP has been achieved.  <b>AND</b>	<input type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	<input type="checkbox"/>
Item 7: Authorized Medical Physicists	<i>For an individual previously identified as an AMP on an NRC or Agreement State license or permit:</i>	
Name(s):	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 an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.	<input type="checkbox"/>

	<i>For an individual qualifying under 10 CFR 35.57(a)(43):</i>	
	<p>Documentation that the medical physicist:</p> <ul style="list-style-type: none"> <li>- used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses <b>at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC before or during the effective period of NRC's waiver of August 31, 2005;</b> and</li> <li>- used these materials for the same medical uses requested.</li> </ul>	<input type="checkbox"/>
	<p><i>For an individual qualifying under 10 CFR 35.51(a):</i></p> <p>Copy of the certification(s) of the specialty board(s) whose certification process has been recognized<sup>5</sup> under 10 CFR 35.51(a).</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>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.</p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p><del>Written attestation, signed by a preceptor physician AMP, that the training and experience specified for certification, as well as the training and experience specified in 10 CFR 35.51(c) have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved;</del></p> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<input type="checkbox"/>



<p>Item 7: Individual Identified Under 10 CFR 35.433</p> <p>Name(s):</p>	<p>Documentation that the individual is an authorized medical physicist.</p> <p style="text-align: center;">OR</p> <p>Documentation of a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.</p> <p style="text-align: center;">AND</p> <p>Documentation of successful completion of 2 years of full time practical training and/or supervised experience in medical physics.</p> <p style="text-align: center;">AND</p> <p>Documentation of training in:</p> <ul style="list-style-type: none"> <li>- The creating, modifying, and completing of written directives;</li> <li>- Procedures for administrations requiring a written directive; and</li> <li>- Performing the calibration measurements of brachytherapy sources as detailed in 10 CFR 35.432.</li> </ul>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>
<p>Item 7: Authorized User for nonmedical uses</p> <p>Name(s):</p> <p>Requested types, quantities, and nonmedical uses for each individual</p>	<p><b>Note:</b> For purposes of this section of the table, the term “authorized user” is used to mean individuals authorized for the nonmedical uses described. See Sections 8.11 and 8.12.</p> <p><i>For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:</i></p> <p>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 an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.</p>	<p style="text-align: center;"><input type="checkbox"/></p>

	<i>For individuals qualifying under 10 CFR 30.33(a)(3):</i>	
	Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	<input type="checkbox"/>
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:	<input type="checkbox"/>
	· Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	<input type="checkbox"/>
	· Drawings should be to scale, indicating the scale used.	<input type="checkbox"/>
	· Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	<input type="checkbox"/>
	· 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, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	<input type="checkbox"/>
	· 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).	<input type="checkbox"/>

	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.	<input type="checkbox"/>
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."  <b>AND/OR</b>	<input type="checkbox"/>
	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."  <b>AND</b>	<input type="checkbox"/>
	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.  <b>AND</b>	<input type="checkbox"/>
	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."	<input type="checkbox"/>
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."	<input type="checkbox"/>

	<p>When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j),</p> <ul style="list-style-type: none"> <li>· A statement that: “Dosages will be determined by relying on the provider’s dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation.”</li> </ul> <p style="text-align: center;"><b>OR</b></p>	<input type="checkbox"/>
	<ul style="list-style-type: none"> <li>· We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer’s calibration instructions), and dosage measurement procedures.</li> </ul>	<input type="checkbox"/>
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.	<input type="checkbox"/>
	<p style="color: red;">We are providing the calibration and use procedures requested by NRC licensing guidance on NRC’s web site for the following 10 CFR 35.1000 medical uses:</p> <p style="color: red;">_____.</p>	<input type="checkbox"/>
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	<input type="checkbox"/>
	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	<input type="checkbox"/>
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	<input type="checkbox"/>
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	<input type="checkbox"/>



	For the following 35.1000 medical uses, we reviewed the licensing guidance on NRC's web site and are applying for approval to revise, without further NRC approval, the radiation safety program for each 35.1000 medical use to conform with revised licensing guidance posted on NRC's on its web site ( <a href="http://www.nrc.gov/materials/miau/med-use-toolkit.html">http://www.nrc.gov/materials/miau/med-use-toolkit.html</a> ).	<input type="checkbox"/>
	For the following 35.1000 medical uses, we reviewed NRC's licensing guidance on NRC's web site and are providing safety and emergency procedures appropriate for each 35.1000 medical use, or explaining why the description is not needed.	<input type="checkbox"/>
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	<input type="checkbox"/>
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 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 Licenses.' "  <b>OR</b>	<input type="checkbox"/>
	A description of an alternative method for demonstrating compliance with the referenced regulations.	<input type="checkbox"/>
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."	<input type="checkbox"/>
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."	<input type="checkbox"/>

Item 10: Spill/Contamination 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."	<input type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested:  _____	<input type="checkbox"/>
	<b>AND</b>	
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.	<input type="checkbox"/>
	<b>AND</b>	
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	<input type="checkbox"/>
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 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities 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 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."	<input type="checkbox"/>
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	<input type="checkbox"/>
	Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs noncommercially transferred under 10 CFR 30.32(j) authorization.	<input type="checkbox"/>

## APPENDIX D

### Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, **Associate Radiation Safety Officer**, Authorized Medical Physicist, **Individual identified in 10 CFR 35.433**, or Authorized Nuclear Pharmacist

**Note:** The most current guidance is found on NRC's public Web site at <http://www.nrc.gov/materials/miau/med-use-toolkit.html> (Medical Uses Toolkit).

## **Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, **Associate Radiation Safety Officer**, Authorized Medical Physicist, **Individual Identified in 10 CFR 35.433**, or Authorized Nuclear Pharmacist**

### **I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, Radiation Safety Officer, or **Associate Radiation Safety Officers****

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), **Radiation Safety Officer (RSO)** or **Associate Radiation Safety Officer (ARSO)** to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the NRC or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master material broad-scope permittee, 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 ANP 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 ANP by a commercial nuclear pharmacy authorized to identify ANPs. 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. Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses.**

In implementing the EPA Act, the NRC “grandfathered” physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for medical or nuclear pharmacy uses at a **Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC**~~before or under the NRC waiver of August 31, 2005~~, when using these materials for the same uses. These individuals, as well as individuals that performed RSO duties only for uses of accelerator-produced radionuclides or discrete sources of Ra-226 at medical or nuclear pharmacy facilities before or during the effective period of the waiver, do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, and G.

The applicant or licensee that is adding one of these experienced individuals to its medical use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

### **III. Applications that Include New Authorized User, Authorized Medical Physicist, Individuals Identified in 10 CFR 35.433, Authorized Nuclear Pharmacist, or Radiation Safety Officer or Associate Radiation Safety Officer Recognition by NRC**

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, the NRC Form 313A series has been separated into six separate forms. The forms are NRC FORM 313A (RSO) for the Radiation Safety Officer and Associate Radiation Safety Officer; NRC FORM 313A (AMP) for the authorized medical physicist and individual identified in 10 CFR 35.433; NRC FORM 313A (ANP) for the authorized nuclear pharmacist; NRC FORM 313A (AUD) for the authorized user of the medical uses included in 10 CFR 35.100, 35.200, and/or 35.500; NRC FORM 313A (AUT) for the authorized user for the medical use included in 10 CFR 35.300; and NRC FORM 313A (AUS) for the authorized user for the medical uses included in 10 CFR 35.400 and/or 35.600.

When an applicant wants to identify one or more ARSO's, it needs to describe the portions of the licensed program for which the ARSO will be assigned oversight duties and tasks.

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, RSO or ARSO. The first is by means of certification by a board recognized by NRC and listed on the NRC Web site as provided in 10 CFR 35.57(a)(2), 35.57(a)(3), 35.57(b)(2), 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), 35.590(a), or 35.690(a). ~~Preceptor attestations must also be submitted for all individuals to qualify under 10 CFR Part 35, Subparts B and D through H.~~ Additional training may also need to be documented for RSOs, ARSOs, AMPs, and AUs under 10 CFR 35.300 and 35.600.

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. In some cases there may be additional training and experience routes for recognized AUs, ANPs, AMPs, RSOs or ARSOs to seek additional authorizations.

### **IV. Recentness of Training**

The required training and experience, including board certification, 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 for physicians 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.

## **V. General Instructions and Guidance for Filling Out NRC Form 313A Series**

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms (i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)). Also, if the applicant requests that a physician be authorized for both high dose-rate remote afterloading and gamma stereotactic radiosurgery under 10 CFR 35.600, only one form, NRC Form 313A (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

To identify an Agreement State license, provide a copy of the license. To identify a Master Materials License permit, provide a copy of the permit. To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following:

" \_\_\_\_\_ (name of supervising individual or preceptor) is authorized under \_\_\_\_\_ (name of licensee/permittee) broad-scope license number \_\_\_\_\_ to use \_\_\_\_\_ (materials) during \_\_\_\_\_ (time frame)."

### **INTRODUCTORY INFORMATION**

#### **Name of individual**

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.

**Note:** Do not include personal or private information (e.g., date of birth, Social Security Number, home address, personal telephone number) as part of your qualification documentation.

### **State or territory where licensed**

The 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, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of “physician”, “dentist”, “podiatrist”, and “pharmacist” in 10 CFR 35.2).

### **Requested Authorization(s).**

Check all authorizations that apply and fill in the blanks as provided.

### **Part I. Training and Experience**

There are always multiple pathways provided for each training and experience section. Select the applicable one.

#### **Item 1. Board Certification**

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by NRC (to confirm that NRC recognizes that board’s certifications, see NRC’s Web site <http://www.nrc.gov/materials/miau/med-use-toolkit.html> or certified prior to October 24, 2005 by a board listed in 10 CFR 35.57).

**Note:** An individual that is board-eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will also not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series.

All applicants under this pathway (except for 10 CFR 35.500 uses) must submit a completed Part II Preceptor Attestation.

#### **Item 2. Current Authorized Individuals Seeking Additional Authorizations**

Provide the information requested for training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series. (**Note:** This section does not include individuals who are authorized only on foreign licenses.)

With the exception of individuals applying under 10 CFR 35.396, board certified applicants do not need to provide a Preceptor Attestation. All other applicants (except those applying under 10 CFR 35.590) under this pathway must submit a completed Part II Preceptor Attestation.

### **Item 3. Alternate Pathway for Training and Experience for Proposed New Authorized Individuals**

This pathway is used for those individuals not listed on the license as authorized individuals, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (a) classroom and laboratory training, or (b) supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and supervised work experience element will depend upon the type of approval sought. Under the “classroom and laboratory training,” provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed authorized individual may obtain the required “classroom and laboratory training” in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret “classroom and laboratory training” to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the “supervised work experience” sections of the forms, provide only the total number of hours of supervised work experience and check the boxes for each of the topics listed in the regulatory requirements to confirm that the listed subject areas were included in the supervised work experience.

The “supervised work experience” for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The NRC recognizes that physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical

activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

For nuclear pharmacists, under the “supervised practical experience” section, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

**Note:** If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

## **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 AU, an AMP, an ANP, **an ARSO**, or an RSO.” 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 individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and **is able** ~~has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently~~ **fulfill the radiation safety-related duties of an authorized individual**. The preceptor language in NRC Forms 313A (AUD), 313A (AUT), and 313A (AUS) does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual **is able** ~~has the knowledge~~ to fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements.

The NRC may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual 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.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and **that the proposed user is able** ~~competency to function~~ **independently fulfill the radiation safety-related duties for the authorization sought**, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

## **VI. RADIATION SAFETY OFFICER and ASSOCIATE RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)**

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

When requesting approval for an RSO or ARSO, the applicant needs to designate whether the individual will be an RSO or ARSO. The applicant must also specify the medical uses for which the RSO will have responsibilities and the portion of the program for which the ARSO will have oversight duties and tasks. The RSO responsibilities are identified by the specific medical uses (35.100, 35.200, etc.). The oversight duties and task for the ARSO also include "other". "Other" may be used to designate program divisions such as different geographic locations or health physics functions.

**Part I. Training and Experience** - select one of four methods below:

### **Item 1. Board Certification**

Provide the requested information (i.e., a copy of the board certification, **and** documentation of specific radiation safety training for all types of use on the license, ~~and a completed preceptor attestation~~). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, **ARSO**, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in **53.c** if the training was provided by an RSO, **ARSO**, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

### **Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.**

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in **53.c**) and a completed preceptor attestation in Part II **is needed if the**

**individual is not board certified**). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, **ARSO**, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 5.c if the training was provided by an RSO, **ARSO**, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

**Item 3. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on a license or permit identified in 10 CFR 35.50(c)(2) the licensee's license**

Provide the requested information (i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in ~~53~~.c)). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, **ARSO**, AMP, ANP, or AU who is authorized for that type of use. ~~Specific information regarding the supervising individual only needs to be provided in the table in table 3.c if the training was provided by an RSO, AMP, ANP, or AU.~~ If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

**Item 4. Individuals applying simultaneously to be the RSO and AU on a new license**

~~When the application is for a new medical use license and the proposed AU has never been recognized as an AU, the RSO status will be based on the training and experience needed for the individual to be recognized as an AU. Therefore, the new license application and documentation of training and experience to be a new AU must be submitted with the NRC Form 313A (RSO).~~

**Item 5. Structured Educational Program for Proposed New Radiation Safety Officer or Associate Radiation Safety Officer**

As indicated on the form, additional information is needed if the training, supervised radiation safety experience and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section ~~53~~.a.

Submit a completed Section ~~53~~.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO **or ARSO**. This is documented in Section 5.b by providing the ranges of dates for supervised radiation safety experience. If there

was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 53.c)). Specific radiation safety training for each type of use on the license may be supervised by an RSO, ARSO, AMP, ANP, or AU who is authorized for that type of use. ~~Specific information regarding the supervising individual only needs to be provided in the table in table 3.c if the training was provided by an RSO, AMP, ANP, or AU.~~ If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

## **Part II. Preceptor Attestation**

The Preceptor Attestation page has four sections.

The attestation for the new proposed RSO's **or ARSO's** training ~~or identification on the license as an AU, AMP, or ANP~~ is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation for the individual's **is able** ~~competency to function independently~~ **fulfill the radiation safety-related duties** as an RSO **or as an ARSO**, and for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as an RSO on a medical use license in addition to the preceptor's signature.

The preceptor for a new proposed RSO must fill out all four sections.

The preceptor for an RSO, **who did not come through the board certification pathway, that is** seeking authorization to be recognized as an RSO for the additional medical use(s) must fill out the second, third, and fourth sections.

## **VII. AUTHORIZED MEDICAL PHYSICIST AND INDIVIDUALS IDENTIFIED IN 10 CFR 35.433 - Specific Instructions and Guidance for Filling Out NRC Form 313A (AMP)**

See Section V, "General Instructions and Guidance for Filling Out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

**When requesting approval for an AMP or an individual identified in 10 CFR 35.433, the applicant needs to designate whether the individual will be an AMP or an individual identified in 10 CFR 35.433.**

**Part I. Training and Experience** - select one of the three methods below:

**Authorized Medical Physicist**

**Item 1. Board Certification**

Provide the requested information (i.e., a copy of the board certification and documentation of device-specific training in the table in 3.c, ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

If the board certification was issued on or before October 24, 2005 and is listed in 10 CFR 35.57(a)(3), attach documentation that the individual performed the requested type of use on or before October 24, 2005. Also provide the dates, duration, and description of continuing education and experience for each requested type of use within the past 7 years.

**Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s)  
Checked above**

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and **for an individual who did not come through the board certification pathway that is seeking a new authorization** complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

**Item 3. Training and Experience for Proposed Authorized Medical Physicist**

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed Section 3.b. The individual must have completed 1 year of full-time training in medical physics and an additional year of full-time work experience, which cannot be

concurrent. This is documented in Section 3.b by providing the ranges of dates for training and work experience.

If the proposed AMP had more than one supervisor, provide the information requested in Section 3.b for each supervising individual. If the supervising individual is not an AMP, the applicant must provide documentation that the supervising individual meets the requirements in 10 CFR 35.51 and 10 CFR 35.59.

Submit a completed Section 3.c for each specific device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

**Individual Identified in 10 CFR 35.433**

- Name of the proposed individual identified in 10 CFR 35.433.  
AND
- Documentation that the individual is an authorized medical physicist  
OR
- Documentation of a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;  
AND
- Documentation of successful completion of 2 years of full-time practical training and/or supervised experience in medical physics  
AND
- Documentation of training in:
  - The creating, modifying, and completing of written directives;
  - Procedures for administrations requiring a written directive; and
  - Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.

Note: A preceptor attestation is not required for this individual.

## **Part II. Preceptor Attestation**

The Preceptor Attestation page has four sections.

The attestation to the proposed AMP's training is in the first section.

The attestation for the device-specific training is in the second section.

The attestation of the individual's **ability** ~~competency to function~~ independently **fulfill the radiation safety-related duties** as an AMP for the specific devices requested by the applicant is in the third section.

The fourth and final section requests specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature.

The preceptor for a proposed new AMP must fill out all four sections of this page. The preceptor for an AMP, **who did not come through the board certification pathway, that is** seeking additional authorizations must complete the last three sections.

## **VIII. AUTHORIZED NUCLEAR PHARMACIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (ANP)**

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

**Part I. Training and Experience** - select one of the two methods below:

### **Item 1. Board Certification**

Provide the requested information (i.e., a copy of the board certification ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

### **Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist**

As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Submit completed Sections 2.a and 2.b. If the proposed new nuclear pharmacist had more than one supervisor, provide the name of each supervising individual in Section 2.b.

Submit a completed Preceptor Attestation.

## **Part II. Preceptor Attestation**

The Preceptor Attestation page has two sections. The preceptor must ~~select either the board certification or the structured educational program when filling out the~~ provide their attestation in the first section on this page.

The second and final section of the page requests specific information about the preceptor's authorization to use licensed material, in addition to the preceptor's signature.

## **IX. 10 CFR 35.100, 35.200, AND 35.500 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUD)**

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

**Part I. Training and Experience** - select one of the three methods below:

### **Item 1. Board Certification**

Provide the requested information (i.e., a copy of the board certification ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

### **Item 2. Current 35.390 Authorized User Seeking Additional 10 CFR 35.290 Authorization**

- (a) Fill in the blank in Section 2.a with the current license number on which the proposed user is listed.
- (b) Provide a description of the proposed user's experience that meets the requirements of 10 CFR 35.290 (c)(1)(ii)(G) as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name and include the license showing the supervising individual as an AU ~~or an ANP if the supervising individual for the 35.290(c)(1)(ii)(G) supervised work experience is an ANP~~.

### **Item 3. Training and Experience for Proposed Authorized Users**

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

**Note:** Providing the training and experience information required under 10 CFR 35.290 will allow the individual to be authorized to use materials permitted by both 10 CFR 35.100 and 10 CFR 35.200.

Submit a completed Section 3.a for each proposed authorized use.

Submit a completed Section 3.b, except for 10 CFR 35.500 uses. If the proposed user had more than one supervisor, provide the information requested in Section 3.b for each supervising individual.

Submit a completed Section 3.c for 10 CFR 35.500 uses.

Submit a completed Preceptor Attestation, except for 10 CFR 35.500 uses.

## **Part II. Preceptor Attestation**

The Preceptor Attestation page has two sections.

The preceptor attestation is provided by either a preceptor AU or residency program director.

The attestations for training and experience requirements in 10 CFR 35.190 and 10 CFR 35.290 are found in the first section.

The second and final section requests specific information about the preceptor's authorization(s) to use licensed material, or the residency program director's attestation, and in addition to the preceptor AU's or residency program director's signature.

The preceptor AU or the residency program director must fill out both sections.

**Note:** The attestation to the proposed user's training and ability competency to function independently fulfill the radiation safety-related duties of an AU under 10 CFR 35.190 covers the use of material permitted by 10 CFR 35.100 only. The attestation for the proposed user's training and ability competency to function independently fulfill the radiation safety related duties of an AU under 10 CFR 35.290 will allow the individual to be authorized to use material permitted by both 10 CFR 35.100 and 10 CFR 35.200.

## **X. 35.300 AUTHORIZED USER - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUT)**

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

**Part I. Training and Experience** - select one of the three methods below:

### **Item 1. Board Certification**

If the applicant is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification, and documentation of supervised clinical experience (complete the table in section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or supervised clinical experience

occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is a radiation oncologist whose board certification is not listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification listed under either 10 CFR 35.400 or 10 CFR 35.600 on NRC's Web site, documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the board certification was issued on or before October, 2005 and is listed in 10 CFR 35.57(b)(2)(ii), provide a copy of the board certification and documentation that the individual performed each use on or before October 24, 2005. As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago.

## **Item 2. Current 10 CFR 35.300, 10 CFR 35.400, or 10 CFR 35.600 Authorized User Seeking Additional Authorization**

Submit a completed Section 2.a, listing the license number and the user's current authorizations.

If the applicant is currently authorized for a subset of clinical uses under 10 CFR 35.300, submit the requested information (i.e., complete the table in Section 3.c to document the new supervised clinical case experience and, if not board certified, the completed Preceptor Attestation). As indicated on the form, additional information is needed if the clinical case experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meets the requirements in 10 CFR 35.396, submit the requested information (i.e., documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

## **Item 3. Training and Experience for Proposed Authorized Users**

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Preceptor Attestation in Part II.

## Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The preceptor attestation is provided by either a preceptor AU or residency program director.

The attestations for training and experience requirements in 10 CFR 35.390, 10 CFR 35.392, and 10 CFR 35.394 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for ~~ability-competency to function independently~~ fulfill the radiation safety-related duties as an AU for specific uses is in the third section.

The attestation for training and experience requirements and ~~ability-competency to function independently~~ fulfill the radiation safety duties as an AU for a radiation oncologist meeting the requirements in 10 CFR 35.396 is in the fourth section.

The fifth and final section requests specific information about the preceptor AU's authorization(s) to use licensed material, ~~or the residency program director's attestation, and in addition to the preceptor AU's or residency program director's signature.~~

There are seven possible categories of individuals seeking AU status under this form. Follow the instructions for the applicable category.

~~The preceptor for a proposed AU who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.390 on NRC's Web site must complete the first, second, third, and fifth sections.~~

The preceptor AU or residency program director for a proposed AU for all the uses listed in 10 CFR 35.390(b)(1)(ii)(G) who is a radiation oncologist with a board certification that is not listed under 10 CFR 35.390 on NRC's Web site or in 10 CFR 35.57(b)(2)(iii) must complete the first, second, third, and fifth sections.

The preceptor AU or residency program director for a proposed AU for 10 CFR 35.390(b)(1)(ii)(G)(iii) and (iv) uses who is a radiation oncologist with a board certification listed

under 10 CFR 35.490 or 10 CFR 35.690 on NRC's Web site or in 10 CFR 35.57(b)(2)(iii) must complete the fourth and fifth sections.

The preceptor **AU or residency program director** for an AU who is not board certified and is currently authorized for a subset of clinical uses under 10 CFR 35.300 must complete the second, third, and fifth sections of this part, except for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394.

The preceptor **AU or residency program director** for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394 must complete the first, second, third, and fifth sections.

The preceptor **AU or residency program director** for an AU currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meeting the requirements in 10 CFR 35.396 must complete the fourth, and fifth sections.

The preceptor **AU or the residency program director** for a proposed new AU must complete the first, second, third and fifth sections.

## **XI. 35.400 AND 35.600 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUS)**

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

**Part I. Training and Experience** - select one of the three methods below:

### **Item 1. Board Certification**

Provide the requested information (i.e., a copy of the board certification **if listed on NRC's board recognition web site**) for 10 CFR 35.600 uses, **and** documentation of device-specific training in the table in 3.e, ~~and for all uses, a completed Preceptor Attestation~~. As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor for new users, or either a supervising AU or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

**If the board certification was issues on or before October, 2005 and is listed in 10 CFR 35.57(b)(2)(iii), provide a copy of the board certification and documentation that the individual performed each use on or before October 24, 2005. As indicated on the form, additional**

information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago.

**Item 2. Current 10 CFR 35.600 Authorized User Requesting Additional Authorization for 10 CFR 35.600 Use(s) Checked Above**

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.e)) and, **if not board certified**, a completed Preceptor Attestation in Part II. As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

**Item 3. Training and Experience for Proposed Authorized Users**

As indicated on the form, additional information is needed if the training, residency program, supervised work, and clinical experience were completed more than 7 years ago.

Submit a completed Section 3.a for each requested use.

Submit a completed Section 3.b if applying for 10 CFR 35.400 uses. However, Section 3.b does not have to be completed when only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.c if only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.d for each requested 10 CFR 35.600 use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.e for each specific 10 CFR 35.600 device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

## Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

The preceptor attestation is provided by either be a preceptor AU or the residency program director.

The attestation to the training and individual's competency for 10 CFR 35.400 ~~uses of~~ strontium-90 eye applicator use is in the first section.

The attestation to the training for the proposed AU for 10 CFR 35.600 uses is in the second section.

The attestation for the 10 CFR 35.600 device-specific training is in the third section.

The attestation of the individual's ~~ability~~ competency to function independently fulfill the radiation safety-related duties as an AU for the specific 10 CFR 35.600 devices requested by the applicant is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, or the residency program director's attestation, and, in addition to the preceptor AU's or residency program director's signature.

The preceptor AU or residency program director for a 10 CFR 35.400 proposed AU must fill out the first and fifth sections.

The preceptor AU or residency program director for a 10 CFR 35.600 proposed AU must fill out the second, third, fourth and fifth sections.

The preceptor AU or residency program director for an AU seeking additional 10 CFR 35.600 authorizations must complete the third, fourth, and fifth sections.

**[The following redline additions to Appendix I reflect the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The revision also reflects the changes to 10 CFR 35.24, adding an Associate Radiation Safety Officer.]**

## **Appendix I**

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

#### **Model Radiation Safety Officer Duties and Responsibilities**

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

Typically, these duties and responsibilities include ensuring the following:

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

- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, **excess breakthrough values for Mo-99/Tc-99m or Sr-82/ Rb-82 generators**, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.
- **Assigning tasks and duties to an ARSO, if applicable;**

### **Model Delegation of Authority**

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

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

---

Signature of Management Representative

---

Date

I accept the above responsibilities,

---

Signature of Radiation Safety Officer

---

Date

cc: Affected department heads

**[The following redline additions to Appendix J reflect changes to 10 CFR 35.2, 35.24, and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433. The revision also reflects changes to 10 CFR 35.610 requiring vendor operational and safety training for remote afterloader, teletherapy, and gamma stereotactic radiosurgery units.]**

## **Appendix J**

### **Model Training Program**

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

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

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

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

#### **Training for Individuals Involved in the Medical Usage of Byproduct Material**

Training for professional staff (e.g., AU, AMP, **individuals identified in 10 CFR 35.433**, ANP, RSO, **ARSO**, nurse, dosimetrist, technologist, therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, *commensurate with their duties*:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA (10 CFR 20.1101);
- Risk estimates, including comparison with other health risks;
- Posting requirements (10 CFR 20.1902);
- Proper use of personnel dosimetry (when applicable);
- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802);
- Proper use of radiation shielding, if used;
- Patient release procedures (10 CFR 35.75);
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Occupational dose limits and their significance (10 CFR 20.1201);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208);
- Worker's right to be informed of occupational radiation exposure (10 CFR 19.13);
- Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12);
- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12);
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11);
- Proper recordkeeping required by NRC regulations (10 CFR 19.12);
- Appropriate surveys to be conducted (10 CFR 20.1501);
- Proper calibration of required survey instruments (10 CFR 20.1501);
- Emergency procedures;
- Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36);
- Dose to individual members of the public (10 CFR 20.1301); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing) (10 CFR 35.27, 10 CFR 30.32(a)(3)).

### **Training for Individuals Involved in Nonmedical Usage of Byproduct Material**

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. Licensees authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to other medical use licensees in the consortium should also provide

training on the production of PET radioactive drugs and special requirements in 10 CFR 30.32(j) and 10 CFR 30.34(j) for this activity. All training should be commensurate with the individual's duties.

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

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

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

- Leak testing of sealed sources (10 CFR 35.67);
- Emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Operating instructions (10 CFR 35.27, 10 CFR 35.610);
- Computerized treatment planning system (10 CFR 35.657);
- Dosimetry protocol (10 CFR 35.630);
- Detailed pretreatment quality assurance checks (10 CFR 35.27, 10 CFR 35.610);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410);
- Patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) (10 CFR 35.41);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.410, 10 CFR 35.610);
- Size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610);
- Previous incidents, events, and/or accidents; and
- For remote afterloaders, teletherapy units, and GSR units, **vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operational and safety of the unit) and licensee operational safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes (10 CFR 35.610):**
  - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;

- Hands-on training in actual operation of the device under the direct supervision of an experienced user, including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures;
- A method, such as practical examinations, to determine each trainee’s competency to use the device for each type of proposed use.

### **Additional Training for Authorized Medical Physicists and Individuals Identified in 10 CFR 35.433**

Applicants for licenses to include AMPs and **individuals identified in 10 CFR 35.433** 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) and **individuals identified in 10 CFR 35.433 are trained in activities specific to 10 CFR 35.433**. Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of Sr-90 sources used for ophthalmic treatments **and assisting the licensee in developing, implementing and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive** (10 CFR 35.433). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 10 CFR 35.51(c).

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

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

### **Training for Ancillary Staff**

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

- Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12);
- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and

functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12);

- The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12);
- Radiation exposure reports that workers may request, as per 10 CFR 19.13 (10 CFR 19.12).

[Redline/strikeout revisions are shown below for several sections of Appendix L. An explanation is provided in at the beginning of each section.]

## Appendix L Model Medical Licensee Audit

[The following redline/strikeout revisions to the “Organization and Scope of Program” section of Appendix L reflect the change to 10 CFR 35.24 adding an Associate Radiation Safety Officer; the changes to 10 CFR 35.65 to prohibit bundling of single sources and clarify that calibration, transmission, or references sources may be used for medical use in accordance with the requirements of 35.500; and changes to 10 CFR 35.400, 35.500, and 35.600 requiring sources be used in accordance with the radiation safety conditions and limitations described in the Sealed Source Device Registration not as approved in the Sealed Source Device Registration. The “Organization and Scope of Program” section of Appendix L begins on page L-1 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

### Organization and Scope of Program

#### A. Radiation Safety Officer:

1. If the RSO was changed, was the license amended [35.13]?
2. Does the new RSO meet NRC training requirements [35.50, 35.57, 35.59]?
3. If the scope of the program expands, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?
4. Is the RSO fulfilling all ~~responsibilities~~ ~~duties~~ [35.24]?
5. Is the written agreement in place for a new RSO [35.24(b)]?

#### B. Associate Radiation Safety Officer:

1. If the ARSO was changed, was the license amended [35.13]?
2. Does the new ARSO meet NRC training requirements [35.50, 35.57, 35.59]?
3. If the scope of the program expands, does the ARSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?
4. Is the ARSO fulfilling all duties and tasks [35.24]?
5. Is the written agreement in place for a new ARSO [35.24(b)]?

- CB. Multiple places of use? If yes, list locations.
- DG. Are all locations listed on license? Includes locations of accelerator-produced radioactive materials and discrete sources of radium-226?
- ED. Were annual audits performed at each location? If no, explain.
- FE. Describe the scope of the program (staff size, number of procedures performed, etc.).
- GF. Licensed Material:
  1. Isotope, chemical form, quantity, and use as authorized? Includes accelerator-produced radioactive materials and discrete sources of radium-226?
  2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is the financial assurance adequate?
  3. Calibration, transmission, and reference sources [35.65]?
    - a. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicuries each [35.65(a)(1) and (2b)]?
    - b. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries [35.65(a)(3e)]?
    - c. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries or 1000 times the quantities in Appendix B of Part 30 [35.65(a)(4d)]?
    - d. Technetium-99m in individual amounts as needed [35.65(a)(5e)]?
    - e. The sealed sources are not combined (bundled or aggregated) to create an activity greater than the maximum activity listed above?
    - f. The sources are not used for medical use except in accordance with the requirements in 35.500 [35.65(b)(1)]?
  4. Unsealed materials used under 10 CFR 35.100, 35.200, and 35.300 are:
    - a. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

**OR**

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

**OR**

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

**OR**

- d. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?
- 5. Production of PET radioactive drugs
  - Authorized under 10 CFR 30.32(j)?
  - For internal use from licensee's PET radionuclide production facility as authorized in 10 CFR 35.100(b), 35.200(b), or 35.300(b)?
- HG. Are the sealed sources possessed and used **under 35.400, 35.500, and 35.600 approved as described** in the Sealed Source and Device Registry (SSDR) certificate in 10 CFR 32.210, ~~35.400, 35.500, 35.600~~? **Are the sealed sources used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry?** Are copies of (or access to) SSDR certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?
- IH. Are there sealed sources containing accelerator-produced radioactive materials or discrete sources of radium-226 that do not have an SSDR certificate? If the sealed source is not generally licensed or exempt from licensing, seek a license amendment providing information under 10 CFR 32(g)(2) or (3).
- JJ. Are the actual uses of medical devices consistent with the authorized uses listed on the license?
- KJ. If places of use changed, was the license amended [35.13(e)]?
- LK. If control of the license was transferred or bankruptcy filed, was NRC's prior consent obtained or notification made [30.34(b) and 30.34(h) respectively]?

**[The following redline additions to the "Radiation Safety Program" section of Appendix L reflect a change to 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses. The "Radiation Safety Program" section of Appendix L appears on page L-3 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]**

## **Radiation Safety**

- A. Minor changes to program [10 CFR 35.26 or, **if license condition permits, changes conforming to revised licensing guidance** for 10 CFR 35.1000 medical uses]?
- B. Records of changes maintained for 5 years [35.2026]?
- C. Content and implementation reviewed annually by the licensee [20.1101(c)]?
- D. Records of reviews maintained [20.2102]?

- E. Changes include addition of accelerator-produced radioactive materials or discrete sources of radium-226 to NRC-regulated Radiation Safety Program?
- F. Changes include authorization to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium [10 CFR 30.32(j)]?

**[The following redline additions to the “Use by Authorized Individuals” section of Appendix L reflect changes to 10 CFR 35.57 including a numbering change and provision to grandfather individuals that were certified by boards listed in NRC regulations prior to March 30, 2005, and the change to 10 CFR 35.433 adding individuals identified by 10 CFR 35.433. The “Use by Authorized Individuals” section of Appendix L begins on page L-3 of the printed copy of NUREG-1556, Vol. 9, Rev. 2]**

### **Use by Authorized Individuals**

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

- A. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59] (**Note:** Does not apply to facilities that are registered with FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a) or registered with the State as a drug manufacturer or PET drug production facility with distribution regulated under 10 CFR 32.72):
  - \_\_\_\_\_ 1. Certified by specialty board?
  - \_\_\_\_\_ 2. Identified on NRC or Agreement State license?
  - \_\_\_\_\_ 3. Identified on permit issued by broad-scope or master materials licensee?
  - \_\_\_\_\_ 4. Identified on permit issued by master materials permittee of broad scope?
  - \_\_\_\_\_ 5. Identified as an ANP by a commercial nuclear pharmacy that has been authorized to identify ANPs?
  - \_\_\_\_\_ 6. Designated as an ANP in accordance with 10 CFR 32.72(b)(4)?
  - \_\_\_\_\_ 7. Meets requirements in 35.57(a)(4~~3~~)?
  - \_\_\_\_\_ 8. Listed on facility license?
- B. Authorized User [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690]:
  - \_\_\_\_\_ 1. Certified by specialty board whose certification process has been recognized under 10 CFR 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a)?

- 2. Identified on NRC or Agreement State license?
  - 3. Identified on permit issued by broad-scope or master materials licensee?
  - 4. Identified on permit issued by master materials permittee of broad scope?
  - 5. Meets requirements in 35.57(b)(2) or (b)(3)?
  - 6. Listed on facility license?
- C. Authorized Medical Physicist [35.51, 35.57, 35.59]:
- 1. Certified by specialty board whose certification process has been recognized under 10 CF 35.51(a)?
  - 2. Identified on NRC or Agreement State license?
  - 3. Identified on permit issued by broad-scope or master materials licensee?
  - 4. Identified on permit issued by master materials permittee of broad scope?
  - 5. Meets requirements in 35.57(a)(3) or (a)(4)?
  - 6. Listed on facility license?
- D. Individual identified in 10 CFR 35.433
- 1. Is an AMP?
  - 2. Meets requirements in 10 CFR 35.433(a)(2)?
  - 3. Listed on facility license?
- E. Nonmedical use authorized users [30.33(a)(3)]:
- Listed on facility license for same materials and uses?

**[The following redline additions to the “Notifications Since Last Audit” section of Appendix L reflect the changes to 10 CFR 35.24 and 35.433 adding an Associate Radiation Safety Officer and individuals identified in 10 CFR 35.433. The “Notifications Since Last Audit” section of Appendix L appears on page L-5 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]**

#### **Notifications Since Last Audit [35.14]**

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

- C. NRC notified within 30 days after: AU, ANP, AMP, individual identified in 10 CFR 35.433, or RSO/ARSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 10 CFR 35.100 or 35.200 use, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from a PET radionuclide production area; the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number [35.14(b)]?

**[The following redline/strikeout revisions to the “Training, Retraining and Instructions to Workers” section of Appendix L reflect the change to 10 CFR 35.610 requiring vendor operational and safety training to be provided prior to the first use of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit. The “Training, Retraining, and Instructions to Workers” section of Appendix L begins on page L-5 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]**

### **Training, Retraining, and Instructions to Workers**

- A. Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?
- B. Have workers been informed of NRC's regulatory authority for accelerator-produced radioactive materials and discrete sources of radium-226?
- C. Is the individual's understanding of current procedures and regulations adequate?
- D. Is the training program implemented?
1. Operating procedures [35.27, 35.310, 35.410, 35.610]?
  2. Emergency procedures [35.27, 35.310, 35.410, 35.610]?
  3. Periodic training required and implemented [35.310, 35.410, 35.610]?
  4. Vendor operational and safety training provided prior to first patient treatment of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit [35.610]?
54. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [19.12]?
65. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [35.27]?
76. Are initial and periodic training records maintained for each individual [35.2310]?

87. Briefly describe training program.
- E. Do additional therapy device instructions/training include:
1. Unit operation, inspection, associated equipment, survey instruments?
  2. License conditions applicable to the use of the unit?
  3. Emergency drills [35.610]?
- F. 10 CFR Part 20 – Are workers cognizant of requirements for:
1. Radiation Safety Program [35.24, 35.26, 20.1101]?
  2. Annual dose limits [20.1201, 20.1301, 20.1302]?
  3. NRC Forms 4 and 5?
  4. 10% monitoring threshold [20.1502]?
  5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
  6. “Grave Danger” Posting [20.1902(c)]?
  7. Procedures for opening packages [20.1906]?
- G. Is supervision of individuals by AU and/or ANP in accordance with 10 CFR 35.27?

**[The following redline/strikeout revisions to the “Dose or Dosage Measuring Equipment” section of Appendix L reflect the change to 10 CFR 35.204 requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The “Dosage or Dosage Measuring Equipment” section of Appendix L begins on page L-7 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]**

### **Dose or Dosage Measuring Equipment**

- A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [35.60] or PET radioactive drugs produced by licensee [30.34(j)]:
1. Types of equipment listed?
  2. Approved procedures for use of instrumentation followed?
  3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer’s instructions?
  4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer’s instructions (e.g.,  $\pm 10\%$ )?
  5. Records maintained and include required information [35.2060]?

- B. Determination of dosages of unsealed byproduct material [35.63, 30.34(j)]?
1. Each dosage determined and recorded prior to medical use [35.63(a)]? Or transfer [30.34(j)]?
  2. Measurement of unit dosages of photon- or beta-emitting radionuclides made either by direct measurement or by decay correction [35.63(b), 30.34(j)(2)(ii)]?
  3. Measurement of unit dosage of alpha-emitting radionuclide by decay correction of the activity provided by the producer licensed in accordance with 10 CFR 32.72 or 30.32(j)?
  4. For other than unit dosages of photon- or beta-emitting radionuclides, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [35.63(c), 30.34(j)(2)(ii)]?
  5. For other than unit dosages of alpha-emitting radionuclide, measurement made by combination using the activity provided by the producer licensed in accordance with 10 CFR 32.72, or 30.32(j) volumetric measurement, and calculation [35.63(c)]?
- C. Licensee uses generators?
1. ~~Each~~First eluate ~~after receipt~~ tested for Mo-99 breakthrough [35.204(b)]?
  2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15  $\mu$ Ci per mCi of Tc-99m [35.204(a)(1)]?
  3. ~~Before first patient use of the day~~First eluate ~~after receipt~~ tested for strontium-82 and strontium-85 when eluting rubidium-82 [35.204(c)]?
  4. No radiopharmaceuticals administered with strontium-82 concentrations over 0.02  $\mu$ Ci per mCi of rubidium-82 or strontium-85 concentrations over 0.2  $\mu$ Ci per mCi of rubidium-82 [35.204(a)(2)]?
  5. Each measurement that exceeds the limits in paragraph 2 or 4 above reported to NRC in accordance with § 35.3204?
  6. Records maintained [35.2204]?
- D. Dosimetry Equipment [35.630]:
1. Calibrated system available for use [35.630(a)]?
  2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 10 CFR 35.630(a)(2)?
  3. Calibrated within the previous 4 years [35.630(a)(2)]?
  4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?

5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

**[The following redline/strikeout revisions to the “Teletherapy and Gamma Stereotactic Radiosurgery” section of Appendix L reflect the change to 10 CFR 35.655 updating the intervals at which full-inspection servicing is required for teletherapy and gamma stereotactic radiosurgery units. The “Teletherapy and Gamma Stereotactic Radiosurgery Servicing” section of Appendix L appears on page L-13 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]**

### **Teletherapy and Gamma Stereotactic Radiosurgery **Full-inspection** Servicing**

- A. **Full inspection and servicing performed following source replacement or at intervals not to exceed 5 years for each teletherapy unit and not to exceed 7 years for each gamma stereotactic radiosurgery unit [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)]?

**[The following redline/strikeout revisions to the “Notification and Reports” section of Appendix L reflect the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The “Notifications and Reports” section of Appendix L appears on page L-19 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]**

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

- A. In compliance with 10 CFR 19.13, and 10 CFR 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?
- B. In compliance with 10 CFR 20.2201, and 10 CFR 30.50 (theft or loss)?
- C. In compliance with 10 CFR 20.2202, and 10 CFR 30.50 (incidents)?
- D. In compliance with 10 CFR 20.2203, and 10 CFR 30.50 (overexposure and high radiation levels)?
- E. In compliance with 10 CFR 35.204(e) (generator eluate that exceeds breakthrough levels)?**
- ~~F.~~ Aware of NRC Operations Center telephone number?

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

**[The following redline/strikeout revisions to Appendix S reflect the change to 10 CFR 35.40 adding separate written directive requirements for permanent implant brachytherapy.]**

## **Appendix S**

### **Model Procedures for Developing, Maintaining, and Implementing Written Directives**

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

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

#### **Written Directive Procedures**

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

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

#### **Discussion**

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of

measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

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

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

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

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

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

- An AU must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.

- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

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

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

- A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.
- B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).
- C. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:
  1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).

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

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

- D. After implantation but before completion of the procedure, **as required by 10 CFR 35.40(b)(6), record in the WD: For temporary implants, record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose); For permanent implants, the number of sources and the total source strength; For either, the signature of an AU for §35.400 uses for manual brachytherapy and the date.** ~~For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength.~~ The WD may be maintained in the patient's chart.
- E. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.
- F. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
  1. An individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51) using a dosimetry system other than the

one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630); or

2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.
- G. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.
- H. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- I. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.
- J. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

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

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

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

As required by 10 CFR 35.41, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment

plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

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

Notify by telephone the NRC Operations Center<sup>1</sup> 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.

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<sup>1</sup>The commercial telephone number of the NRC Operations Center is (301) 816-5100. The Center will accept collect calls.

[The following redline/strikeout revision to Appendix X reflects the change to 10 CFR 35.655 updating the intervals at which full-inspection servicing is required for teletherapy and gamma stereotactic radiosurgery units.]

## Appendix X

### Recordkeeping Requirements

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

<b>Record</b>	<b>Survey Requirement</b>	<b>Recordkeeping Requirement</b>	<b>Retention Period</b>
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

**Table X.1 Typical Records and Retention Times**

<b>Record</b>	<b>Survey Requirement</b>	<b>Recordkeeping Requirement</b>	<b>Retention Period</b>
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

**Table X.1 Typical Records and Retention Times (continued)**

<b>Record</b>	<b>Survey Requirement</b>	<b>Recordkeeping Requirement</b>	<b>Retention Period</b>
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
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

**Table X.1 Typical Records and Retention Times**

<b>Record</b>	<b>Survey Requirement</b>	<b>Recordkeeping Requirement</b>	<b>Retention Period</b>
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 or strontium-82 or strontium-85 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

**Table X.1 Typical Records and Retention Times**

<b>Record</b>	<b>Survey Requirement</b>	<b>Recordkeeping Requirement</b>	<b>Retention Period</b>
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
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
<del>5-year inspection</del> Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit

[The following redline addition to Appendix Y reflects the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a).]

## Appendix Y

### Reporting Requirements

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

<b>Event</b>	<b>Telephone Notification</b>	<b>Written Report</b>	<b>Regulatory Requirement</b>
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)

**Table Y.1 Typical NRC Notifications and/or Reports**

<b>Event</b>	<b>Telephone Notification</b>	<b>Written Report</b>	<b>Regulatory Requirement</b>
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)
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)

**Table Y.1 Typical NRC Notifications and/or Reports**

<b>Event</b>	<b>Telephone Notification</b>	<b>Written Report</b>	<b>Regulatory Requirement</b>
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 10 CFR 35.100 or 35.200 use of byproduct material identified in application or license if the change or addition did not involve movement of a PET radionuclide production facility or transfer line from a PET radionuclide production facility	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
Eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	1 day	15 days	10 CFR 35.3204

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

## **PART 2**

**Draft Supplemental Guidance for NUREG-1556,  
Volume 13, Revision 1, Consolidated Guidance About  
Materials Licenses: Program-Specific Guidance About  
Commercial Radiopharmacy Licenses**

**The following redline/strikeout changes Section 8.6.1 reflect new Mo-99 breakthrough reporting requirements for generator manufacturer/distributors in 10 CFR 30.50**

## **8.6.1 DISTRIBUTION AND REDISTRIBUTION OF SEALED AND UNSEALED MATERIALS**

**Regulations:** 10 CFR 30.41, **10 CFR 30.50**, 10 CFR 32.71, 10 CFR 32.72, and 10 CFR 32.74.

**Criteria:** The applicant must specify the radioactive material it intends to distribute and redistribute.

**Discussion:** Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a non-10 CFR 32.72 supplier (chemical grade materials). Radioactive drugs are those materials suitable for human use and include radiobiologics (e.g., monoclonal antibodies and technetium-99m-tagged red blood cells) and radiopharmaceuticals. However, the terms, “radiopharmaceutical” and “radioactive drug” will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either “distribution” or “redistribution.” “Distribution” applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. “Redistribution” refers to those materials received from another person, authorized pursuant to either 10 CFR 32.71, 10 CFR 32.72, or 10 CFR 32.74, depending on the product distributed (i.e., *in vitro* kits, other radiopharmaceuticals, or sealed sources for medical use, respectively).

The distribution of radioactive materials to other persons requires specific approval from NRC, either by NRC regulation or by a license authorizing the activity. The initial distribution of radioactive drugs for medical use must be prepared by a person licensed pursuant to 10 CFR 32.72. The redistribution of *in vitro* kits and sealed sources containing byproduct material for medical use is authorized pursuant to 10 CFR 32.71 and 10 CFR 32.74, respectively, provided that the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to 10 CFR 32.71 or 10 CFR 32.74, respectively. The transfer of radioactive materials for nonmedical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to 10 CFR 30.41.

All radioactive material listed above shall be distributed only to persons authorized by an NRC or Agreement State license to receive such materials, or by a general license (10 CFR 31.11, or equivalent Agreement State regulation) to receive *in vitro* test materials.

Initial distribution of unsealed byproduct material in the form of radiopharmaceuticals intended for human diagnostic and therapeutic use by medical licensees comprises the bulk of virtually all radiopharmacy activities. Prior to the transfer, distribution, or redistribution of any licensed material, the radiopharmacy must verify that the transferee’s license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. The pharmacy should verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer’s license. Five methods that can be used to meet the license verification

requirement are listed in 10 CFR 30.41(d). The most common form of verification is for the radiopharmacy to possess a valid copy of the customer's NRC or Agreement State license or other applicable document (e.g., *in vitro* registration certificate/NRC Form 483).

**Response From Applicant:** Provide the following, as applicable:

For radiopharmaceuticals:

- Confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and
- Describe all licensed material to be distributed or redistributed.

For generators:

- Confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and
- Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For redistribution of used generators:

- Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport;
- Confirm that the manufacturer's packaging and labeling will not be altered;
- Confirm that the generator will not be distributed beyond the expiration date shown on the generator label;
- Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator;
- Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed: and
- Confirm that there are procedures to ensure that reports required by 10 CFR 30.50 are made for redistributed used generators when notified that a generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m);

**Note:** Although redistribution of used generators may be authorized by NRC, NRC approval does not relieve the licensee from complying with applicable Food and Drug Administration (FDA) or other Federal and State requirements.

For redistribution of sealed sources — for brachytherapy or diagnosis:

- Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed

sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74, or under equivalent Agreement State requirements; and

- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of calibration and reference sealed sources:

- Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements, to initially distribute such sources; and
- Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of prepackaged units for *in vitro* tests:

- Confirm that the prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 10 CFR 32.71, or under an equivalent license of an Agreement State.

For redistribution to general licensees:

- Confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way; and
- Confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

For redistribution to specific licensees:

- Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11); and
- Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 10 CFR 20.1901 and 20.1904.

For redistribution of discrete sources of radium-226:

- Confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute it.
- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing sources.
- If the above cannot be confirmed, contact the appropriate NRC Regional Office for assistance.

**The following redline/strikeout changes for Section 8.7.2. reflect the changes to 10 CFR 35.55 removing the preceptor attestation requirement from the nuclear pharmacist board certification pathway and changes to the attestation statement for the alternate training and experience pathway.**

## **8.7.2 AUTHORIZED NUCLEAR PHARMACIST (ANP)**

**Regulations:** 10 CFR 32.72 (b)(2), (4), and (5); 10 CFR 35.2; 10 CFR 35.55(a) and (b); and 10 CFR 35.59.

**Criteria:** The ANP must be a State-licensed or State-registered pharmacist with adequate training and experience.

**Discussion:** Each commercial nuclear pharmacy must have an ANP to prepare or supervise the preparation of radioactive drugs for medical use. An individual who is not qualified to be an ANP may work under the supervision of an ANP.

The criteria for a pharmacist to work as an ANP at a commercial radiopharmacy are described in 10 CFR 32.72(b)(2) and (4). This section of the regulation refers to the training for an ANP, which includes the definition of an ANP in 10 CFR 35.2 (which in turn includes the board certification requirements in 10 CFR 35.55(a)); the training and experience criteria for the alternate pathway described in 10 CFR 35.55(b); and the recentness of training criteria in 10 CFR 35.59 that requires the successful completion of training within 7 years preceding the date of the application. Additional training and experience may be necessary if the time interval is greater than 7 years. Applicants may find it convenient to present this documentation using NRC Form 313A (ANP) in Appendix G. Each hour of training may be listed only once, (i.e., under the most applicable category). The recentness of training requirements apply to board certification as well as to other recognized training pathways.

In implementing the EPA Act, NRC "grandfathered" nuclear pharmacists by permitting the licensee to designate a pharmacist as an ANP, if the pharmacist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, in the practice of nuclear pharmacy for the uses performed before November 30, 2007, or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 32.72(b)(2)(i) or (ii). However, the applicant must document that the individual meets the criteria in 10 CFR 32.72(b)(4).

On-the-job training may not be counted toward the hours listed above unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to NRC upon request;
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to NRC upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile; and
- A permanent record that the student successfully completed the course is kept at the institution.

**Response from Applicant:** For each proposed ANP, provide the following:

- Name of the proposed ANP.

**AND**

- Pharmacist's license number and issuing entity.

*For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)):*

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Material License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs,

**OR**

*For an individual qualifying under 10 CFR 32.72(b)(4):*

- Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material,

**AND**

- Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC,

**OR**

*For an individual qualifying under 10 CFR 35.55(a):*

- Copy of the certification(s) of the specialty board whose certification process has been recognized<sup>2</sup> under 10 CFR 35.55(a),
- ~~Written attestation, signed by a preceptor ANP, that training and experience required for certification have 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.

**OR**

*For an individual qualifying under 10 CFR 32.72(b)(2)(ii):*

- Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience,
- Written attestation, signed by a preceptor ANP, that **the individual has satisfactorily completed the training and experience requirements in 10 CFR 35.55(b)(1)** certification ~~have has been satisfactorily completed and is able that a level of competency sufficient to function independently fulfill the radiation safety-related duties as an ANP has been achieved,~~

**AND**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

**Notes:**

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b).
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2) are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.

The following redline changes to Section 8.10.6 reflect revisions to 10 CFR 30.34(g) and 35.204 adding new molybdenum-99/technetium-99m generator elution test frequencies and new reporting requirements when the Molybdenum-99/technetium-99m and strontium-82/rubidium-82 generator elution exceed breakthrough values.

## 8.10.6 SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES

**Regulations:** 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201, 10 CFR 20.2202, 10 CFR 20.2203, 10 CFR 30.34(g), 10 CFR 30.50, 10 CFR 19.11(a)(3).

**Criteria:** Licensees are required to do the following:

- Keep radiation doses to workers and members of the public ALARA;
- Ensure security of licensed material; and
- Make the required notifications of events to NRC.

**Discussion:** Licensees are responsible for the security and safe use of all licensed material from the time it arrives or is produced at their facility until its use, transfer, and/or disposal. Licensees should develop written procedures to ensure safe use of licensed material, and the procedures should also include operational and administrative guidelines, **as well as procedures to assure reports of events are made promptly and completely in accordance with reporting requirements.** The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

### General Safety Procedures

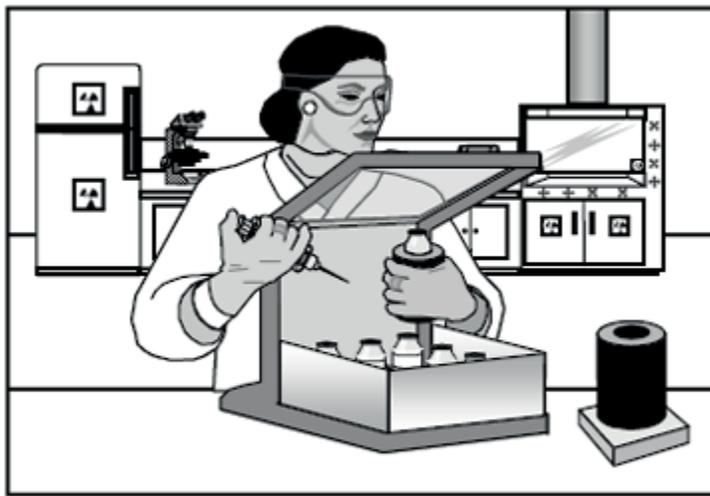
The written procedures should include the following elements:

- Contamination controls;
- Waste disposal practices;
- Personnel and area monitoring (including limits);
- Use of protective clothing and equipment;
- Safe handling of radioactive materials;
- Recording requirements;
- Reporting requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Performing molybdenum-99 breakthrough measurements on **each** ~~the first eluate after receipt~~ of a molybdenum-99/technetium-99m generator;

- Reporting to NRC when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate;
- The reporting requirements in 10 CFR 30.50 if notified that a redistributed used generators generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m);
- Use of appropriate shielding (see Figure 8.8);
- Frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the facility; and
- Special procedures for higher risk activities, such as use of radioiodine and repair of chemistry synthesis equipment for PET radiopharmaceuticals.



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**Figure 8.8 Use of Appropriate Shielding.**

Applicants should also develop radionuclide-specific procedures based on the respective hazards associated with the radionuclides. General safety guidelines are described in Appendix Q. Applicants should use these guidelines to aid in the development of their own procedures for the safe use of radionuclides.

Furthermore, applicants that produce radioactive materials using an accelerator should also refer to the safety procedures found in NUREG-1556, Vol. 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator."

Licensees should determine if they have areas that require posting in accordance with 10 CFR 20.1902, unless they meet the exemptions listed in 10 CFR 20.1903. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 10 CFR 20.1904, unless they meet the exemptions in 10 CFR 20.1905.

## **Emergency Procedures**

Accidents and emergencies can happen during any operation with radionuclides, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, and fires involving radioactive material, can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize, to the extent practical, the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the RSO. In addition, the licensee should develop procedures for routine contacts with its local fire department officials to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with step-by-step instructions and clear direction of whom to contact. The licensee should establish clear delineations between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix Q includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

Certain incidents and emergencies require notification of NRC. Appendix T provides a list of major NRC reporting and notification requirements relevant to commercial radiopharmacies.

**Response from Applicant:** Submit the following statement:

"We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:

- Facility and personnel radioactive contamination minimization, detection, and control;
- Performing molybdenum-99 breakthrough measurements on ~~each the first eluate of the after receipt of the~~ molybdenum-99/technetium-99m generator;
- ~~Reporting under the requirements in 10 CFR 30.34(g) if there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in an elution;~~
- ~~Reporting under the requirements in 10 CFR 30.50 if notified that a redistributed used generators generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); and~~
- Use of protective clothing and equipment by personnel

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), ~~10 CFR 35.50~~ and 10 CFR 19.11(a)(3), as applicable;"

**AND**

"We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:

- Lost, stolen, or missing licensed material;
- Exposures to personnel and the public in excess of NRC regulatory limits;
- Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits;
- Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas;
- Radioactive spills and contamination;
- Fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and
- Routine contacts with local fire departments and local law enforcement agencies (LLEA),

that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 30.50, and other requirements, as applicable;"

**The following redline revisions to Section 8.10.8 reflect the conforming changes needed for commercial nuclear pharmacies that prepare radiopharmaceuticals used primarily for their alpha emitting radiation characteristics in response to the revision of 10 CFR 35.390(b)(1)(G)(4) to specifically include these radionuclides.**

## **8.10.8 DOSAGE MEASUREMENT SYSTEMS**

**Regulation:** 10 CFR 32.72(c).

**Criteria:** Commercial radiopharmacy licensees must possess and use instrumentation capable of accurately measuring the radioactivity in radioactive drugs.

**Discussion:** Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured prior to transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request.

The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by a combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, gamma-, or photon-emitting radioactive drugs prior to their transfer for commercial distribution.

These procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. This is accomplished by performing periodic checks and tests prior to first use, followed by checks at specified intervals, and following repairs that could affect system performance. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured. For most photon-emitters, activity measurement is a fairly straightforward determination; however, for **low energy photon-, beta-emitters, and alpha-emitters** a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of **low-energy photon-, beta- and alpha-correction** factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST)-traceable standard for all radionuclides currently in use. If radiopharmacies intend to initially distribute ( i.e., measure, prepare, and label) **low-energy photon-, beta-, and alpha-emitting** radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use **low-energy photon-, beta-, and alpha-**correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor. If radiopharmacy applicants intend to only redistribute **low-energy photon-, beta-, and alpha-emitting** radionuclides that have been previously prepared and distributed by other persons licensed pursuant to 10 CFR 32.72, then the correction factor calculation is not required.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded

that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix O contains a model procedure for dose calibrator testing.

**Response from Applicant:** The applicant shall describe the types of systems (measurement or combination of measurement and calculation) it intends to use for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;

**AND**

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";

**AND**

If applicable, e.g., when dose calibrators are used to measure photon emissions associated with beta or alpha emissions, the applicant must include a sample calculation for determining **low-energy photon**, beta-, and alpha-correction factors for dose calibrators with ionization chambers;

Radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) **low-energy photon**-, beta-, and alpha-emitting radionuclides must provide the calculation to demonstrate its ability to accurately dispense such materials; however, a correction factor calculation is not required if radiopharmacy applicants intend to only redistribute **low-energy photon**-, beta- or alpha-emitting radionuclides that were previously prepared and distributed by others who are licensed pursuant to 10 CFR 32.72.

**OR**

If applicable, the applicant must include a means for ensuring the accuracy of **low-energy photon**-, beta-, and alpha-correction factors supplied by the instrument manufacturer, or other entity.

**The following red line changes in Section 9 are conforming change to recognition that the medical use license does not need to submit 2 copies of the NRC 313 and when submitting a letter it must contain all the information included in the NRC Form 313.**

## **9 AMENDMENTS AND RENEWALS TO A LICENSE**

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place; however, in accordance with 10 CFR 32.72(b)(5), commercial radiopharmacy licensees may allow individuals not named on their licenses to work as ANPs, provided that the individuals meet the minimum training and experience requirements of 10 CFR 32.72(b)(2) or (4), and the licensee notifies NRC in writing, with the documentation specified in 10 CFR 32.72(b)(5), as applicable, no later than 30 days after the licensee allows the individual to work as an ANP. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Applications for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request;
- Submit ~~in duplicate~~, either an NRC Form 313 or a letter **containing all the information required in the NRC Form 313** requesting amendment or renewal;
- Provide the license number and docket number;
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or its Radiation Protection Program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions; and
- If a renewal is requested, provide the appropriate fee.

**Using the suggested wording of responses and committing to using the model procedures in this report will expedite NRC's review.**

Redline/strikeout revisions are shown below for several sections of Appendix C. An explanation is provided in at the beginning of each section.

## APPENDIX C

### Suggested Format for Providing Information Requested in Items 5 through 11 of NRC Form 313

[The following redline revision to the Item 6, “Purpose(s) for which licensed material will be used,” section of Appendix C reflects the change to 10 CFR 30.50 requiring generator manufacturers/distributors to report to NRC when they are notified of Mo-99 breakthrough under the provision of 10 CFR 35.3204(a). The Item 6, “Purpose(s) for which licensed material will be used,” section of Appendix C starts on page C-2 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

Item No.	Title and Criteria	Yes	Description Attached
6.	<p><b>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</b></p> <p>For radiopharmaceuticals:</p> <ul style="list-style-type: none"> <li>• We confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72; and</li> <li>• Describe all licensed material to be distributed or redistributed.</li> </ul> <p>For generators:</p> <ul style="list-style-type: none"> <li>• We confirm that the generators will be obtained from a manufacturer licensed pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and</li> <li>• We confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.</li> </ul> <p>For redistribution of used generators:</p> <ul style="list-style-type: none"> <li>• Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of</li> </ul>	<input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>  <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>  <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>	<input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>  <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>  <input type="checkbox"/> <hr style="width: 50%; margin: 0 auto;"/>

	<p>migration of radioactive fluids out of the generator during transport;</p> <ul style="list-style-type: none"> <li>• We confirm that the manufacturer's packaging and labeling will not be altered;</li> <li>• We confirm that the generator will not be distributed beyond the expiration date shown on the generator label;</li> <li>• We confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator; and</li> <li>• We confirm that only generators used in accordance with the manufacturer's instructions will be redistributed; and</li> <li>• We confirm that we have procedures to ensure that reports required by 10 CFR 30.50 are made for redistributed used generators when notified that a generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m);</li> </ul>	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	
6.	<b>PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED (Cont.)</b>		
	<p>For Redistribution of Sealed Sources -- for Brachytherapy or Diagnosis:</p> <ul style="list-style-type: none"> <li>• We confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements; and</li> <li>• We confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.</li> </ul> <p>For Redistribution of Calibration and Reference Sealed Sources:</p> <ul style="list-style-type: none"> <li>• We confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a</li> </ul>	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	

<p>person licensed pursuant to 10 CFR 32.74 to initially distribute such sources; and,</p> <ul style="list-style-type: none"> <li>We confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.</li> </ul>	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	
<p>For Redistribution of Prepackaged Units for <i>In Vitro</i> Tests:</p> <ul style="list-style-type: none"> <li>We confirm that the prepackaged units for <i>in vitro</i> tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for <i>in vitro</i> tests in accordance with a specific license issued pursuant to 10 CFR 32.71 or under an equivalent license of an Agreement State.</li> </ul>	<hr/> <input type="checkbox"/> <hr/>	
<p>For Redistribution to General Licensees:</p> <ul style="list-style-type: none"> <li>We confirm that the manufacturer's packaging and labeling of the prepackaged units for <i>in vitro</i> tests will not be altered in any way; and</li> <li>We confirm that each redistributed prepackaged unit for <i>in vitro</i> tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.</li> </ul>	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	
<p>For Redistribution to Specific Licensees:</p> <ul style="list-style-type: none"> <li>We confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for <i>in vitro</i> tests will NOT reference general licenses, exempt quantities, or NRC's regulations that authorize a general license (e.g., 10 CFR 31.11); and</li> <li>We confirm that the labeling on redistributed prepackaged units for <i>in vitro</i> tests will conform to the requirements of 10 CFR 20.1901 and 20.1904.</li> </ul>	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	
<p>For Redistribution to Discrete Sources of radium-226:</p> <ul style="list-style-type: none"> <li>We confirm that the discrete sources of radium-226 will be obtained by a manufacturer authorized to distribute it.</li> <li>We confirm that the manufacturer's packaging, labeling, and</li> </ul>	<hr/> <input type="checkbox"/> <hr/>	



	<p>[The following redline/strikeout revision to the Item 7, “Individual(s) responsible for radiation safety program and their training and experience,” section of Appendix C reflects the change to 10 CFR 35.55 removing the preceptor attestation requirement from the nuclear pharmacist board certification pathway and changes to the attestation statement for the alternate training and experience pathway. The Item 7, “Individual(s) responsible for radiation safety program and their training and experience,” section of Appendix C starts on page C-5 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</p>		
7.	<p><b>INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE</b></p> <p>For applicant's management structure, provide:</p> <ul style="list-style-type: none"> <li>• An organizational chart describing the management structure, reporting paths, and flow of authority between executive management and the RSO.</li> </ul> <p><b>For the Radiation Safety Officer (RSO), provide:</b></p> <ul style="list-style-type: none"> <li>• Name of the proposed RSO;</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p>A copy of the license (NRC or Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO, an ANP, or an AU;</p> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>• Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.</li> </ul> <p><b>Note:</b> See Appendix G for convenient formats to use for documenting hours of training in basic radioisotope handling techniques and hours of experience using radioisotopes.</p> <p><b>For each proposed Authorized Nuclear Pharmacist (ANP), provide the following:</b></p> <ul style="list-style-type: none"> <li>• Name of the proposed ANP;</li> </ul> <p style="text-align: center;"><b>AND</b></p>	<input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/> <input type="checkbox"/> <hr/>	

- Pharmacist's license number and issuing entity;

**AND**

*For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs (10 CFR 32.72(b)(2)(i)):*

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

**OR**

*For an individual qualifying under 10 CFR 32.72(b)(4):*

- Documentation that the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material,

**AND**

- Documentation that the individual practiced at a pharmacy, a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

**OR**

*For an individual qualifying under 10 CFR 35.55(a):*

- Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a);

**AND**

- ~~Written attestation, signed by a preceptor ANP, that training and experience required for certification have 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.



**OR**

*For an individual qualifying under 10 CFR 32.72(b)(2)(ii):*

- 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 individual has the training and experience required for certification have been~~ satisfactorily completed **the requirements in 10 CFR 35.55(b)** and ~~is able that a level of competency sufficient to function independently~~ **fulfill the radiation safety-related duties** as an ANP ~~has been achieved~~;



**AND**

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.



**Notes:**

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b).
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2), are met. If the training and experience do not appear to meet the criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

**For each proposed Authorized User (AU), provide the following:**

- Name of each proposed AU;



**AND**

- Types, quantities, and proposed uses of licensed material;

**AND**

- A copy of license (NRC or Agreement State) on which the individual was specifically named as an AU for the types, quantities, and proposed uses of licensed materials;



**OR**

- A copy of the permit maintained by a licensee of broad scope that identifies the individual as an AU for the types, quantities, and proposed



	<p>uses of licensed materials;</p> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"><li>• Description of the training and experience demonstrating that the proposed AU is qualified by training and experience to use the requested licensed materials. The applicant may find it convenient to describe this training and experience using a format similar to Tables G-1 and G-2 in Appendix G.</li></ul>		<input type="checkbox"/> <input type="checkbox"/>
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	<p><b>[The following redline/strikeout revision to the Item 10, “Radiation Safety Program, Safe Use of Radionuclides and Emergency Procedures,” section of Appendix C reflects the changes to 10 CFR 35.204 increasing the frequency for performing the Mo-99 breakthrough test and 10 CFR 35.3204 Mo-99 breakthrough reporting requirements. The Item 10, “Radiation Safety Program, Safe Use of Radionuclides and Emergency Procedures,” section of Appendix C starts on page C-12 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</b></p>	
10.		
	<p><b>Safe Use of Radionuclides and Emergency Procedures</b></p> <p>We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:</p> <ul style="list-style-type: none"> <li>• facility and personnel radioactive contamination minimization, detection, and control;</li> <li>• performing molybdenum-99 breakthrough measurements on <b>all the first eluate after receipt</b> of the molybdenum-99/technetium-99m generator; and</li> <li>• <b>Reporting to NRC when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate;</b></li> <li>• <b>Reporting under the requirements in 10 CFR 30.50 if notified that a redistributed used generators generator elution exceed 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m)and</b></li> <li>• use of protective clothing and equipment by personnel</li> </ul> <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), and 10 CFR 19.11(a)(3), as applicable;</p> <p style="text-align: center;"><b>AND</b></p> <p>We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:</p> <ul style="list-style-type: none"> <li>• lost, stolen, or missing licensed material;</li> <li>• exposures to personnel and the public in excess of NRC regulatory limits;</li> <li>• releases of licensed materials in effluents and the sanitary sewer in</li> </ul>	<p><input type="checkbox"/></p> <hr/> <p><input type="checkbox"/></p>

	<p>excess of NRC regulatory limits;</p> <ul style="list-style-type: none"><li>• excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas;</li><li>• radioactive spills and contamination;</li><li>• fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and</li><li>• routine contacts with local fire departments and local law enforcement agencies.</li></ul> <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203, and 10 CFR 30.50 and other requirements, as applicable.</p>		
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**[The following redline revision to the Item 10, "Radiation Safety Program, Dosage Measurements Systems," section of Appendix C reflects conforming changes for the radiopharmacy from the revision of 10 CFR 35.390 with the addition alpha emitters. The Item 10, "Radiation Safety Program, Dosage Measurements Systems," section of Appendix C starts on page C-13 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]**

**Dosage Measurement Systems**

Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;

**AND**

For each dose measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma-, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";

**AND**

If applicable, include a sample calculation for determining low-energy photon-, beta-, and alpha-correction factors for dose calibrators with ionization chambers;

**OR**

If applicable, include a means for ensuring the accuracy of low-energy photon-, beta-, and alpha-correction factors supplied by the instrument manufacturer or other entity.

Redline/strikeout revisions are shown below for several sections of Appendix D. An explanation is provided in at the beginning of each section.

## APPENDIX D

### Checklist for License Application

[The following redline/strikeout revision to the D.5 Items 5 & 6 : “Materials to be possessed and proposed uses,” section of Appendix D corrects a citation in 10 CFR Part 35 for calibration and reference sources. The D.5 Items 5 & 6 :” Materials to be possessed and proposed uses,” section of Appendix D starts on page D-1 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

#### D.5 ITEMS 5 & 6 : MATERIALS TO BE POSSESSED AND PROPOSED USES

Yes	No	Radioisotope	Form or Mfg/Model No.	Quantity	Purpose of Use	Specify Other Uses Not Listed on SSD Certificate
		Byproduct Materials with Atomic No. 1-83	Any	_____millicuries per nuclide, 1 curie total possession, except as noted:	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
		Molybdenum-99	Any	_____curies	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:

	Technetium-99m	Any	_____curies	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Iodine-131	Any	_____millicuries	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Fluorine-18	Any	_____millicuries	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Iodine-123	Any	_____millicuries	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Xenon-133	Any	_____curies	10 CFR 32.72 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Any Byproduct Material in a Brachytherapy	Sealed Sources	_____millicuries	10 CFR 32.74 and 10 CFR 30.41	<input type="checkbox"/> Not applicable

	Source, as listed in 10 CFR 35.400				----- [ ] Uses are:
	Any Byproduct Material in a sealed source for diagnosis, as listed in 10 CFR 35.500	Sealed Sources	_____ curies per source and curies total	10 CFR 32.74 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Any byproduct material listed in 10 CFR 31.11(a)	Prepackaged units for <i>in vitro</i> diagnostic tests	_____ millicuries	10 CFR 31.11	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Any byproduct material authorized under 10 CFR 35.6557(a)	Sealed Sources	_____ millicuries	Calibration and checking of the licensees instruments and 10 CFR 32.74 and 10 CFR 30.41	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Depleted Uranium	Metal	_____ kilograms	Shielding for molybdenum-99/technetium-99m generators	<input type="checkbox"/> Not applicable ----- <input type="checkbox"/> Uses are:
	Cesium-137	Sealed sources in compatible device as specified in	Not to exceed maximum activity per source as specified in Sealed Source and Device Registry Sheet	Instrument calibration	<input type="checkbox"/> Not applicable -----

			Sealed Source and Device Registry Sheet			<input type="checkbox"/> Uses are:
		Other (specify)				





*For an individual qualifying under 10 CFR 35.55(a):*

- Copy of the certification(s) of the specialty board whose certification process has been recognized under 10 CFR 35.55(a);

**AND**

- ~~Written attestation, signed by a preceptor ANP, that training and experience required for certification have 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.

**OR**

*For an individual qualifying under 10 CFR 32.72(b)(2)(ii):*

- 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 training and experience required for certification have been satisfactorily completed and **is**

	<p>able that a level of competency sufficient to function independently fulfill the radiation safety-related duties as an ANP has been achieved;</p> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>• If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55(a) or (b).</li> <li>• Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR 32.72(b)(2) are met. If the training and experience do not appear to meet the criteria, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.</li> </ul>		
<p><b>7. Individual(s) Responsible for Radiation Safety Program and</b></p>	<p>For each proposed AU:</p>	<input type="checkbox"/>	<input type="checkbox"/>



	<p>[The following redline/strikeout revisions to D.10 Item 10.6: “Safe Use of Radionuclides and Emergency Procedures,” section of Appendix D reflects the changes to 10 CFR 35.204 increasing the frequency of the Mo-99 breakthrough test and 10 CFR 30.34(g) reporting requirements for Mo-99 breakthrough. The D.10 Item 10.6: “Safe Use of Radionuclides and Emergency Procedures,” section of Appendix D starts on page D-9 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</p>	
<p><b>10. Radiation Safety Program</b></p> <p><b>10.6 Safe Use of Radionuclides and Emergency Procedures</b></p>	<p>We have developed and will implement and maintain written procedures for the safe use of radioactive materials that address:</p> <ul style="list-style-type: none"> <li>• Facility and personnel radioactive contamination minimization, detection, and control;</li> <li>• Performing molybdenum-99 breakthrough measurements on <del>the first eluate after receipt of</del> all molybdenum-99/technetium-99m generator eluates;</li> <li>• Reporting to NRC when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in the eluate; and</li> <li>• Use of protective clothing and equipment by personnel</li> </ul> <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 30.34(g), and 10 CFR 19.11(a)(3), as applicable.</p> <p style="text-align: center;"><b>AND</b></p> <p>We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including:</p> <ul style="list-style-type: none"> <li>• Lost, stolen, or missing licensed material,</li> <li>• Exposures to personnel and the public in excess of NRC regulatory limits,</li> <li>• Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits,</li> <li>• Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas,</li> <li>• Radioactive spills and contamination,</li> </ul>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

	<ul style="list-style-type: none"><li>• Fires, explosions, and other disasters with the potential for the loss of containment of licensed material, and</li><li>• Routine contacts with local fire departments and local law enforcement agencies</li></ul> <p>that meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201, 20.2202, 20.2203, and 10 CFR 30.50 and other requirements, as applicable.</p>		
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	<p><b>[The following redline revisions to D.10 Item 10.8, “Dosage Measurement,” section of Appendix D reflects the conforming radiopharmacy changes resulting from adding alpha emitters in 10 CFR 35.390. D.10 Item 10.8, “Dosage Measurement,” section of Appendix D starts on page D-10 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]</b></p>		
<p><b>10. Radiation Safety Program</b></p> <p><b>10.8 Dosage Measurement Systems</b></p>	<p>Describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs;</p> <p style="text-align: center;"><b>AND</b></p> <p>For each dosage measurement system used to measure the amount of radioactivity in alpha-, beta-, gamma, or photon-emitting radioactive drugs, state: "We have developed, and will implement and maintain, a written procedure for the performance of dosage measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)";</p> <p style="text-align: center;"><b>AND</b></p> <p>If applicable, include a sample calculation for determining <b>low-energy photon-, beta-, and alpha-</b>correction factors for dose calibrators with ionization chambers;</p> <p style="text-align: center;"><b>OR</b></p> <p>If applicable, include a means for ensuring the accuracy of <b>low-energy photon-, beta-, and alpha-</b>correction factors supplied by the instrument manufacturer or other entity.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

The following redline/strikeout revisions and the revised NRC Form 313A (ANP) in Appendix G reflect the changes to the training and experience requirements in 10 CFR 32.72, and 10 CFR 35.55 for the Authorized Nuclear Pharmacist.

## APPENDIX G

### Formats for Documenting Training and Experience for Individuals Responsible for Radiation Protection Program

**Table G-1 Authorized User or Radiation Safety Officer Training in Basic  
Radioisotope Handling Techniques**

Name (Last, First, Initial)								
Location of Training	Dates	Title	Total Hours	Breakdown of Course in Clock Hours				
				RPP	BH	IR	INST	REG
			<b>TOTALS</b>					

RPP - Radiation Protection Principles

BH - Biological Hazards

IR - Ionizing Radiation Units & Characteristics

INST - Radiation Detection Instrumentation

REG - NRC Regulations and Standards

**Table G-2 Authorized User and Radiation Safety Officer Experience in Handling Radioisotopes**

**(Actual use of radioisotopes under the supervision of an authorized user or Radiation Safety Officer, respectively)**

Name (Last, First, Initial)				
Isotope(s) used	Maximum amount used at any one time	Location of use	Purpose of use*	Total Hours of Experience

**\* Description of experience**

1. Shipping, receiving, and performing related radiation surveys.
2. Using and performing checks for proper operation of dose calibrators, survey meters, and other instruments used to measure photon- and high-energy beta-emitting radionuclides.
3. Using and performing checks for proper operation of instruments used to measure alpha- and low energy beta-emitting radionuclides.
4. Calculating, assaying, and safely preparing radioactive materials.
5. Use of procedures to prevent or minimize contamination and/or use of proper decontamination procedures.

## **Documentation of Training and Experience to Identify an Individual on a License as an Authorized Nuclear Pharmacist.**

### **I. Experienced Authorized Nuclear Pharmacists**

An applicant or licensee that is adding an experienced Authorized Nuclear Pharmacist (ANP) to its commercial radiopharmacy license only needs to provide evidence that the individual is listed on a license issued by the NRC or Agreement State, a permit issued by an NRC Master Materials Licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master materials broad-scope permittee, and that the individual meets the recentness of training criteria described in 10 CFR 35.59. 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 ANP by a commercial nuclear pharmacy authorized to identify ANPs. 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. Experienced Nuclear Pharmacists Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses**

During the implementation of the EPAct, NRC "grandfathered" nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for nuclear pharmacy uses under the NRC waiver of August 31, 2005, when using these materials for the same uses. Nuclear pharmacists that used accelerator-produced radionuclides or discrete sources of Ra-226 during the effective period of the waiver do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subpart B for those materials and uses.

The applicant or licensee that is adding one of these experienced individuals to its commercial nuclear pharmacy license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, for nuclear pharmacy uses during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

### **III. Applications that Include Individuals for Authorized Nuclear Pharmacist Recognition by NRC**

Applicants should submit NRC Form 313A (ANP) to show that the individual meets the correct training and experience criteria in 10 CFR Part 35, Subpart B. There are two primary training and experience routes to qualify an individual as an ANP. The first is by

means of certification by a board recognized by NRC and listed on the NRC website (<http://www.nrc.gov/materials/miau/med-use-toolkit.html>) as provided in 10 CFR 35.55(a).

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35.55(b), Subpart B.

#### **IV. Recentness of Training**

The required training and experience, including board certification, 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 practice of nuclear pharmacy, and
- Practical experience in nuclear pharmacy under the supervision of an ANP at the same or another licensed facility that is authorized as a nuclear pharmacy.

#### **V. General Instructions and Guidance for Filling Out NRC Form 313A Series**

If the applicant wishes to identify a license and it is an Agreement State license, the applicant should provide a copy of the license. If the applicant wishes to identify a Master Materials License permit, the applicant should provide a copy of the permit. If the applicant wishes to identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, the applicant should provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, the applicant may provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following: " \_\_\_\_\_(name of supervising individual or preceptor) is authorized under \_\_\_\_\_(name of licensee/permittee) broad-scope license number \_\_\_\_\_ to use \_\_\_\_\_(materials) during \_\_\_\_\_( time frame)".

#### **INTRODUCTORY INFORMATION**

##### **Name of Individual**

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.

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

##### **State or Territory where Licensed**

Note that the NRC requires pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

## **Requested Authorization(s)**

Check all authorizations that apply and fill in the blanks as provided.

## **Part I. Training and Experience**

There are always multiple pathways provided for each training and experience section. Select the applicable one.

### **Item 1. Board Certification**

The applicant or licensee may use this pathway if the proposed nuclear pharmacist is certified by a board recognized by NRC (to confirm that NRC recognizes that board's certifications, see NRC's web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

#### **Note:**

- An individual that is board eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will also not be considered for this pathway.
- The applicant or licensee must provide a copy of the board certification ~~and completed attestation~~ as indicated on the attached NRC Form 313A (ANP).
- As indicated on the form, additional information is needed if the board certification was greater than 7 years ago.

### **Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist**

This pathway is used for those individuals not listed on the license as an ANP, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to a structured educational program consisting of both (a) classroom and laboratory training, and (b) supervised practical experience in nuclear pharmacy. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in 10 CFR 35.55 (b)(1)(i).

The proposed ANP may receive the required classroom and laboratory training, and supervised practical experience at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

Under the "classroom and laboratory training," provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed ANP may obtain the required "classroom and laboratory training" in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught on consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the "supervised practical experience" section of the form, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

**Note:** As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

## **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 practical experience in nuclear pharmacy 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 individual and attest that the individual has satisfactorily completed the appropriate training and experience criteria and **is able** ~~has achieved a level of competency sufficient to function independently~~ **fulfill the radiation safety-related duties of a authorized nuclear pharmacist**. This preceptor also has to meet specific requirements.

The NRC Form 313A (ANP) Part II - Preceptor Attestation has two sections. The preceptor must ~~selects either the board certification or~~ **complete the** structured educational program ~~when filling out~~ **attestation in** the first section on this page. The second and final sections of the page request specific information about the preceptor's authorization to use licensed material in addition to the preceptor's signature.



**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND  
EXPERIENCE AND PRECEPTOR ATTESTATION**  
[10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (MM/DD/YYYY)

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed

**PART I – TRAINING AND EXPERIENCE**  
*(Select one of the two methods below)*

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

- 1. Board Certification**
  - a. Provide a copy of the board certification.
  
- 2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist**
  - a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
<b>Total Hours of Training:</b> <input style="width: 50px;" type="text"/>			

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION (continued)**

**2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)**

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys			
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides			
Calculating, assaying, and safely preparing dosages for patients or human research subjects			
Using administrative controls to avoid medical events in administration of byproduct material			
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures			
<b>Total Hours of Experience:</b> <input type="text"/>			
<b>Supervising Individual</b>			
<input type="text"/>			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION (continued)**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

**First Section**

Complete the following:

**Structured Educational Program**

I attest that \_\_\_\_\_ has satisfactorily completed a 700-hour structured  
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

**Second Section**

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for \_\_\_\_\_,  
Nuclear Pharmacy (or Medical Facility)  
\_\_\_\_\_  
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
_____	_____	_____	_____

The following redline revisions in Appendix H reflect the new reporting Mo-99 breakthrough requirements in 10 CFR 30.34(g) and 10 CFR 30.50(b)(2).

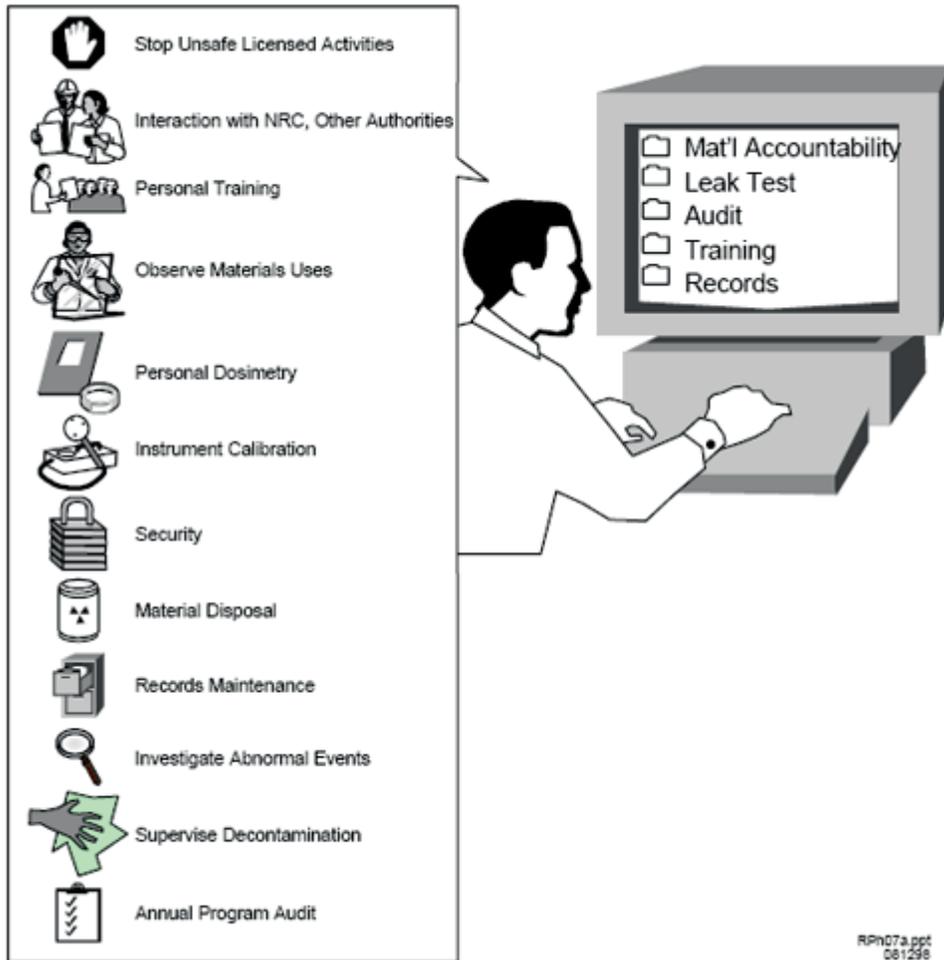
## APPENDIX H

### Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations, and with the conditions of the license (see Figure H.1). Typically, these duties and responsibilities include ensuring that:

- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events;
- Incidents are responded to, investigated, their cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Proper authorities are notified of incidents such as damage, fire, or theft;
- Proper NRC notification when required. (e.g., over exposures, leaking sources, when there is more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) in an eluate, etc.,)
- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified;
- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety;
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility;
- All radiation workers are properly trained;
- Procedures for the safe use of radioactive materials are developed and implemented;
- The license's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit;
- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events.
- Incidents are responded to, investigated, their cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.

- Proper authorities are notified of incidents such as damage, fire, or theft.
- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified.
- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety.
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility.
- All radiation workers are properly trained.
- Procedures for the safe use of radioactive materials are developed and implemented.
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit.
- Prospective evaluations are performed of occupational exposures, and those individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices.
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- The performance of fume hoods and gloveboxes used for volatile radioactive material work are monitored for proper operation.
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated.
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license.
- Sealed sources are leak-tested at required intervals.
- There is effective management of the radioactive waste program, including effluent monitoring.
- Packaging and transport of radioactive material is in accordance with all applicable DOT requirements.
- An up-to-date license is maintained and amendment and renewal requests and notifications of new ANPs are submitted in a timely manner.
- Radiation Safety Program audits are performed at least annually and documented.
- He or she acts as liaison to NRC.
- All required records are properly maintained.



**Figure H.1 Typical Duties and Responsibilities of the RSO.**

Redline/strikeout revisions are shown below for one section of Appendix I. An explanation is provided in at the beginning of this section.

## APPENDIX I.

### Suggested Commercial Radiopharmacy Audit Checklist

[The following redline revision to the “Notification and reports,” section of Appendix I reflects the addition of new mo-99 breakthrough reporting requirements in 10 CFR 30.34(g), and 10 CFR 30.50(b)(5). The “Notification and reports,” section of Appendix I starts on page I-7 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

#### Notification and Reports

A. Was any radioactive material lost or stolen? Were reports made? [10 CFR 20.2201, 10 CFR 30.50]

B. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.34(g), 10 CFR 30.50, 10 CFR 30.50(b)5]

C. Did any overexposures or high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]

D. Were any contaminated packages or packages with surface radiation levels exceeding 200 mrem received? Reported to NRC?

E. If any events (as described in items A through D above) did occur, what was root cause? Were appropriate notifications made and corrective actions taken?

F. Is the management/RSO aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]

Redline/strikeout revisions are shown below for one section of Appendix Q. An explanation is provided in at the beginning of this section.

## APPENDIX Q

### General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

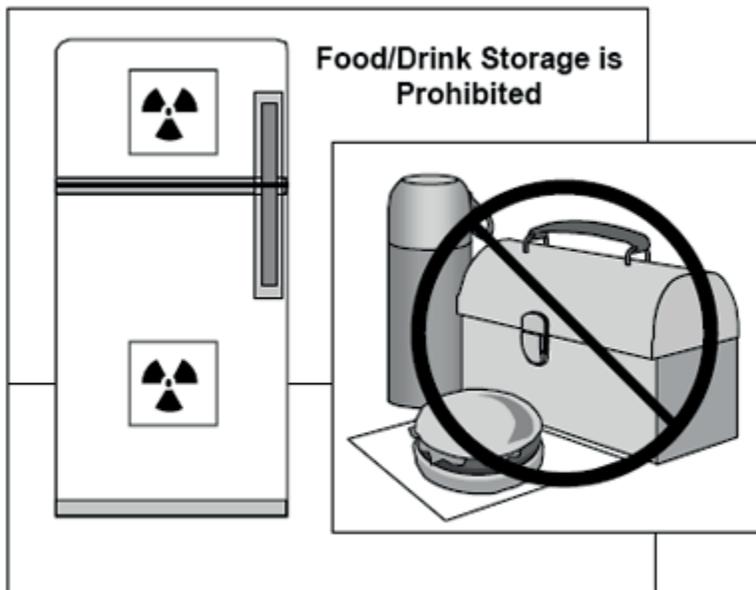
[The following redline revision to the “General Topics for Safe Use of Radioisotopes,” section of Appendix Q reflects the increased frequency of Mo-99 breakthrough measurements in 10 CFR 35.204 and new reporting requirements for Mo-99 breakthrough in 10 CFR 30.34. The “General Topics for Safe Use of Radioisotopes,” section of Appendix Q starts on page Q-1 of the printed copy of NUREG-1556, Vol. 139, Rev. 1.]

#### General Topics for Safe Use of Radioisotopes

Each licensee using radioactive material should establish general rules for the safe use of the material so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times when working with radioactive materials;
- Use syringe shields and vial shields when preparing and handling radioactive drugs;
- Measure all radiopharmaceuticals prior to transfer;
- **Measure the molybdenum-99 content of each generator elution. Do not transfer those radiopharmaceuticals for human medical use that will contain more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m at the time of administration, and report each eluent that exceeds this limit to NRC;**
- Wear disposable gloves at all times when handling radioactive materials and change gloves frequently to minimize the spread of contamination;
- Before leaving the hot lab, monitor hands, shoes, and clothing for contamination in a low-background area, allowing sufficient time for instrument response;
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink, or personal effects in areas where licensed material is stored or used (see Figure Q.1). Personal items brought into the restricted area (radios, compact discs, notepads, books, etc.) should be surveyed for contamination before removal from the area;

- Food and beverages used in the preparation of radiopharmaceuticals should be clearly labeled "Not for personal consumption" if stored with radioactive materials;
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored;
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).



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**Figure Q.1 Storage of Food and Drink.** *Food or drink for personal consumption should not be stored in refrigerators with radioisotopes.*

The following redline revisions in Appendix H reflect the new reporting Mo-99 breakthrough requirements in 10 CFR 30.34(g), 10 CFR 30.50(b)(2).

## APPENDIX T

### NRC Incident Notifications

#### NRC Incident Notifications

**Table T.1 Typical Notifications Required for Radiopharmacy Licensees**

Event	Telephone Notification	Written Report	Regulatory Requirement
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)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Intake of five times the annual limit on intake	immediate	30 days	10 CFR 20.2202(a)(2)
Removable contamination exceeding the limits of 10 CFR 71.87(i) - (beta/gamma/low toxicity alpha - 22 dpm/cm <sup>2</sup> ; all other alpha - 2.2 dpm/cm <sup>2</sup> )	immediate	none	10 CFR 20.1906(d)(1)
External radiation levels exceeding the limits of 10 CFR 71.47 - (any point on the surface - 2 mSv/hr (200 mrem/hr))	immediate	none	10 CFR 20.1906(d)(2)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Intake of one annual limit on intake	24 hours	30 days	10 CFR 20.2202(b)(2)
Occupational dose greater than the applicable limit in 10 CFR 20.1201	none	30 days	10 CFR 20.2203(a)(2)(i)

Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Report molybdenum-99 content of a generator elution that is more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m	No later than next calendar day	15 days	10 CFR 30.34(g)
Report when notified as required by 10 CFR 35.3204 that molybdenum-99 content from a redistributed used generator elution is more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m	24 hours	30 days	10 CFR 30.50(b)5)
Filing petition for bankruptcy under 11 U.S.C.	none	immediately after filing petition	10 CFR 30.34(h)
Expiration of license	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities at <i>entire site</i>	none	60 days	10 CFR 30.36(d)
Decision to permanently cease licensed activities in any <i>separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>at the entire site</i>	none	60 days	10 CFR 30.36(d)
No principal activities conducted for 24 months <i>in any separate building or outdoor area</i> that is unsuitable for release for unrestricted use	none	60 days	10 CFR 30.36(d)
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)
An unplanned contamination event involving greater than 5 times the ALI, and half-life greater than 24 hours requiring access to be restricted for more than 24 hours	24 hours	30 days	10 CFR 30.50(b)(1)
Equipment is disabled or fails to function as	24 hours	30 days	10 CFR

designed when required to prevent radiation exposure in excess of regulatory limits			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)

**Note:** Telephone notifications shall be made to NRC Operations Center, at 301-816-5100 or 301-951-0550.

## **Part 3**

# **Draft Medical Use Questions and Answers For the 2013 Proposed Expanded 10 CFR Part 35 Rulemaking**

## **Amendment and Notifications – General information**

### **1. What is the proposed change to 10 CFR 35.12, “Application for license, amendment, or renewal”?**

*This section would be amended to remove the requirement to submit additional copies of the NRC Form 313 or letter when applying for a license, amendment, or renewal; clarify what information should be submitted; and add a requirement to submit information on an individual seeking to be identified as an ARSO.*

### **2. Does the proposed rule require a medical use licensee who is already authorized for manual brachytherapy to receive a license amendment before obtaining and using a new type of source?**

*10 CFR 35.14(b)(6) allows a medical use licensee to obtain a sealed source for manual brachytherapy from a different manufacturer or with a different model number than authorized by its license, as long as the licensee notifies the NRC within 30 days. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.*

## **Training and Experience**

### **3. What are the major proposed changes to the training and experience requirements for authorized individuals?**

*Two types of authorized individuals were added: Associate Radiation Safety Officer and the individual identified in 10 CFR in 35.433. The written attestation requirement was removed for nearly all individuals meeting the board certification training and experience pathway. The attestation statement wording was revised to remove attestation of competency. For most categories of authorized user physicians, the residency program director may now sign the attestation. The certification boards formerly listed in 10 CFR Part 35, Subpart J are now listed in 10 CFR 35.57 allowing individuals certified by these boards on or before October 24, 2005 to be authorized for those materials and uses that they performed on or before October 24, 2005.*

### **4. What are the training and experience (T&E) requirements for 10 CFR 35.1000?**

*The training and experience requirements for 10 CFR 35.1000 medical uses are determined on a case-by-case basis. NRC has developed licensing guidance, including T&E guidance, for certain § 35.1000 medical uses. This is posted on the NRC public website at <http://www.nrc.gov/materials/miau/med-use-toolkit.html#other> in the section titled “Other Guidance.”*

## **Board Certification Changes**

### **5. What individuals are impacted by the acceptance of Ritenour petition?**

*The impacted individuals are those meeting all three of the following conditions: They are certified by boards that were formerly listed in 10 CFR Part 35, Subpart J and now listed in § 35.57 of the proposed rule; they were certified on or before October 24, 2005; and they are*

requesting authorization for only those materials and uses that they performed on or before October 24, 2005.

## **Preceptor Attestations**

### **6. Why is NRC eliminating the requirement for preceptor attestations for most individuals certified by boards identified on the NRC website or in NRC regulations?**

*In order for the boards to be recognized, they had to give an examination that assessed knowledge and competency in areas that included radiation safety. Therefore, staff believes that preceptor attestations are not warranted for the currently recognized boards or for “grandfathered” certified individuals in 10 CFR 35.57, so long as the provisions of § 35.59 are met.*

### **7. Are attestations eliminated for all board-certified individuals?**

*Attestations are eliminated for almost all individuals certified by boards recognized by NRC on its website and in its regulations. The attestation remains for the training and experience required by 10 CFR 35.396(e)(1) and (2) for board-certified individuals requesting approval under 35.396.*

### **8. Who will continue to need a preceptor attestation?**

*Individuals applying under the “alternate T&E pathway” and all physicians applying to be authorized users under the provisions of 10 CFR 35.396 will continue to need a preceptor attestation.*

### **9. If a physician authorized user met the training and experience criteria under 10 CFR 35.390 or 35.690 and receives additional training and experience for a new medical use under the same section of the regulation, is another attestation statement needed?**

*Maybe. Another attestation statement is not needed if the authorized user initially qualified under the board certification pathway. However, another attestation is needed if the authorized user initially qualified for § 35.390 or 35.690 under the alternate training and experience pathway.*

### **10. If an authorized medical physicist met the training and experience criteria under 10 CFR 35.51 and receives additional training and experience for a new medical use under the same section of the regulation, is another attestation statement needed?**

*Maybe. Another attestation statement is not needed if the authorized medical physicist initially qualified under the board certification pathway. However, another attestation is needed if the authorized medical physicist initially qualified under the alternate training and experience pathway.*

### **11. If a licensee is authorized for specific medical uses, wants to expand those medical uses, and the RSO receives additional training specified in 35.50(d) for the new uses, does the RSO need a new attestation statement for this training?**

Maybe. Yes, an additional attestation statement is needed if the RSO initially qualified under the alternate training and experience pathway, i.e., 35.50(b)(1). No, if you came through any other pathway.

**12. Why is NRC amending the wording of attestation statements?**

*In spite of NRC's assurances that the term "level of competency" in current attestations refers to radiation safety competency, the medical community continued to see it as a statement of medical competency. Therefore, NRC's proposed attestation statements no longer include the word "competency."*

**13. May a non-authorized user residency program director sign an attestation form?**

*Yes, in most cases. The regulations specify the conditions necessary for a residency program director to sign an attestation. The attestation must represent the consensus of the residency program faculty where at least one faculty member is an authorized user for the same use and concurs with the attestation. The residency program must be approved by one of the accreditation organizations listed in the regulation.*

**14. May an individual who qualifies as an AU or AMP under 10 CFR 35.57 serve as a preceptor or supervisor for an applicant seeking authorization on NRC licenses for the same uses?**

Yes.

**15. The wording of attestation statements is changed in the proposed rule and the number of individuals needing attestations has decreased. If a licensee submits an older version of the NRC Form 313A series for a proposed authorized individual and it includes an attestation that is now unnecessary or does not match the wording of the revised attestation, is it necessary for the proposed authorized individual to obtain a new NRC Form 313A?**

*No. Submission of information such a preceptor statement that is not required is neither reviewed nor part of the license. While NRC expects future attestations to conform to the new rule, the former attestation language will be accepted as adequate to meet the current attestation requirements.*

**Radiation Safety Officers and Associate Radiation Safety Officers**

**16. Why would a licensee want to have an Associate Radiation Safety Officer (ARSO)?**

*The licensee may want to request a license amendment to identify one or more individuals to assist the RSO. The approved ARSO(s) would be listed on the license. The ARSO(s) would be assigned to oversee the radiation safety operations of designated sections of the licensed program, while reporting to the named RSO.*

*An ARSO is required to complete the same training and experience requirements as the named RSO for the ARSO's assigned sections of the radiation safety program. The ARSO would oversee the radiation safety operations of their assigned functions, while reporting to the named RSO. The regulations continue to allow a licensee to name only one RSO on a license, who would be responsible for the day-to-day oversight of the entire radiation safety program.*

*Similarly, licensees with multiple program components or operating locations could appoint one or more qualified ARSOs to oversee designated program components or locations of byproduct material use.*

**17. Will the ARSO have any responsibility for the Radiation Protection Program?**

*No, only the RSO has responsibility for the Radiation Protection Program.*

**18. How does an Associate Radiation Safety Officer differ from an Assistant Radiation Safety Officer?**

*NRC recognizes that licensees may use a variety of different terms to identify members of their radiation safety staff. It was necessary for NRC to select a single term to describe the person other than the Radiation Safety Officer identified in 10 CFR 35.2, 35.24, 35.50 and on the license. Several different terms were considered, but "Associate Radiation Safety Officer" was chosen.*

**19. What training and experience requirements need to be satisfied for an ARSO to be named in a medical license? And how do they differ from the RSO training and experience requirements?**

*An ARSO is required to complete the same training and experience requirements as a named RSO for the same parts of a radiation safety program.*

**20. Can an ARSO provide a preceptor statement for someone applying to be an RSO?**

*Yes, provided the ARSO has experience with the radiation safety aspects of similar types of use of byproduct material for which the ARSO is providing the attestation.*

**21. How does the proposed rule change the potential pool of RSOs and RSO supervisors/preceptors?**

*It increases the potential pool, because when an ARSO that meets the same training and experience requirements as an RSO, the ARSO may supervise and preceptor other individuals training to become RSOs or ARSOs for the same types of use for which the ARSO is qualified.*

*In addition, because an AU, AMP, or ANP listed on any license or permit may serve as an RSO or ARSO, there are now an increased number of qualified individuals available to serve as RSOs and ARSOs on NRC medical licenses.*

**22. Can a licensee assign duties and tasks to any individual who is not an ARSO?**

*Yes, a duty or task can be assigned to any individual a licensee feels can perform the assignment with appropriate training and supervision. However, it is necessary to amend the license to expand the oversight duties and tasks assigned to an ARSO.*

**23. Will a license amendment be required before a licensee allows an individual to work as an ARSO?**

*Yes, a licensee must request and receive an amendment before allowing an individual to work as an ARSO. An amendment is also required before the RSO assigns the ARSO to oversee a new section of the radiation safety program for which they are not currently authorized.*

**24. Will a licensee need to notify the Commission when the ARSO discontinues performance of duties?**

*Yes, a licensee is required to notify the Commission no later than 30 days after the ARSO discontinues performance of duties under the license.*

**25. If a licensee is authorized for specific medical uses and wants to expand those medical uses, does the RSO need additional training specified in 10 CFR 35.50(d) for the new uses?**

*Yes. The RSO needs to obtain additional training or document that they received related training and experience within the past 7 years.*

**26. It appears that 10 CFR 35.50(c)(2) and (3) are the same for physicians. What is the difference?**

*Current regulations, under 10 CFR 35.50(c)(2), allow a physician who is an AU on a medical license or permit to be named as the RSO on the same license for the same byproduct material for which the AU is authorized. The revised § 35.50(c)(2) would permit the AU to be named as an RSO on any license. NRC regulatory changes in § 35.50(c)(3) would allow an individual who is not yet named as an AU on a medical license or permit but is qualified to be an AU, to be named simultaneously as the RSO and the AU on the same new medical license.*

**27. What is the proposed change to 10 CFR 35.50(c)(2)?**

*Previously 10 CFR 35.50(c)(2) permitted only an AU, AMP, or ANP that was listed on the licensee's license to be named as the RSO. The new § 35.50(c)(2) will allow the licensee to name an AU, AMP, or ANP on any medical license or permit as the RSO or ARSO when the individual has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual will have RSO responsibilities or ARSO duties and tasks.*

## **Generator Breakthrough**

**28. Why is NRC requiring an increased frequency for Mo-99 breakthrough tests?**

*Prior to 2002, licensees' data showed few breakthroughs and those that did occur were identified on the first elution. For this reason, the 2002 revision of Part 35 removed the requirement to test breakthrough on each elution. However, in 2006, medical use licensees reported that numerous generators had shown no Mo-99 breakthrough on the first elution, but failed the Mo-99 breakthrough tests performed on subsequent elutions. NRC now believes that it is important to measure Mo-99 breakthrough on each elution to ensure patients are not administered amounts of Mo-99 in excess of regulatory limits.*

**29. Who needs to report breakthrough values in excess of regulatory limits for Mo-99/Tc-99m and Sr-82/Rb-82 generators? Who do they have to report to?**

*The person that elutes the generator has to report the results to the NRC and the manufacturer/distributor. This could be a commercial nuclear pharmacy or a medical use licensee who elutes their own generators. The manufacturer/distributor then needs to also make a report to the NRC.*

*After the manufacturer/distributor receives a report from a customer, it has to conduct an investigation and provide a more detailed report of the event, its causes, and corrective actions to the NRC.*

**30. How long do licensees that elute generators and manufacturers/distributors of generators have to notify the NRC when an eluate from a generator exceeds the permissible concentration listed in 10 CFR 35.204(a)?**

*Licensees eluting generators must make a telephone notification to the NRC Operations Center and the manufacturer/distributor no later than the next calendar day after discovering that an eluate exceeded the permissible concentration listed in § 35.204(a). The licensee must also submit a written report to the NRC within 15 days of this discovery.*

*The manufacturer/distributor must make a telephone notification to the NRC Operations Center within 24 hours after discovering that an eluate exceeded the permissible concentration listed in § 35.204(a) and provide a written follow-up report to the NRC within 30 days.*

**31. What is the difference between the reports made to NRC by the licensee who eluted the generator and reports made to NRC by the manufacturer/distributor?**

*The licensee eluting the generator must report generator and elution information, whether dosages were administered, and whether the manufacturer/distributor was notified. If patient dosages were administered, a dose assessment must be performed and reported. The manufacturer/distributor must report a description of the event including generator information, probable cause, evaluations or assessments, and corrective actions.*

**Calibration, transmission, and reference sources**

**32. Is bundling or aggregating of single calibration, transmission, or reference sealed sources authorized by 10 CFR 35.65 allowed under proposed regulation?**

*Sometimes. Bundling or aggregating of single sealed sources is allowed when the combined source activity is not greater than the activities authorized by 10 CFR 35.65. Bundling or aggregating of single sealed sources is not allowed when the combined source activity is greater than the activities authorized by § 35.65, and in this case, the source needs to be specifically listed on the license.*

**33. May a licensee use calibration, transmission, or reference sources to aid in performance of patient imaging and localization procedures if the sources otherwise meet the requirements of 10 CFR 35.65?**

*Yes. Some licensees may not recognize that use of calibration, transmission, or reference sources during imaging procedures meets the definition of medical use to the patient. 10 CFR 35.65(b)(1) recognizes that medical use of calibration, transmission, and reference sources must be performed in accordance with the requirements in § 35.500, "Use of Sealed Sources*

*and Devices for Medical Diagnosis,” and a physician authorized for § 35.200 medical uses is automatically authorized to use these sources under § 35.500.*

**34. If a licensee uses calibration, transmission, or reference sources in patient imaging and localization procedures when the sources otherwise meet the requirements of 10 CFR 35.65, do these sources need to be specifically listed on the license?**

*No. Calibration, transmission, or reference sources that are used for medical use in accordance with the requirements of 10 CFR 35.500, and are not bundled to result in an activity greater than that specified in § 35.65, do not have to be listed on the license.*

### **Permanent implant Brachytherapy**

**35. How were the revised written directive requirements and medical event reporting requirements for permanent implant brachytherapy developed?**

*The revised regulations are based on recommendations provided to the NRC in February 2012 by its Advisory Committee on the Medical Uses of Isotopes plus stakeholder input obtained during two stakeholder public workshops held in 2011 that focused on issues associated with medical event definitions for permanent implant brachytherapy. Staff’s recommendations, based on this input and other stakeholder input, were approved by the Commission in SRM-SECY-12-0053, “Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs,” issued August 2012 and available on the NRC public web site at [www.nrc.gov](http://www.nrc.gov).*

### **Written Directives**

**36. Why are the written directive requirements in 10 CFR 35.40, “Written Directives,” and the medical event reporting requirements in 10 CFR 35.3045, “Reporting and Notification of a Medical Event,” being changed for permanent implant brachytherapy medical use?**

*The currently applicable regulations for manual brachytherapy primarily reflect operational aspects of temporary implant brachytherapy medical use. Not all of these required information elements are appropriate for characterizing permanent implant brachytherapy use. Moreover, for permanent implant brachytherapy, the current requirements have been judged to interfere with physicians’ ability to take actions relating to delivered dose that they deem to be medically appropriate for patients being treated.*

**37. What are the main changes to the written directive requirements in 10 CFR 35.40, “Written Directives,” for permanent implant brachytherapy use?**

*The changes are:*

- a. Requiring inclusion in the pre-implantation portion of the written directive of the total source strength required to deliver the intended (prescribed) absorbed dose to the treatment site; and*
- b. Requiring completion of the post-implantation portion of the written directive before the patient leaves the post-treatment recovery area, and requiring the signature of an authorized user for Section 35.400 uses to complete the post-implantation portion of the written directive.*

**38. For the two part written directive required for permanent implant brachytherapy medical use, when is the signature of an authorized user for Section 35.400 uses (manual brachytherapy) required?**

*An authorized user (AU) for Section 35.400 uses must sign the written directive after completion of the pre-implantation portion of the document (but before the administration begins) and also after completion of the post-implantation portion of the written directive (after implantation but before the patient leaves the post-treatment recovery area). The current date must also be entered each time that the written directive is signed by an AU.*

**39. What information is required for proper completion of the written directive?**

*The information required is:*

- a. Before implantation: the treatment site, the radionuclide, the intended absorbed dose to the treatment site and normal tissues as necessary, and the corresponding calculated total source strength required; and*
- b. After implantation (but before the patient leaves the post-treatment recovery area): the number of sources implanted, the total source strength implanted, the signature of an authorized user for § 35.400 uses for manual brachytherapy, and the date.*

*Note that “normal tissues as necessary” means non-malignant tissues in structures located outside of but adjacent to the treatment site, i.e., in organs at risk, or within the treatment site.*

**Written Procedures in 10 CFR 35.41**

**40. What are the main changes to the procedures requirements in 10 CFR 35.41, “Procedures for Administrations Requiring a Written Directive,” for permanent implant brachytherapy use?**

*The main changes are requiring development, implementation, and maintenance of written procedures for:*

- a. Determining if a medical event, as defined in Section 35.3045, has occurred; and*
- b. Determining within 60 days of the implant procedure:*
  - i. The fraction of implanted total source strength administered outside of the treatment site (as described in the pre-implant portion of the written directive);*
  - ii. The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located outside of the treatment site; and*
  - iii. The absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissue located within the treatment site.*

**41. What is the basis for the 60 day limit on verifying implanted source positioning and resultant absorbed doses to normal tissues outside of and, when applicable, within the treatment site?**

*The 60 day time limit was recommended by NRC’s Advisory Committee on the Medical Uses of Isotopes and reflects the American Association of Medical Physicists’ (AAPM’s) suggested time to post implant dosimetry being 30 days for the presently longest half life radioactive source used in permanent implant brachytherapy, 125-I ( $t_{1/2} = 60$  days). Refer to AAPM Report 137, “AAPM Recommendations on Dose Prescription and Reporting Methods for Permanent Interstitial Brachytherapy for Prostate Cancer,” which is available on the AAPM web site at [www.aapm.org](http://www.aapm.org).*

**42. What if the patient is not available within the 60 day limit for post-implant imaging for implanted source position verification and determination of resultant absorbed doses to the treatment site and involved normal tissues?**

*The authorized user and licensee must provide a written justification for not carrying out the source position and resultant dosimetry determinations within the required 60 days, based on the unavailability of the patient. The written justification should be placed in the file for the patient, and efforts to complete the determinations, i.e., to have the patient's implant imaged, should ideally be continued, if appropriate.*

**43. Does NRC require licensees conducting permanent implant brachytherapy to perform post-implant imaging?**

*The requirements in 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," are performance based and do not explicitly direct licensees as to how the objectives are to be achieved. Accordingly, post-implant imaging, as well as the use of treatment planning software, are not required. However, NRC's expectation is that the use of both will be necessary in order to make the determinations of implanted source positioning and normal tissue doses that are required to decide whether a medical event has occurred according to the criteria in 10 CFR 35.3045, "Report and Notification of a Medical Event."*

**44. How does NRC anticipate that licensees will make the determination required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," of absorbed dose to the maximally exposed 5 contiguous cubic centimeters of normal tissues located both outside of and within the treatment site?**

*While not explicitly required, NRC expects that when making these determinations, licensees will utilize post-implant imaging, as currently employed by many practitioners conducting permanent implant brachytherapy, along with a version of treatment planning software having the capability to provide this desired information. (At least one presently available commercial treatment planning software package can perform this calculation.) A possible alternative to contiguous volume analysis software might be the following: Generate a dose calculation and view the isodose distribution on multiple slices. Perform a visual examination of the isodose distribution to determine if any hot spots exist in normal tissue. If so, create an additional calculation structure by contouring the hot spot on multiple adjacent slices. Re-generate the dose calculation and assess the volume of tissue and dose in the new structure that represents the hot spot.*

## **Medical Event Reporting**

**45. What are the main changes to the medical event reporting requirements in 10 CFR 35.3045, "Report and Notification of a Medical Event," for permanent implant brachytherapy use?**

*The main changes are:*

- a. For the treatment site, replacement of the criterion involving delivered dose variance from prescribed dose with a criterion involving the fraction of implanted source strength administered outside of the treatment site defined in the pre-implantation portion of the written directive.*

- b. *The criterion for variance in dose to normal tissue now has a minimum volume requirement/descriptor for the tissue.*
- c. *Sealed sources directly delivered to the wrong treatment site or containing the wrong radionuclide are now criteria for reporting a medical event.*
- d. *Total source strength difference between that implanted and that entered into the post-implant portion of the written directive now has a threshold for ME reporting.*

**46. Suppose that during a prostate implantation procedure several sealed sources are deposited into the adjacent urinary bladder, instead of into tissue comprising the intended treatment site. Also, suppose that the incorrect placement of those sources is promptly identified and the sources are removed before the implantation procedure is completed. Does this occurrence require reporting as a medical event?**

*This occurrence does not require reporting of a medical event. If the sources deposited into the urinary bladder are removed before the implantation procedure is completed, they are not considered to have been implanted and would not be included in the source count/total source strength implanted entry for the post-implantation portion of the written directive. Although sources were directly deposited into the urinary bladder, because the bladder is not distant from but is adjacent to the intended treatment site and because prompt removal of the deposited sources occurred, rather than permanent residency at the deposition site, medical event reporting criterion 10 CFR 35.3045(a)(2)(v)(C) (direct delivery to the wrong site) would not apply*

**47. Are there any related changes to the medical event reporting criteria for temporary implant brachytherapy medical use?**

*Yes. Implantation of sealed sources containing the wrong radionuclide (i.e., not agreeing with the radionuclide entered into the pre-administration portion of the written directive) is now a criterion for reporting a medical event.*



## **Abnormal Occurrence Subcommittee Report**

April 15, 2013

Susan M. Langhorst, Ph.D.

Advisory Committee on the Medical Uses of Isotopes

## **Subcommittee Charge**

To review the refined abnormal occurrence criteria and provide recommendations to the NRC staff.

2

## **December 2011 ACMUI Recommendation**

### **Abnormal Occurrence (AO) Criteria for Medical Licensees**

- A medical event that results in death; or
- A significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the normal treatment regimen, as determined by an NRC or Agreement State – designated consultant physician(s).

3

## **NRC PROPOSED REFINEMENT**

### **Events Involving Patients or Human Research Subjects – September 2012**

- A medical event that results in a dose other than the dose to the intended target that is:
  - Greater than or equal to 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye;
  - Greater than or equal to 2.5 Gy (250 rad) to the gonads; **or**
  - Greater than or equal to 10 Gy (1,000 rad) to any other unintended organ or tissues other than the treatment site;

**and**

4

## **NRC PROPOSED REFINEMENT**

- Results in a significant impact on patient health that would result in **one or more of the following**, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State:
  - Unintended permanent functional damage to an organ.
  - Unintended permanent functional damage to a physiological system.
  - A significant unexpected adverse health effect.
  - Death.

5

## **Energy Reorganization Act of 1974, as Amended**

- In Section 208. Abnormal Occurrence Reports

“For the purposes of this section an abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety.”

6

## **Current Abnormal Occurrence Criteria**

### **I. For All Licensees**

- A. Human Exposure to Radiation from Licensed Material
  - 1. lists criteria for unintended exposure to an adult
  - 2. lists criteria for unintended exposure to a minor or embryo/fetus
  - 3. lists criteria for permanent medical harm

7

## **Current Abnormal Occurrence Criteria**

### **III. Events at Facilities Other than Nuclear Power Plants and All Transportation Events**

- C. For Medical Licensees A medical event that:
  - 1. Results in a dose
    - a.  $\geq 1$  Gy (100 rad) to bone marrow/lens; or  $\geq 2.5$  Gy (250 rad) to gonads; **or**
    - b.  $\geq 10$  Gy (1,000 rad) to other organ/tissue;

**and**

8

**Current Abnormal Occurrence Criteria**

- 2. Represents either
  - a. dose or dosage > 50% prescribed; **or**
  - b. prescribed dose or dosage that involves
    - i. wrong radiopharmaceutical/byproduct material;
    - ii. wrong route;
    - iii. wrong treatment site;
    - iv. wrong treatment mode;
    - v. leaking source(s) ; **or**
    - vi. wrong individual.

**Abnormal Occurrences Reported to Congress**

FY	All AO	Medical Use AO I.A.2.	Medical Use AO III.C.	Non-Medical Use
2011	24	2	19	3
2010	15	3	12	0
2009	9	2	7	0
2008	10	2	8	0
2007	11	1	10	0

**Abnormal Occurrence Criteria Recommendations - title**

In section III. C., agree with redefining title as

- C. For Events Involving Patients or Human Research Subjects
  - Limited to events involving medical administrations
  - Clarifies that other AO criteria applicable to material licensees also apply to other parts of a medical licensee’s program

**Abnormal Occurrence Criteria Recommendations – Medical Event**

- ACMUI discussions during December 15, 2011 teleconference and September 21, 2012 meeting and
- AO Subcommittee discussions

**Conclusion:** dose-based screening criteria would not provide a reliable method to identify medically significant incidents in all cases; should not be used

**Abnormal Occurrence Criteria  
Recommendations – Medical Event (cont.)**

In section III. C., redefine –

1. Medical event involving a patient or human research subject that, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State, results in one or more of the following:

13

**Abnormal Occurrence Criteria  
Recommendations – Medical Event (cont.)**

- a. Unintended or unexpected permanent functional damage to an organ.
- b. Unintended or unexpected permanent functional damage to a physiological system.
- c. A significant unexpected adverse health effect.
- d. Death.

14

**Abnormal Occurrence Criteria  
Recommendations – Medical Event (cont.)**

- Subcommittee explored possibility of other screening criteria
- Concluded there are no practical and implementable screening criteria to include in the AO medical event criteria definition
- Suggested the NRC Staff use existing NRC inspection policy regarding use of medical consultants as a reasonable and practical screening tool

15

**Abnormal Occurrence Criteria  
Recommendations – § 35.3047 Notification**

- “For All Licensees” category I.A.3 not appropriate in judging medical use AO – every § 35.3047 notification is automatically an AO
- This unintended dose to embryo/fetus or nursing child only happens from a medical administration

**Conclusion** : § 35.3047 notifications should be included in the AO criteria III.C.

16

**Abnormal Occurrence Criteria  
Recommendations – § 35.3047 Notification  
(cont.)**

In section I. A., add –

4. These criteria do not apply to events included in criteria III.C. involving medical administrations using byproduct material to patients or human research subjects.
- This exclusion is similar to the transportation event exclusion in criteria I.B.

17

**Abnormal Occurrence Criteria  
Recommendations – § 35.3047 Notification  
(cont.)**

In section III. C., redefine –

2. Notification under 10 CFR 35.3047 of an event involving an unintended dose to an embryo/fetus or a nursing child that results in a significant adverse health impact to the embryo/fetus or child, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State.

18

**Additional Subcommittee  
Discussion Points**

1. What is the difference between medical events or notifications of embryo/fetus or child dose versus abnormal occurrences?
2. Could a minimum number of medical use-related event reports per licensee to be considered as a screening criterion for abnormal occurrence definition?

19

**Additional Subcommittee  
Discussion Points**

3. Could a measure of rate be used rather than an absolute number of events reported in a year by a medical licensee?

20

### **Abnormal Occurrence Subcommittee**

- D. Bailey
- S. Langhorst, Ph.D. - Chair
- S. Mattmuller
- C. Palestro, M.D.
- B. Thomadsen, Ph.D.
- L. Weil
- J. Welsh, M.D.

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2  
3 **Advisory Committee on the Medical Use of Isotopes (ACMUI)**

4  
5 **Report on Abnormal Occurrence Criteria for Medical Use**

6  
7 **April 9, 2013 Draft**

8  
9  
10 **Subcommittee Members:** D. Bailey; S. Langhorst, Ph.D. (Chair); S. Mattmuller; C. Palestro,  
11 M.D.; B. Thomadsen, Ph.D.; L. Weil; J. Welsh, M.D.

12  
13 **Charge:** To review the refined abnormal occurrence criteria for events involving patients or human  
14 research subjects and to provide recommendations to the NRC staff.

15  
16  
17 **Recommendations:**

18  
19 **The following changes are recommended to Appendix A: Abnormal Occurrence**  
20 **Criteria in the current Abnormal Occurrence Revised Policy Statement<sup>1</sup>.**

21  
22 **1. In section I. A., add new paragraph 4. to read as follows:**

- 23  
24 4. These criteria do not apply to events included in criteria III.C. involving medical  
25 administrations using byproduct material to patients or human research subjects.

26  
27 **2. In section III. C., redefine title; replace paragraphs 1. and 2. with the following**  
28 **paragraphs 1. and 2.:**

29  
30 C. For Events Involving Patients or Human Research Subjects

- 31  
32 1. Medical event involving a patient or human research subject that, as  
33 determined by a consultant physician(s) deemed qualified by NRC or an  
34 Agreement State, results in one or more of the following:  
35  
36 a. Unintended or unexpected permanent functional damage to an organ.  
37  
38 b. Unintended or unexpected permanent functional damage to a  
39 physiological system.  
40  
41 c. A significant unexpected adverse health effect.  
42  
43 d. Death.  
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<sup>1</sup> Nuclear Regulatory Commission, "Revised Policy Statement on Abnormal Occurrence Criteria," 71 FR 60198, October 12, 2006, <http://www.gpo.gov/fdsys/pkg/FR-2006-10-12/pdf/E6-16871.pdf> (accessed March 25, 2013).

- 45 2. Notification under 10 CFR 35.3047 of an event involving an unintended dose  
46 to an embryo/fetus or a nursing child that results in a significant adverse  
47 health impact to the embryo/fetus or child, as determined by a consultant  
48 physician(s) deemed qualified by NRC or an Agreement State.  
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51 **Need for Medical Abnormal Occurrence Criteria Update:**  
52

53 The Nuclear Regulatory Commission (NRC) is required to annually report abnormal  
54 occurrences to Congress as defined in Section 208 of the Energy Reorganization Act of 1974<sup>2</sup>. This  
55 section states:

56  
57 “For the purposes of this section an abnormal occurrence is an unscheduled incident or event  
58 which the Commission determines is significant from the standpoint of public health or  
59 safety.”  
60

61 Establishment of the NRC Policy Statement on Abnormal Occurrence Criteria<sup>3</sup> provides  
62 explanation of how the Commission determines the incidents or events to be significant and  
63 included in the annual abnormal occurrence (AO) report. The NRC Staff and the Advisory  
64 Committee on the Medical Use of Isotopes (ACMUI) have discussed concerns that the medical use-  
65 related incidents and events being included in AO reports may not be significant from the  
66 standpoint of public health or safety. During an ACMUI teleconference in December 2011<sup>4</sup>, the  
67 ACMUI endorsed their 2008 position, which is summarized by the following: AOs for medical  
68 licensees should be events which result in death or threaten life; AOs should not capture those  
69 occurrences that are accepted risks of the treatment; AOs should be of significant adverse effect;  
70 AO criteria should be qualitative and not quantitative<sup>5</sup>.  
71

72 At the September 2012 ACMUI meeting<sup>6</sup>, the NRC Staff asked the Committee to consider  
73 their proposal to add dose-based criteria for medical licensee AO criteria (see Attachment 1) to  
74 allow the NRC Staff a screening tool to decide which medical events should then be evaluated by a  
75 consultant physician to determine significant adverse effect. During discussion of this proposal, the  
76 ACMUI again voiced their concerns of using dose-based criteria to judge medical AOs. The  
77 ACMUI established a subcommittee to develop recommendations concerning the AO criteria  
78 related to medical use incidents and events.

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<sup>2</sup> U.S. Energy Reorganization Act of 1974, as Amended (Public Law 93-438), pages 252-253,  
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0980/v1/sr0980v1.pdf#page=241> (accessed March 25,  
2013).

<sup>3</sup> Nuclear Regulatory Commission, “Revised Policy Statement on Abnormal Occurrence Criteria,” 71 FR 60198,  
October 12, 2006, <http://www.gpo.gov/fdsys/pkg/FR-2006-10-12/pdf/E6-16871.pdf> (accessed March 25, 2013).

<sup>4</sup> Official Transcript of Proceedings, Nuclear Regulatory Commission Advisory Committee on the Medical Use of  
Isotopes Teleconference, December 15, 2011, <http://pbadupws.nrc.gov/docs/ML1206/ML12062A278.pdf> (accessed  
March 25, 2013).

<sup>5</sup> Meeting Summary, Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes  
Teleconference, December 15, 2011, <http://pbadupws.nrc.gov/docs/ML1135/ML11355A253.pdf> (accessed April 4,  
2013).

<sup>6</sup> Official Transcript of Proceedings, Nuclear Regulatory Commission Advisory Committee on the Medical Use of  
Isotopes Teleconference, September 21, 2012, <http://pbadupws.nrc.gov/docs/ML1232/ML12324A222.pdf> (accessed  
April 4, 2013).

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**Development of Recommendations:**

The Subcommittee reviewed medical use-related abnormal occurrences reported to Congress in the past five years, as summarized in this table, discussed the NRC Staff’s proposed criteria, and came to the conclusions as described here. Additional Subcommittee discussion points pertinent to these conclusions are included in Attachment 2.

**Abnormal Occurrences Reported to Congress**

<b>FY</b>	<b>All AO</b>	<b>AO I.A.2.<sup>①</sup> from Medical Use</b>	<b>AO III.C.<sup>②</sup> from Medical Use</b>
<b>2011<sup>7</sup></b>	24	2	19
<b>2010<sup>8</sup></b>	15	3	12 <sup>③</sup>
<b>2009<sup>9</sup></b>	9	2	7
<b>2008<sup>10</sup></b>	10	2	8 <sup>③</sup>
<b>2007<sup>11</sup></b>	11	1	10

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- ① Each AO listed here involved one I-131 therapy patient who was found to be in early stage pregnancy following her therapy. No medical licensee reported more than one patient.
- ② Each AO listed here involved one or two radiation therapy patients per medical licensee, except as noted.
- ③ One AO in this total involved three or more radiation therapy patients at one medical licensee.

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<sup>7</sup> NUREG-0090, Vol. 34, “Report to Congress on Abnormal Occurrences – Fiscal Year 2011,” Nuclear Regulatory Commission, <http://pbadupws.nrc.gov/docs/ML1214/ML12142A194.pdf> (accessed March 25, 2013).  
<sup>8</sup> NUREG-0090, Vol. 33, “Report to Congress on Abnormal Occurrences – Fiscal Year 2010,” Nuclear Regulatory Commission, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/v33/sr0090v33.pdf> (accessed March 25, 2013).  
<sup>9</sup> NUREG-0090, Vol. 32, “Report to Congress on Abnormal Occurrences – Fiscal Year 2009,” Nuclear Regulatory Commission, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/v32/sr0090v32.pdf> (accessed March 25, 2013).  
<sup>10</sup> NUREG-0090, Vol. 31, “Report to Congress on Abnormal Occurrences – Fiscal Year 2008,” Nuclear Regulatory Commission, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/v31/sr0090v31.pdf> (accessed March 25, 2013).  
<sup>11</sup> NUREG-0090, Vol. 30, “Report to Congress on Abnormal Occurrences – Fiscal Year 2007,” Nuclear Regulatory Commission, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/v30/sr0090v30.pdf> (accessed March 25, 2013).

98  
99 Title Change for Medical Use AO Criteria

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101 The Subcommittee agreed with the NRC Staff’s proposed medical use AO criteria title, “For  
102 Events Involving Patients or Human Research Subjects.” This title change makes clear that these  
103 AO criteria refer only to incidents related to medical administrations using byproduct materials, and  
104 that other parts of a medical licensee’s program are subject to the other AO criteria applicable to  
105 material licensees.

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107  
108 Use of Screening Criteria for Medical Use AO Criteria

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110 At the September 2012 ACMUI meeting<sup>12</sup>, the NRC Staff voiced concern that without dose-  
111 based AO criteria, all medical events may require the NRC to have every medical event reviewed  
112 by a medical consultant, resulting in significant costs and time delays. The Committee’s  
113 discussions at that meeting and continued discussions by the Subcommittee led the Subcommittee to  
114 conclude that dose-based screening criteria would not provide the NRC Staff a reliable method to  
115 identify medically significant incidents in all cases and therefore should not be included in the AO  
116 criteria.

117  
118 The Subcommittee discussed the NRC Staff’s request to establish screening criteria for  
119 identifying those medical events that require an additional medical consultant review. ACMUI’s  
120 annual review of the medical events and the Subcommittee’s review of the AO reports for the past  
121 five years indicate there are few medical events reported each year that have the potential to cause  
122 significant harm. The Subcommittee believed that requiring an additional medical consultant  
123 review of every medical event to determine the significance of the event would be an unnecessary  
124 expenditure of resources. The Subcommittee explored the use of alternative screening criteria, such  
125 as setting a minimum number or rate of individuals significantly harmed by a medical event(s)  
126 reported by a medical licensee in one AO report year (see Attachment 2, Discussion Points 2 and 3  
127 for additional information on these discussions). The NRC Staff informed the Subcommittee that a  
128 screening criterion using a threshold number of individuals would not be acceptable from a  
129 regulatory point of view. In addition, the Subcommittee was unable to come to a unanimous  
130 consensus on what the threshold number of individuals should be for an AO definition.

131  
132 The Subcommittee concluded that there are no practical and implementable screening  
133 criteria which could be included with the NRC Staff’s proposed AO criteria definition of significant  
134 harm (see Attachment 1, Item 2). However, the Subcommittee suggested that the NRC Staff could  
135 rely on the existing NRC policy regarding the use of medical consultants<sup>13</sup> as a reasonable and  
136 practical screening tool to determine the need for a consultant physician (see Attachment 3).  
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<sup>12</sup> Official Transcript of Proceedings, Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Meeting, September 21, 2012, <http://pbadupws.nrc.gov/docs/ML1232/ML12324A222.pdf> (accessed March 25, 2013).

<sup>13</sup> NRC Inspection Manual Chapter 1360: “Use of Physician and Scientific Consultants in the Medical Consultant Program”, IMC 1360-04.02, November 2, 2006, <http://pbadupws.nrc.gov/docs/ML0627/ML062720195.pdf> (accessed March 25, 2013).

138 Embryo/Fetus or Nursing Child Dose

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140 The Subcommittee also reviewed the reporting criteria of abnormal occurrences involving  
141 medical licensee notification of unintended dose to an embryo/fetus or nursing child. The past five  
142 years of AO reports included notifications of unintended dose to an embryo/fetus that were due to I-  
143 131 therapy patients unknowingly being pregnant at the time of their therapy despite appropriate  
144 pre-treatment pregnancy screening. These incidents were reported as abnormal occurrences due to  
145 the low dose threshold criterion defined the “For All Licensees” AO criteria I.A.3.

146  
147 The Subcommittee did not believe use of the “For All Licensees” criteria I.A.3 is  
148 appropriate in judging a medical use AO, even though dose to the embryo/fetus or child may be  
149 considered a public dose. The Subcommittee considered it inappropriate because the mother is  
150 undergoing a medical treatment and the unintended dose to the embryo/fetus or child should not be  
151 considered separate from the medical administration. In a regulatory sense, this is consistent with  
152 how the NRC requires embryo/fetus or nursing child dose reporting to be done under the medical  
153 use regulations<sup>14</sup> rather than under the protection against radiation regulations<sup>15</sup>. The Subcommittee  
154 recommended that the “For All Licensees” AO criteria I.A. be modified to exclude events that are  
155 included in criteria III.C involving medical administrations using byproduct material to patients or  
156 human research subjects. This recommended modification is made in a similar way the “For All  
157 Licensees” criteria I.B. excludes transportation events. The Subcommittee recommended that the  
158 AO criteria III.C. also include the unintended dose reported under 10 CFR 35.3047 to an  
159 embryo/fetus or a nursing child which results in a significant medical harm to the embryo/fetus or  
160 child because this abnormal occurrence can only happen as a result of medical administration to a  
161 patient or human research subject.

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<sup>14</sup> 10 CFR 35.3047, “Report and notification of a dose to an embryo/fetus or a nursing child,”  
<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3047.html> (accessed March 25, 2013).

<sup>15</sup> 10 CFR 20.2203(a)(2)(iv), “Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits,” <http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-2203.html> (accessed March 25, 2013).

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**Attachment 1**

**Medical AO Draft Criteria Discussed at the September 2012  
ACMUI Meeting**

**For Events Involving Patients or Human Research Subjects**

1. A medical event that results in an unintended dose to the target or a dose other than the dose to the intended target that is:
  - a. Greater than or equal to 1 Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; **or**
  - b. Greater than or equal to 2.5 Gy (250 rad) to the gonads; **or**
  - c. Greater than or equal to 10 Gy (1,000 rad) to any other unintended organ or tissues other than the treatment site; **and**
  
2. Results in a significant impact on patient health that would result in **one or more** of the following, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State:
  - a. Unintended or unexpected permanent functional damage to an organ.
  - b. Unintended or unexpected permanent functional damage to a physiological system.
  - c. A significant unexpected adverse health effect.
  - d. Death

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**Attachment 2**

**Additional Subcommittee Discussion Points  
Concerning Medical Use Abnormal Occurrence Criteria**

In developing recommendations for medical use abnormal occurrence (AO) criteria, the Subcommittee discussed the following points.

**1. What is the difference between medical events or notifications of embryo/fetus or child dose versus abnormal occurrences?**

The Subcommittee recognized that regulations for medical events and notifications of unintended embryo/fetus or child dose provide indicators of errors in a medical administration using byproduct materials worthy of close evaluation by the licensee and the regulators. The fact that these incidents may not be considered abnormal occurrences does not diminish the seriousness of the incident, the requirements to evaluate cause and corrective action, or the need for regulatory enforcement. Medical licensees have demonstrated a good safety record with low incident rates less than 0.3 % for medical events affecting the medical treatment of 50 to 100 patients a year<sup>16</sup>. In most cases, these medical events do not result in a significant adverse effect to the patient or human research subject.

In the end, the Subcommittee distinguished regulatory criteria defining medical events and notifications of unintended embryo/fetus or child dose as being chosen to protect the individual member of the public, while AO criteria are used to define which of these medical events and notifications should be considered as significant from the standpoint of public health and safety for the annual report to Congress.

**2. Could a minimum number of medical use-related event reports per licensee to be considered as a screening criterion for abnormal occurrence definition?**

The Subcommittee explored the meaning of “public health or safety” used in the definition of an abnormal occurrence by considering the definitions of the following terms:

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<sup>16</sup> Byproduct Material Events Subcommittee Report, Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Meeting, April 2011, <http://pbadupws.nrc.gov/docs/ML1109/ML11095A086.pdf> (accessed April 4, 2013).

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**Public**<sup>17</sup> –

1. of, belonging to, or concerning the people as a whole; of or by the community at large
3. as regards community, rather than private, affairs

**Public Health**<sup>18</sup> –

The science and practice of protecting and improving the health of a community, as by preventive medicine, health education, control of communicable diseases, application of sanitary measures, and monitoring of environmental hazards.

**Public Health Ethics**<sup>19</sup> -

Public health ethics involves a systematic process to clarify, prioritize and justify possible courses of public health action based on ethical principles, values and beliefs of stakeholders, and scientific and other information.

The Subcommittee considered that incidents or events should have the potential for significant medical harm to more than one individual to be considered as significant from a public health or safety standpoint. The NRC has used this sort of threshold criteria for determining whether an Incident Investigation Team (IIT) or an Augmented Inspection Team (AIT) is warranted for a Medical Event Assessment (MEA)<sup>20</sup>.

The Subcommittee discussed what might be an appropriate number of individuals for a threshold criterion. One Subcommittee member felt any number greater than one would not be acceptable because of the adverse medical consequence criteria. Another Subcommittee member suggested two individuals would be the appropriate threshold criterion because one adverse event could happen anywhere, and not signify a threat to public health, but a second similar adverse event could indicate a failure in the cause analysis and correction process. The remaining Subcommittee members thought three individuals would be an appropriate threshold criterion, but also suggested that the Commission should consider providing summary information of medical use-related events resulting in medical harm not meeting this AO criterion as part of the AO report under the AO criteria IV. Other Events of Interest.

The NRC Staff told the Subcommittee that this sort of screening criterion would not be acceptable from a regulatory point of view. They noted that the regulatory philosophy of the NRC considers harm to any individual. As noted in Discussion Point 1, every medical event is subject to regulation and therefore no event posing harm to an individual would avoid regulatory scrutiny. The majority of

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<sup>17</sup> Webster’s New World College Dictionary, <http://www.yourdictionary.com/public> (accessed March 25, 2013).

<sup>18</sup> The American Heritage® Medical Dictionary, <http://medical.yourdictionary.com/public-health> (accessed March 25, 2013).

<sup>19</sup> Centers for Disease Control and Prevention, <http://www.cdc.gov/od/science/integrity/phethics/> (accessed March 25, 2013)

<sup>20</sup> NRC Medical Event Assessment Program Directive 8.10, July 6, 1994, <http://pbadupws.nrc.gov/docs/ML0414/ML041410592.pdf> (accessed April 8, 2013)

276 Subcommittee members did not see a conflict between using a threshold number of  
277 individuals as a screening criterion and the NRC’s regulatory philosophy.

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280 **3. Could a measure of rate be used rather than an absolute number of events reported in**  
281 **a year by a medical licensee?**

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283 The Subcommittee discussed whether consideration should be included for an AO  
284 criterion that evaluates the difference between a small clinic medical licensee  
285 reporting multiple events out of a low number of medical administrations a year  
286 versus a large university hospital medical licensee reporting the same number of  
287 events out of a much higher number of medical administrations. The Subcommittee  
288 concluded that use of a rate-based AO criterion would be impractical because  
289 medical licensees are not required to report the number of medical administrations  
290 per year. The Subcommittee did recognize that the evaluation of this kind of event  
291 rate is an important aspect of the NRC or Agreement State inspection of the medical  
292 licensee’s compliance and subsequent enforcement actions.

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**Attachment 3**

**NRC INSPECTION MANUAL  
Manual Chapter 1360**

**Use of Physician and Scientific Consultants  
in the Medical Consultant Program**

(<http://pbadupws.nrc.gov/docs/ML0627/ML062720195.pdf>)

1360-04 POLICY ON USE OF MEDICAL CONSULTANTS

04.01 The time frame for initial activation of the procedures in this Manual Chapter should be based on the initial assessment of the severity of the event. This assessment will typically be performed by the regional office with input from MSSA/FSME, as necessary.

The following guidelines may be used when establishing the time frame for activation<sup>1</sup>:

- a. Radiation Exposure Incident resulting in a fatality - 2 working days after NRC is informed of the event.
- b. Radiation Exposure Incident determined to:
  - 1. be a medical event; and
  - 2. result in a total dose in excess of the prescribed total dose to a patient – 5 working days after the event is determined to be a medical event by NRC.
- c. Radiation Exposure Incident determined to:
  - 1. be a medical event where the reporting requirement was based on the fractionated dose; and
  - 2. result in an overexposure that exceeds the prescribed total dose or three times the fractionated dose, whichever occurs first - 10 working days after the event is determined to be a medical event by NRC.
- d. Radiation Exposure Incident (other than a medical event) that has not resulted in a fatality - 10 working days after NRC is informed of the event.

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<sup>1</sup> The specified time frame assumes that the radiation exposure incident occurred within the last 2 months. If the radiation exposure incident occurred in the past, consideration should be given to extending the time frame.

- 337 04.02 Medical Consultants must be used under the following circumstances:  
338 a. Incidents where an individual has received one or more of the following doses:  
339  
340 1. A suspected total effective dose equivalent of 0.25 sievert (Sv) (25 rem) or more.  
341  
342 2. A suspected lens of the eye dose equivalent of 0.75 Sv (75 rem) or more.  
343  
344 3. A shallow-dose equivalent to the skin or extremities of 2.5 Gray (250 rad or more).  
345  
346 4. A suspected committed effective dose of 2.5 Sv (250 rem) or more to any individual  
347 organ or tissue other than the lens of the eye.  
348  
349 b. Incidents where an individual is demonstrating physical symptoms (erythema, nausea,  
350 vomiting, etc.) consistent with radiation syndromes, and the source of the radiation may be  
351 attributable to NRC-licensed radioactive material.  
352  
353 c. Incidents where NRC staff believe permanent functional damage to an organ or a  
354 physiological system is possible.  
355  
356 d. Incidents where a nursing infant or an embryo/fetus may have been inadvertently exposed to  
357 radiation or radioactive material as a result of the intentional or unintentional exposure of  
358 the mother of the nursing infant or an embryo/fetus to radiation or radioactive material.  
359  
360 e. A medical consultant shall be contacted for all medical events involving an overexposure in  
361 accordance with Management Directive 8.10, "NRC Medical Event Assessment Program."  
362 With the exception of the case identified in item c. above (for which site visits are required),  
363 a site visit by the medical consultant will not normally be required. A site visit by the  
364 medical consultant would be appropriate if the region and consultant agree that a site visit is  
365 necessary for NRC to understand the event, its causes, and its ramifications to the NRC's  
366 programs. Section 05.04e describes documentation required when the medical consultant  
367 determines that a site visit or consulting services are not necessary.  
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369 04.03 Medical Consultants may be used under the following circumstances:  
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- 371 a. Incidents where members of the public or occupationally exposed individuals may have  
372 been exposed to radiation during a radiation exposure incident.  
373  
374 b. Incidents where the staff believes that the assistance of a medical consultant would be  
375 beneficial to fulfilling the NRC mission.  
376

agreement involved. A copy of the executed agreement should be provided to the DFO prior to the beginning of the meeting for admittance to the closed session.

Dated: October 5, 2006.

**Andrew L. Bates,**

*Advisory Committee Management Officer.*

[FR Doc. E6-16870 Filed 10-11-06; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

### Abnormal Occurrence Reports: Implementation of Section 208 of the Energy Reorganization Act of 1974; Revised Policy Statement

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Issuance of Revised Policy Statement on Abnormal Occurrence Criteria.

**SUMMARY:** This policy statement presents the revised abnormal occurrence (AO) criteria the Commission uses for selecting AO's for the annual report to Congress as required by Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438). Section 208 of the act defines an AO as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The AO criteria have been amended to ensure that the criteria are consistent with the NRC's Strategic Plan for Fiscal Year (FY) 2004-2009 and the NRC rulemaking on Title 10, Part 35, of the Code of Federal Regulations (10 CFR Part 35), "Medical Use of Byproduct Material." Additionally, risk-informed criteria based on the NRC Accident Sequence Precursor (ASP) Program and Reactor Oversight Process (ROP) have been added for selecting abnormal occurrences at commercial nuclear power plants for the report to Congress. The ASP program assesses the risk significance of issues and events. The ROP is a risk-informed, tiered approach to ensuring the safety of nuclear power plants. The ROP is a process for collecting information about licensee performance, assessing the safety significance of the information, taking appropriate actions, and ensuring that licensees correct deficiencies. Some sections of the AO criteria have been restructured. The restructuring accommodates the changes in the criteria and minimizes duplication.

**DATES:** *Effective Date:* All revisions included in this publication are

complete and accurate as of September 21, 2006.

**FOR FURTHER INFORMATION CONTACT:** Sheryl A. Burrows, telephone: (301) 415-6086; e-mail: [SAB2@nrc.gov](mailto:SAB2@nrc.gov); USNRC, Office of Nuclear Regulatory Research, Mail Stop T9-F31, Washington, DC 20555-0001.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 208 of the Energy Reorganization Act of 1974 (Pub. L. 93-438) defines an abnormal occurrence (AO) as an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety. The Federal Reports Elimination and Sunset Act of 1995 (Public Law 104-66) requires that AOs be reported to Congress annually. Section 208 requires that the discussion of each event include the date and place, the nature and probable consequences, the cause or causes, and the action taken to prevent recurrence. The Commission must also widely disseminate the AO report to the public within 15 days of sending it to Congress.

##### Abnormal Occurrence Reporting

The AO policy statement has been developed to comply with Section 208 of the Energy Reorganization Act of 1974, as amended. The intent of the act is to keep Congress and the public informed of unscheduled incidents or events which the Commission considers significant from the standpoint of public health and safety. The policy reflects a range of health and safety concerns and applies to incidents and events involving a single individual, as well as those having overall impact on the general public. The AO criteria results in reports to Congress only for those events considered significant from the standpoint of public health and safety.

##### Licensee Reports

This general policy statement will not change the reporting requirements for NRC licensees in Commission regulations, license conditions, or technical specifications (TS). NRC licensees will continue to submit required reports on a wide range of events, including instrument malfunctions and deviations from normal operating procedures that are not significant from the standpoint of the public health and safety but provide data useful to the Commission in monitoring operating trends at licensed facilities and in comparing the actual performance of the facilities with their design and/or licensing basis.

##### Applicability

Implementation of Section 208 of the Energy Reorganization Act of 1974, as amended, "Abnormal Occurrence Reports", involves the conduct of Commission business and does not impose requirements on licensees or certified facilities. The reports cover certain unscheduled incidents or events related to the manufacture, construction, or operation of a facility or conduct of an activity subject to the requirements of Parts 20, 30 through 36, 39, 40, 50, 61, 70, 71, 72 or 76 of Chapter I of Title 10 of the Code of Federal Regulations (10 CFR).

Agreement States provide information to the NRC on incidents and events involving applicable nuclear materials in their States. Events reported by Agreement States that reach the threshold for reporting as AOs are also published in the "Report to Congress on Abnormal Occurrences."

##### Abnormal Occurrence General Statement of Policy

The Commission will apply the following policy in determining whether an incident or event at a facility or involving an activity that is licensed or otherwise regulated by the Commission is an AO.

An incident or event is considered an AO if it involves a major reduction in the protection of public health or safety. The incident or event has a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:

- (1) Moderate exposure to, or release of, radioactive material licensed or otherwise regulated by the Commission,
- (2) Major degradation of essential safety-related equipment, or
- (3) Major deficiencies in the design, construction, or use of management controls for facilities or radioactive material.

The criteria for determining whether to consider an incident or event for reporting as an AO are set forth in Appendix A of this policy statement.

##### Commission Dissemination of AO Information

The Commission widely disseminates the AO reports to the public. The Commission submits an annual report to Congress on AOs at or associated with any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This report gives the date, place, nature, and probable consequences of each AO, the cause or causes of each AO, and any actions taken to prevent recurrence.

**APPENDIX A: Abnormal Occurrence Criteria**

The following criteria are used to determine whether to consider events for reporting as AOs:

**I. For All Licensees****A. Human Exposure to Radiation from Licensed Material**

1. Any unintended radiation exposure to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 mSv (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ other than the lens of the eye, the bone marrow, and the gonads of 2,500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow of 1 Sv (100 rem) or more; or a committed dose equivalent to the gonads of 2,500 mSv (250 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2,500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or dispersal of radioactive material from its intended place of confinement which results in the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceeds 5,000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with § 20.1301 using § 20.1302(b)(1) or § 20.1302(b)(2)(ii).

This criterion does not apply to transportation events.

**C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach<sup>1 2</sup>**

1. Any unrecovered lost, stolen, or abandoned sources that exceed the

values listed in Appendix P to Part 110, "High Risk Radioactive Material, Category 2." Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur while the source was missing; and unrecoverable sources (sources that have been lost and for which a reasonable attempt at recovery has been made without success) lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 are not known to have occurred and the agency has determined that the risk of theft or diversion is acceptably low.

2. A substantiated<sup>3</sup> case of actual theft or diversion of licensed, risk-significant radioactive sources or a formula quantity<sup>4</sup> of special nuclear material; or act that results in radiological sabotage.<sup>5</sup>

3. Any substantiated<sup>3</sup> loss of a formula quantity<sup>4</sup> of special nuclear material or a substantiated<sup>3</sup> inventory discrepancy of a formula quantity<sup>4</sup> of special nuclear material that is judged to be caused by theft or diversion or by a substantial breakdown<sup>6</sup> of the accountability system.

4. Any substantial breakdown<sup>6</sup> of physical security or material control (i.e., access control containment or accountability systems) that

as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

<sup>2</sup> Due to increased terrorist activities worldwide, the AO report would not disclose specific classified information and sensitive information, the details of which are considered useful to a potential terrorist. Classified information is defined as information that would harm national security if disclosed in an unauthorized manner.

<sup>3</sup> "Substantiated" means a situation where an indication of loss, theft, or unlawful diversion such as: an allegation of diversion, report of lost or stolen material, statistical processing difference, or other indication of loss of material control or accountability cannot be refuted following an investigation; and requires further action on the part of the Agency or other proper authorities.

<sup>4</sup> A formula quantity of special nuclear material is defined in 10 CFR 70.4.

<sup>5</sup> Radiological sabotage is defined in 10 CFR 73.2.

<sup>6</sup> A substantial breakdown is defined as a red finding in the security inspection program, or any plant or facility determined to have overall unacceptable performance, or in a shutdown condition (inimical to the effective functioning of the nation's critical infrastructure) as a result of significant performance problems and/or operational events.

significantly weakened the protection against theft, diversion, or sabotage.

5. Any significant unauthorized disclosures (loss, theft, and/or deliberate) of classified information that harms national security or safeguards information that harms the public health and safety.

**D. Initiation of High-Level NRC Team Inspections<sup>7</sup>****II. For Commercial Nuclear Power Plant Licensees****A. Malfunction of Facility, Structures, or Equipment**

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

**B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy**

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any reactor events or conditions that are determined to be of high safety significance.<sup>8</sup>

<sup>7</sup> Initiation of any Incident Investigation Teams, as described in NRC Management Directive (MD) 8.3, "NRC Incident Investigation Program," or initiation of any Accident Review Groups, as described in MD 8.9, "Accident Investigation."

<sup>8</sup> The NRC ROP uses four colors to describe the safety significance of licensee performance. As defined in NRC Management Directive 8.13, "Reactor Oversight Process," green is used for very low safety significance, white is used for low to moderate safety significance, yellow is used for substantial safety significance, and red is used for

Continued

<sup>1</sup> Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the ERA of 1974,

D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).<sup>9</sup>

### III. Events at Facilities Other Than Nuclear Power Plants and All Transportation Events

#### A. Events Involving Design, Analysis, Construction, Testing, Operation, Transport, Use, or Disposal of Licensed Facilities or Regulated Materials

1. An accidental criticality [10 CFR 70.52(a)].
2. A major deficiency in design, construction, control, or operation having significant safety implications that require immediate remedial action.
3. A serious safety-significant deficiency in management or procedural controls.
4. A series of events (in which the individual events are not of major importance), recurring incidents, or incidents with implications for similar facilities (generic incidents) that raise a major safety concern.

#### B. For Fuel Cycle Facilities

1. Absence or failure of all safety-related or security-related controls (engineered and human) for an NRC-regulated lethal hazard (radiological or chemical) while the lethal hazard is present.
2. An NRC-ordered safety-related or security-related immediate remedial action.

#### C. For Medical Licensees A medical event that:

1. Results in a dose that is
  - a. Equal to or greater than 1Gy (100 rad) to a major portion of the bone marrow or to the lens of the eye; or equal or greater than 2.5 Gy (250 rad) to the gonads; or
  - b. Equal to or greater than 10 Gy (1,000 rad) to any other organ or tissue; and
2. Represents either
  - a. A dose or dosage that is at least 50 percent greater than that prescribed, or

high safety significance. Reactor conditions or performance indicators evaluated to be red are considered Abnormal Occurrences. Additionally, Criterion II.C also includes any events or conditions evaluated by the NRC ASP program to have a conditional core damage probability (CCDP) or change in core damage probability (CDP) of greater than  $1 \times 10^{-3}$ .

<sup>9</sup> Any plants assessed by the ROP to be in the unacceptable performance column, as described in NRC Inspection Manual Chapter 0305, "Operating Reactor Assessment Program." This assessment of safety performance is based on the number and significance of NRC inspection findings and licensee performance indicators.

- b. A prescribed dose or dosage that
  - (i) Uses the wrong radiopharmaceutical or unsealed byproduct material; or
  - (ii) Is delivered by the wrong route of administration; or
  - (iii) Is delivered to the wrong treatment site; or
  - (iv) Is delivered by the wrong treatment mode; or
  - (v) Is from a leaking source or sources; or
  - (vi) Is delivered to the wrong individual or human research subject.

### IV. Other Events of Interest

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an appendix to the AO report as "Other Events of Interest." Such events may include, but are not necessarily limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner. 5 U.S.C. 552(a)]

Dated at Rockville, Maryland, this 5th day of October 2006.

For the U.S. Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. E6-16871 Filed 10-11-06; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[NUREG-1852]

### "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire, Draft Report for Comment"

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of availability of NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire, Draft Report For Comment," and request for public comment.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is announcing the availability of and is seeking comments on NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire, Draft Report For Comment."

**DATES:** Comments on this document should be submitted by November 6, 2006. Comments received after that date will be considered to the extent practical. To ensure efficient and complete comment resolution, comments should include references to the section, page, and line numbers of the document to which the comment applies, if possible.

**ADDRESSES:** Members of the public are invited and encouraged to submit written comments to Michael Lesar, Chief, Rulemaking, Directives, and Editing Branch, Office of Administration, Mail Stop T6-D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand-deliver comments attention to Michael Lesar, 11545 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Comments may also be sent electronically to [NRCREP@nrc.gov](mailto:NRCREP@nrc.gov).

This document, NUREG-1852, is available at the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> under Accession No. ML062350285; on the NRC Web site <http://www.nrc.gov/reading-rm/doc-collections/nuregs/docs4comment.html>; and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. The PDR's mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4205; fax (301) 415-3548; e-mail [PDR@NRC.GOV](mailto:PDR@NRC.GOV). **FOR FURTHER INFORMATION, CONTACT:** Erasmia Lois, Human Factors and Reliability Branch, Office of Nuclear Regulatory Research, telephone (301) 415-6560, e-mail [exl1@nrc.gov](mailto:exl1@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

NUREG-1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire, Draft Report For Comment," September 2006

This NUREG provides criteria that licensees may use to demonstrate the feasibility and reliability of operator manual actions in response to fire. This NUREG does not clarify circumstances under which licensees may use operator manual actions in lieu of fire barriers. Licensees should refer to 10 CFR 50.48 and their license bases to determine applicable regulatory requirements with respect to operator manual actions in fire protection. Additional guidance on regulatory requirements pertaining to operator manual actions are provided in Regulatory Issue Summary 2006-10, "Regulatory Expectations with

other interested Federal, State, and local agencies, and the views of interested persons, including electric utilities, citizens' groups, and others, shall be solicited and considered.

Definition.

(2) For purposes of this section, the term "nuclear energy center site" means any site, including a site not restricted to land, large enough to support utility operations or other elements of the total nuclear fuel cycle, or both including, if appropriate, nuclear fuel reprocessing facilities, nuclear fuel fabrication plants, retrievable nuclear waste storage facilities, and uranium enrichment facilities.

(3) The survey shall include—

(a) a regional evaluation of natural resources, including land, air, and water resources, available for use in connection with nuclear energy center sites; estimates of future electric power requirements that can be served by each nuclear energy center site; an assessment of the economic impact of each nuclear energy site; and consideration of any other relevant factors, including but not limited to population distribution, proximity to electric load centers and to other elements of the fuel cycle, transmission line rights-of-way, and the availability of other fuel resources;

(b) an evaluation of the environmental impact likely to result from construction and operation of such nuclear energy centers, including an evaluation whether such nuclear energy centers will result in greater or lesser environmental impact than separate siting of the reactors and/or fuel cycle facilities; and

(c) consideration of the use of federally owned property and other property designated for public use, but excluding national parks, national forests, national wilderness areas, and national historic monuments.

Report to Congress and Council on Environmental Quality; public availability.

(4) A report of the results of the survey shall be published and transmitted to the Congress and the Council on Environmental Quality not later than one year from the date of the enactment of this Act and shall be made available to the public, and shall be updated from time to time thereafter as the Commission, in its discretion, deems advisable. The report shall include the Commission's evaluation of the results of the survey and any conclusions and recommendations, including recommendations for legislation, which the Commission may have concerning the feasibility and practicality of locating nuclear power reactors and/or other elements of the nuclear fuel cycle or nuclear energy center sites. The Commission is authorized to adopt policies which will encourage the location of nuclear power reactors and related fuel cycle facilities on nuclear energy center sites insofar as practicable.

42 USC 5848. Reports to Congress. 42 USC 2011 note.

**Sec. 208. Abnormal Occurrence Reports**

The Commission shall submit to the Congress an annual report listing for the previous fiscal year any abnormal occurrences at or associated with any facility which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954 as amended, or pursuant to this Act. For the purposes of this section an abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. Nothing in the preceding sentence shall limit the authority of a court to review the determination of the Commission. Each such report shall contain—

- (1) the date and place of each occurrence;
- (2) the nature and probable consequence of each occurrence;
- (3) the cause or causes of each; and

Public dissemination of information.	(4) any action taken to prevent reoccurrence; the Commission shall also provide as wide dissemination to the public of the information specified in clauses (1) and (2) of this section as reasonably possible within fifteen days of its receiving information of each abnormal occurrence and shall provide as wide dissemination to the public as reasonably possible of the information specified in clauses (3) and (4) as soon as such information becomes available to it. <sup>15</sup>
<b>42 USC 5849.</b> Executive Director.	<b>Sec. 209. Other Officers</b> (a) The Commission shall appoint an Executive Director for Operations, who shall serve at the pleasure of and be removable by the Commission.
Functions.	(b) The Executive Director shall perform such functions as the Commission may direct, except that the Executive Director shall not limit the authority of the director of any component organization provided in this Act to communicate with or report directly to the Commission when such director of a component organization deems it necessary to carry out his responsibilities. Notwithstanding the preceding sentence, each such director shall keep the Executive Director fully and currently informed concerning the content of all such direct communications with the Commission. <sup>16</sup>
Equal employment opportunity, Annual status report.	(c) The Executive Director shall report to the Commission at semiannual public meetings on the problems, progress, and status of the Commission's equal employment opportunity efforts. <sup>17</sup>
Report to Congress.	(d) <sup>18</sup> The Executive Director shall prepare and forward to the Commission an annual report (for the fiscal year 1978 and each succeeding fiscal year) on the status of the Commission's programs concerning domestic safeguards matters including an assessment of the effectiveness and adequacy of safeguards at facilities and activities licensed by the Commission. The Commission shall forward to the Congress a report under this section prior to February 1, 1979, as a separate document, and prior to February 1 of each succeeding year as a separate chapter of the Commission's annual report (required under section 307(c) of the Energy Reorganization Act of 1974) following the fiscal year to which such report applies.
42 USC 5877. Other officers.	(e) <sup>19</sup> There shall be in the Commission not more than five additional officers appointed by the Commission. The positions of such officers shall be considered career positions and be subject to subsection 161 d. of the Atomic Energy Act.
<b>42 USC 5850.</b> Progress reports. Submittal to Congress.	<b>Sec. 210. Unresolved Safety Issues Plan</b> <sup>20</sup> The Commission shall develop a plan providing for the specification and analysis of unresolved safety issues relating to nuclear reactors and shall take such action as may be necessary to implement corrective measures with respect to such issues. Such plans shall be submitted to the Congress on or before January 1, 1978, and progress reports shall be included in the annual report of the Commission thereafter.

<sup>15</sup> Amended by P.L. 104-66, Title II, Subtitle Q, § 2171, 109 Stat. 731 (1995).

<sup>16</sup> Amended by P.L. 95-601, § 4(a), 92 Stat. 2949 (1978).

<sup>17</sup> Amended by P.L. 95-601, § 4(b), 92 Stat. 2949 (1978), by adding a new subsection (c) and redesignating it as subsection (e).

<sup>18</sup> Added by P.L. 95-601, § 6, 92 Stat. 2949 (1978). As a result of P.L. 104-66, § 3003, 109 Stat. 734 (1995), reporting requirements ceased to be effective after December 21, 1999.

<sup>19</sup> Amended by P.L. 95-601, § 4(b), 92 Stat. 2949 (1978). Formerly, subsection (c). See footnote 17.

<sup>20</sup> Added by P.L. 95-209, § 3, 91 Stat. 1482 (1977).



## **10 CFR Part 35 Rulemaking Update**

**Neelam Bhalla and Ed Lohr  
Rulemaking and Project Management  
Branch  
DILR/FSME**

### **Current Status**

- **ACMUI review**
- **Agreement States preliminary review**
- **Part 35 working group has started ACMUI and Agreement State comment resolution**

2

### **ACMUI Comments**

- **Convey to the Commission:**
  - 1. The working group would provide the ACMUI comments**
  - 2. The working group would provide the comment resolution and the reasons for not accepting any particular comment**

3

### **Current Schedule**

**Proposed Rule to the Commission:  
Mid- 2013**

**Final Rule to the Commission:  
Late- 2014**

4

  
 United States Nuclear Regulatory Commission  
 Protecting People and the Environment

## Patient Release Health and Safety

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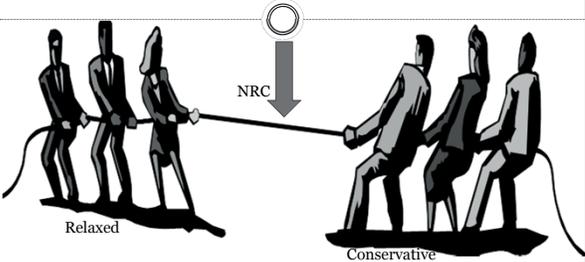
### A REVIEW OF CURRENT REGULATIONS AND PRACTICES

Mohammad Saba, Office of Nuclear Regulatory Research

ACMUI Public Meeting, April 15, 2013

  
 United States Nuclear Regulatory Commission  
 Protecting People and the Environment

### Patient Release Criteria



  
 United States Nuclear Regulatory Commission  
 Protecting People and the Environment

### Previous Rule

- The current rule in 10 CFR Part 35.75 became effective in 1997. Prior to 1997, patient release was based on:
 

*A licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either: (1) The measured dose rate from the patient or human research subject is less than 5 millirems per hour at a distance of 1 meter; or (2) The activity in the patient or the human research subject is less than 30 millicuries.*

  
 United States Nuclear Regulatory Commission  
 Protecting People and the Environment

- A major advantage of the previous rule was that release was based on directly measurable criteria, namely retained activity or dose rate from the patient.
- A significant disadvantage of the previous rule was that it made no allowance for the specific conditions of the patient following release.



### Current Rule

- *A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem).*



- The current rule is based on dose to a member of the public. It does not provide the licensee with a measurable quantity to be used for releasing the patient.
- A model is therefore required to translate the release criterion into an operational quantity.



- The model suggested by NRC for use by licensees to determine the release criteria is described in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials."
- The model provides two main options for the licensee: use default parameters, or use patient specific parameters.



- Model parameters include effective half-life of the radioisotope, duration of exposure of a member of the public, attenuation of radiation in the patient and the target, etc.
- It is interesting to note that use of the default parameters in the model leads to a release criterion that is nearly identical to the 30 mCi retained activity criterion in the old rule. This is coincidental.



- The Commission directed NRC staff to review publicly available data on doses being received by members of the public as a result of application of the 10 CFR Part 35.75 release criteria. The review is to include surveys of the technical literature as well as performance of measurements in areas where data is sparse or unavailable. Assessment of the rule itself is not within the scope of this work.
- The objective is to see how well patient release practices are working and the extent to which the dose criterion is being met.



- In addition, the Commission directed staff to re-examine the methods used in Regulatory Guide 8.39 to calculate dose to members of the public, and to recommend changes as deemed appropriate.
- The items to be reviewed include:
  - Use of point source and point target.
  - Use of the gamma ray constant.
  - No credit for self absorption in patient or target.
  - No credit for biological elimination .
  - Occupancy factor of 0.25.



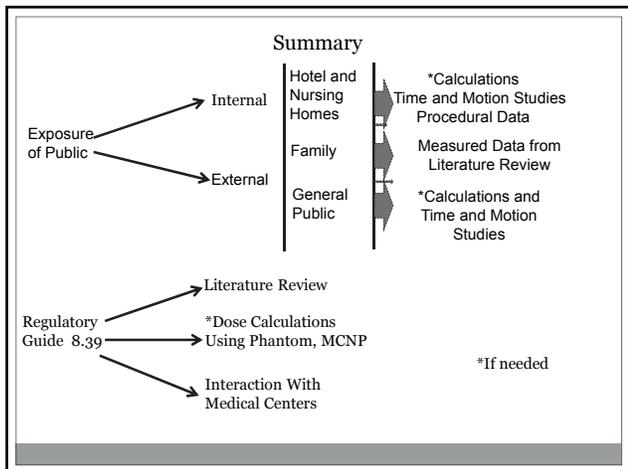
### Current Status of Work

- There appears to be sufficient data in the literature to reach reliable conclusions on exposures of members of the public, both external and internal. With the exceptions of exposure to hotel and nursing home workers.
- NRC is conducting calculations using state-of-the-art anthropomorphic phantoms and Monte Carlo calculations to represent the patient and the target and to calculate doses.
- Calculations are designed to assess doses in various situations, such as public transportation, hotels, at home, etc.



### Current status of Work

- It is still unclear if any NRC-initiated measurements will be needed. This will be determined as the literature review progresses.
- NRC staff have been in contact with several medical facilities to discuss their patient release practices and calculations, and any data they have concerning exposure of members of the public.
- The work is scheduled to be completed by the end of 2016.



U.S. DEPARTMENT OF ENERGY **Global Threat Reduction Initiative** NNSA  
 Defense Nuclear Nonproliferation

**GTRI's Efforts to Minimize the Use of Highly Enriched Uranium in Mo-99 Production**

ACMUI Meeting  
 April 15-16, 2013

U.S. DEPARTMENT OF ENERGY **GTRI Mission & Program Goals** NNSA  
 Defense Nuclear Nonproliferation

**MISSION**  
 REDUCE AND PROTECT VULNERABLE NUCLEAR AND RADIOLOGICAL MATERIAL LOCATED AT CIVILIAN SITES WORLDWIDE.

**GOALS**  
 1. CONVERT  
 2. REMOVE  
 3. PROTECT

**CONVERT**

CONVERT RESEARCH REACTORS AND ISOTOPE PRODUCTION FACILITIES FROM THE USE OF HIGHLY ENRICHED URANIUM (HEU) TO LOW ENRICHED URANIUM (LEU).

THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY MINIMIZING AND, TO THE EXTENT POSSIBLE, ELIMINATING THE NEED FOR HEU IN CIVILIAN APPLICATIONS - EACH REACTOR CONVERTED OR SHUT DOWN ELIMINATES A SOURCE OF BOMB MATERIAL.

**REMOVE**

REMOVE AND DISPOSE OF EXCESS NUCLEAR AND RADIOLOGICAL MATERIALS.

THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY ELIMINATING BOMB MATERIAL AT CIVILIAN SITES - EACH KILOGRAM OR CURIE OF THIS DANGEROUS MATERIAL THAT IS REMOVED REDUCES THE RISK OF A TERRORIST BOMB.

**PROTECT**

PROTECT HIGH PRIORITY NUCLEAR AND RADIOLOGICAL MATERIALS FROM THEFT AND SABOTAGE.

THESE EFFORTS RESULT IN THREAT REDUCTION BY IMPROVING SECURITY ON THE BOMB MATERIAL REMAINING AT CIVILIAN SITES - EACH WHEN TRAILER BUILDING THAT IS PROTECTED REDUCES THE RISK THAT A PERMANENT THREAT REDUCTION POSITION CAN BE IMPLEMENTED.

2

U.S. DEPARTMENT OF ENERGY **GTRI & Mo-99** NNSA  
 Defense Nuclear Nonproliferation

**International & U.S. Domestic Approaches**

- Under its long-standing HEU minimization mission, GTRI provides assistance to research reactors and isotope production facilities to convert from the use of HEU to LEU.
- GTRI's mission includes accelerating the establishment of a reliable U.S. domestic supply of Mo-99 produced without the use of HEU.

**INTERNATIONAL EFFORTS**

Assisting global Mo-99 production facilities to convert to use LEU targets

**U.S. DOMESTIC EFFORTS**

Accelerating the establishment of commercial non-HEU-based Mo-99 production in the United States

Achieve HEU Minimization

Establish reliable supplies of Mo-99 produced without HEU

3

U.S. DEPARTMENT OF ENERGY **GTRI & Mo-99** NNSA  
 Defense Nuclear Nonproliferation

**Strategy for Reliable Non-HEU-Based Mo-99 Supply**

**Global Mo-99 Market - Major Producers**

				HEU	Non-HEU
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Covidien (Netherlands)	IRE (Belgium)	AECL-Nordion (Canada)	
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Covidien (Netherlands)	IRE (Belgium)	AECL-Nordion (Canada)	
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Covidien (Netherlands)	IRE (Belgium)		2016

**U.S. Domestic Mo-99 Projects**

1

2

3

4

→

4

U.S. DEPARTMENT OF ENERGY **ENERGY** **GTRI & International Mo-99**  
**Assisting Conversion from HEU Targets to LEU Targets** **NNSA**  
National Nuclear Security Administration  
Defense Nuclear Nonproliferation

GTRI provides assistance to isotope production facilities to convert from the use of HEU to LEU.

- **Four-party joint statement at the 2012 Nuclear Security Summit on the minimization of HEU and the reliable supply of medical radioisotopes**  
 "...Belgium, the Netherlands, and France, in cooperation with the United States, reaffirm their determination to support conversion of European production industries to non-HEU-based processes by 2015....."
- **GTRI offers support to international Mo-99 producers to convert Mo-99 production from HEU targets to LEU targets**  
South Africa  
 GTRI has provided NTP Radioisotopes in South Africa up to \$25M in support to convert Mo-99 production from HEU targets to LEU targets by the end of 2015, and to address the HEU in Mo-99 waste residue.  
  
 In June 2010 South Africa successfully achieved the first large-scale production of Mo-99 using LEU targets, and the first shipment of FDA-approved Mo-99 produced with LEU targets was received in the United States in December 2010.



**Nuclear Security Summit**  
Seoul 2012



SAFARI-1 Reactor (South Africa)

5

U.S. DEPARTMENT OF ENERGY **ENERGY** **GTRI & International Mo-99**  
**Assisting Conversion from HEU Targets to LEU Targets** **NNSA**  
National Nuclear Security Administration  
Defense Nuclear Nonproliferation

- **GTRI offers support to international Mo-99 producers to convert Mo-99 production from HEU targets to LEU targets**  
Belgium  
 GTRI has contributed \$4.8M towards the conversion of the IRE isotope production facility in Belgium from HEU targets to LEU targets for completion by the end of 2015.  
  
The Netherlands  
 Covidien is leading the conversion project to LEU targets by the end of 2015.  
  
Canada  
 The NRU reactor in Canada is expected to cease isotope production in 2016.



**Nuclear Security Summit**  
Seoul 2012

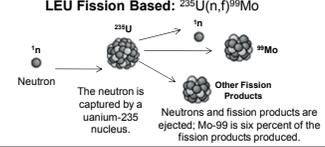


SAFARI-1 Reactor (South Africa)

6

U.S. DEPARTMENT OF ENERGY **ENERGY** **GTRI and U.S. Domestic Mo-99: Non-HEU Production Methods**  
**NNSA**  
National Nuclear Security Administration  
Defense Nuclear Nonproliferation

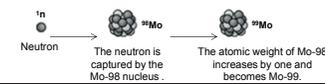
**LEU Fission Based:  $^{235}\text{U}(n,f)^{99}\text{Mo}$**



The neutron is captured by a uranium-235 nucleus. Neutrons and fission products are ejected; Mo-99 is six percent of the fission products produced.

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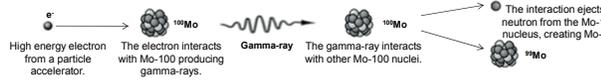
**Neutron Capture:  $^{98}\text{Mo}(n,\gamma)^{99}\text{Mo}$**



The neutron is captured by the Mo-98 nucleus. The atomic weight of Mo-98 increases by one and becomes Mo-99.

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**Accelerator Based:  $^{100}\text{Mo}(\gamma,n)^{99}\text{Mo}$**



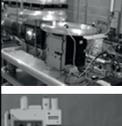
High energy electron from a particle accelerator. The electron interacts with Mo-100 producing gamma-rays. Gamma-ray. The gamma-ray interacts with other Mo-100 nuclei. The interaction ejects a neutron from the Mo-100 nucleus, creating Mo-99.

7

U.S. DEPARTMENT OF ENERGY **ENERGY** **GTRI and U.S. Domestic Mo-99: Cooperative Agreement Partners**  
**NNSA**  
National Nuclear Security Administration  
Defense Nuclear Nonproliferation

**Objective:** To accelerate existing commercial projects to meet at least 100% of the U.S. demand of Mo-99 produced without HEU.

- **NorthStar Medical Radioisotopes, LLC**  
 NNSA has awarded a total of \$25 million to NorthStar Medical Radioisotopes to pursue accelerator technology.
- **Morgridge Institute for Research/SHINE Medical Technologies**  
 NNSA has awarded a total of \$10.7 million to Morgridge Institute for Research to pursue accelerator with LEU fission technology in cooperation with SHINE Medical Technologies.
- **Babcock and Wilcox (B&W):**  
 NNSA has awarded \$9.1 million to Babcock and Wilcox (B&W) to pursue LEU solution reactor technology.
- **General Electric-Hitachi (GEH):**  
 NNSA awarded \$2.3 million to General Electric-Hitachi to pursue neutron capture technology. On February 7, 2012, GEH announced its business decision to suspend progress on the project indefinitely due to market conditions.

Each cooperative agreement is currently limited to \$25M, under a 50% - 50% cost-share arrangement.

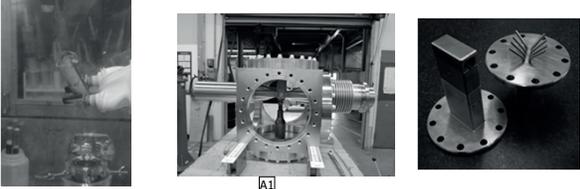
8

U.S. DEPARTMENT OF ENERGY **U.S. National Laboratories Support to Mo-99 Production** **NNSA**  
National Nuclear Security Administration  
Defense Nuclear Cooperation

GTRI makes the expertise of the U.S. National Laboratories available to:

- Support technical development of each of the Mo-99 technical pathways
- Ensure the expertise at the national laboratories is available to support the acceleration of commercial projects using non-HEU technologies

All work packages funded by NNSA outside the cooperative agreement are open-source, non-proprietary, non-critical-path activities.



A1

9

U.S. DEPARTMENT OF ENERGY **U.S. Government Public Statement** **NNSA**  
National Nuclear Security Administration  
Defense Nuclear Cooperation

**Encouraging Reliable Supplies of Molybdenum-99 Produced without Highly Enriched Uranium**

Issued by the White House Press Secretary on June 7, 2012

- Calling upon the Mo-99 industry to voluntarily establish a unique product code or similar identifying markers for Mo-99-based radiopharmaceutical products that are produced without the use of HEU;
- Preferentially procuring, through certain U.S. government entities, Mo-99-based products produced without the use of HEU, whenever they are available, and in a manner consistent with U.S. obligations under international trade agreements;
- Examining potential health-insurance payment options that might promote a sustainable non-HEU supply of Mo-99;
- Taking steps to further reduce exports of HEU that will be used for medical isotope production when sufficient supplies of non-HEU-produced Mo-99 are available to the global marketplace;

10

U.S. DEPARTMENT OF ENERGY **U.S. Government Public Statement** **NNSA**  
National Nuclear Security Administration  
Defense Nuclear Cooperation

**Encouraging Reliable Supplies of Molybdenum-99 Produced without Highly Enriched Uranium**

Issued by the White House Press Secretary on June 7, 2012

- Continuing to encourage domestic commercial entities in their efforts to produce Mo-99 without HEU during the transition of the Mo-99 industry to full-cost-recovery, and directing those resources to the projects with the greatest demonstrated progress; and
- Continuing to provide support to international producers to assist in the conversion of Mo-99 production facilities from HEU to LEU.

11

U.S. DEPARTMENT OF ENERGY **The American Medical Isotopes Production Act of 2012** **NNSA**  
National Nuclear Security Administration  
Defense Nuclear Cooperation

**The American Medical Isotopes Production Act of 2012 (formerly known as H.R.3276 and S.99) was incorporated into the National Defense Authorization Act. President Obama signed the legislation on January 2, 2013.**

- Requires the Secretary of Energy to establish a technology-neutral program to provide assistance to commercial entities to accelerate production of Mo-99 in the United States without the use of HEU.
- Requires public participation and review of the program
- Requires development assistance for fuels, targets, and processes
- Establishes a Uranium Lease and Take Back program
- Requires DOE and NRC to coordinate environmental reviews where practicable
- Provides a cutoff in exports of HEU for isotope production in 7 years, with possibility for extension in the event of a supply shortage
- Requires reports to be submitted to Congress on an annual basis

12

## Slide 9

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**A1** Captions down below might make the slide more interesting.

Hot cell photo -- no idea

Middle photo -- Target cube assembly, which has inlet ports for the OTR/IR camera, He cooling and the electron beam

Right photo -- Target assembly which holds the Mo-100 disks. It sits in the target cube. Those prongs on the right are inlets for the He cooling (I believe).

Author, 03/07/2013

### Acronyms

- AECL – Atomic Energy of Canada Limited
- ANSTO – Australian Nuclear Science and Technology Organisation
- DOE – Department of Energy
- FDA - Food and Drug Administration
- GTRI – Global Threat Reduction Initiative
- HEU – Highly Enriched Uranium
- IRE – The National Institute for Radioelements
- LEU – Low Enriched Uranium
- Mo – Molybdenum
- NNSA – National Nuclear Security Administration
- NRC – Nuclear Regulatory Commission
- NRU – National Research Universal
- NTP – Nuclear Technology Products

## 2013 Tc-99m Reimbursement Policy



## OECD Targeted Principles

### OECD GOAL: STABLE SUPPLY

- Relevant Consumer Principles
  - Principle 1: Promote FCR
  - Principle 3: Encourage market
  - Principle 4: Promote non-HEU
- US Commitment: Examine health insurance payment options to promote sustainable non-HEU supply of Mo-99
- U.S. Goal: STABLE SUPPLY BASED ON NON-HEU
  - Encourage (Protect) Market

## CMS Principles

GOAL: STABLE SUPPLY (Population) of Diagnostic Tests (Patient) at Affordable Cost (Cost)

- Encourage (Protect) Market
  - Promote FCR
- Promote Efficiency
- Support Presidential Initiatives (GTRI)
  - To the extent allowed by law

## CMS Constraints

- Reimbursement vs. Incentive
  - Incentive: a “bonus” to create new behavior
  - Reimbursement: compensation for existing behavior
- Must be consistent with statutory authority
  - Must equal reimbursement
  - If it creates an incentive, that is an incidental benefit
  - Must go to healthcare delivery entities (e.g. hospitals)
- Must be acceptable to healthcare industry
- Should be simple and transferable to other payers

### Economic Constraints

- FCR is not easily audited or tracked
- Unbundling Radiopharmaceutical does not create payment offset for Non-HEU/FCR
- Unbundling Radioisotope does not create payment offset for Non-HEU/FCR
- Unbundling is not consistent with CMS reimbursement models to increase hospital and physician choice

### The Solution

- Link Non-HEU conversion to FCR at the consumer end
  - Correlation: Non-HEU sourced production is newer and more consistently based on FCR
  - Non-HEU sourcing is more easily tracked and audited
  - Non-HEU sourcing creates an artificial benefit as a proxy for FCR (co-attribute)
- Unbundling of the Non-HEU attribute creates a defined and visible payment differential
  - CMS could reimburse hospitals for that differential
  - Weakness: Only the industry can move the payment from the hospital back to the reactor and processor

### The Intent

- Create a payment to *cover increased costs of Medicare portion* of FCR and non-HEU sources
- Create a signal that Medicare backs sustainable pricing
- Create a model for use by other payers
- Minimize hospital administrative burden
- Reimburse supply costs not transition externalities (tracking, scheduling)

### The Payment: Q9969

- CMS created a new payment effective 1/1/2013 to cover the added cost of producing Tc-99m from non-HEU sources using Full Cost Recovery
- This is a \$10 per dose add-on payment by Medicare for all hospital outpatient Tc-99m tests
  - As a practical matter, the inpatient payment system does not support small added payments.
  - The legal authority for the payment does not extend to physician offices.
  - Many Medicaid and commercial programs follow CMS practices in paying claims

## The Impact

- The payment could allow a radiopharmacy to absorb a doubling of generator cost
- Total payment will (initially) be less than maximum because all payers will not accept coding and all hospitals will not bill
- Important signal that Medicare is absorbing added cost is already triggering market changes to increase non-HEU/FCR supply
- The function of the payment is to reimburse additional production cost (non-HEU and FCR) not to create incentives within the supply chain

## Analysis Conclusions

- **The industry has not disclosed any information to suggest a significant deviation from the range of the OECD models**
  - The model does not suggest a high likelihood of a non-competitive *end user product* ( the tracer dose) using Non-HEU sources at FCR, i.e. Tc-99m changes are relatively inconsequential to the test consumer
- A competitive advantage of subsidized (HEU or non-HEU) production will continue to exist in the early steps in the supply chain
  - This is not reduced by increasing prices/revenue of the (undifferentiated) Tc-99m dose

## Analysis Conclusions

- Modest increases in payments will cover increased Mo-99 costs, but there is no guarantee and in fact little economic pressure to ensure that increased payments will flow back to producers and processors
- **Payment initiatives cannot promote FCR; they can only support an industry-wide movement to FCR**

## Payment Initiatives Cannot Support FCR in the US Market

- Since there is no difference in benefit between FCR doses and subsidized doses, market reforms depend on equalizing user costs (taxes, subsidies, pass through payments)
- Cost differential is at the reactor (and processor) level, so cost equalizing initiative must be passed up to that level
- Payment differential does not pass through the generator/extraction steps because there is not a 1:1 correspondence between Ci Mo-99 and Ci Tc-99m
- Payment differential can provide a tool BUT any benefit to a stable supply depends on the way the tool is used

## Acronyms

- FCR: Full Cost Recovery
- GTRI: Global Threat Reduction Initiative
- HEU: Highly Enriched Uranium
- Mo-99: Molybdenum-99
- OECD: Organisation for Economic Co-operation and Development
- Tc-99m: Technetium-99 metastable

## Questions?

Daniel.Duvall@CMS.HHS.GOV



**Status of Medical Events FY 2012**

Donna-Beth Howe, Ph.D.  
 Medical Radiation Safety Team  
 April 16, 2013



**Medical Events 2012**

- 58 Medical events reported - FY 2011
- 48 Medical events reported - FY 2012

	<u>FY11</u>	<u>FY12</u>
35.200	3	2
35.300	6	2
35.400	26 (??)	15
35.600	12	13
35.1000	11	20



**Medical Events 2012**

**Diagnostic Medical Event**

35.200 (4 patients) 2

- Pharmacy filled vial labeled Gallium with thallium – 6.2 rem - 1 patient
- Sr-82/Sr-85 breakthrough exceeded limits over 5 rem – 3 patients



**Medical Events 2012**

35.300 2

Oral Sodium Iodide I-131

- Pharmacy sent two 50 mCi capsules one stuck in vial discovered when returned to pharmacy
- Prescribed 100 mCi received 163 mCi – misinterpretation of an admission order as a written directive – written directive never received under new system



## Medical Events 2012

**35.400 Medical events** **11**

- Brachy-mesh 1
- Prostate (22 patients) 10

5



## 35.400 Medical Events

**Brachy-mesh** I-125 1

- 76% of intended dose – device failure seeds loose from mesh – by day seven 24 % were not visible in lung - all outside lung by 2 months

6



## 35.400 Medical Events

**Prostate (22 Patients)** 10

- 1 licensee reported multiple patients in one medical event report – 13 patients
- 1 licensee made 3 separate medical event reports -3 patients
- 6 separate licensees – 1 patient each

7



## 35.400 Medical Events

### Prostate (continued)

- 1 Leaking I-125 seed – thyroid 330 cGy (rad) found 1 month later when surveying packing material
- 1 Wrong patient - wrong written directive - gave second patient treatment developed for first – written directives same # seeds, same activity, same dose only received 73% of prescribed dose
- 1 Wrong site – penile bulb - mistook it for prostate
- 13 One overdose to prostate, 7 under dose to prostate (includes 2 overdose to rectum), 5 over doses to rectum - human error and not comparing to medical event criteria

8

## 35.400 Medical Events

### Prostate (continued)

- 54% of dose passed 2 strands - patient saw strands after left facility one down sewer other patient kept retained
- 68 % of dose prostate volume increased - reimages and prostate was smaller but not as small as originally determined - dose did not change between 1st and 2nd CT determinations
- 3 patients 72.8% of dose and 58.9% of dose June 2009, and 54% of the dose Oct 2009
- Cs-131 48% of dose Sep 2007 - human error

9

## Medical Events 2012

**35.600 Medical events** 13

– HDR	12
• Mammosite	1
• Sacral	1
• Common Bile Duct	1
• Arm	1
• Nose	1
• GYN	7
– Gammaknife	1

10

## 35.600 Medical Events

### HDR (continued)

- Mammosite - wrong patient treatment plans essentially the same 95% of dose
- Sacral Region - incorrectly entered distance between treatment planes as 3 cm instead of 3 mm overdosed two treatment planes 22,200 instead of 15,00cGy

11

## 35.600 Medical Events

### HDR (continued)

- Common bile duct – 2 fractions 4 cm from desired location - error correcting dwell position after catheter migration adjusted out when should have been in – 1,400 cGy(rad) to 4 cm of unintended bile duct and hepatic tissue
- Left arm went from one treatment to 8 fractions did not revise isodose line 87% less on first 2 fractions 25 cGy instead of 200 cGy per fraction

12

## 35.600 Medical Events

### HDR (continued)

- Sides of Nose - 2 fractions received 925 instead of 600 cGy (rad) dwell time correct but data entered incorrectly into HDR unit found error before 3rd fraction

13

## 35.600 Medical Events

### HDR GYN (continued)

- Reddening of skin to upper thigh @ 1,200 cGy (rad) doses to both upper thighs -substituted replacement catheter (slightly larger) source got caught on constriction in tandem
- Necrotic tissue on inner thigh - compression fitting not tight enough, catheter slipped in handling or when positioning patient
- Wire drift error treatment terminated prior to completion 73 of 600 cGy (rad)

14

## 35.600 Medical Events

### HDR GYN (continued)

- Tandem catheter not fully inserted - 1st fraction dose to rectum 256 not intended 157 cGy (rad) 63% over dose vaginal tissue 70% over dose
- Error message about channel not being used at completion of 1 channel during first fraction 120 of 600 cGy(rad) terminated when could not clear error message – appear to blame dust.

15

## 35.600 Medical Events

### HDR GYN (continued)

- Treatment planning software malfunction - over dose 1st fraction 600 instead of 340 cGy (rad)– indexer lengths were corrected and device erroneously recalculated dwell times and printed incorrect dose to verification point
- No reason given - scheduled to receive 1,500 but received 1,000 cGy - will use the QA software in future

16

## 35.600 Medical Events

### **Gammaknife** **1**

- Aborted - mechanical failure latch fasteners fastening immobilizing frame of head of couch failed

17

## Medical Events 2012

### **35.1000 Medical events** **20**

- Perfexion 1
- Y-90 Microspheres (21 patients) 19

18

## 35.1000 Medical Events

### **Perfexion** **1**

- Overdose –
  - patient fell dislodged stereotactic frame –
  - it was reattached and plan recalculated
  - but treatment did not restarted at correct site

19

## 35.1000 Medical Events

### **Y-90 Microspheres (21 Patients)** **19**

- 10 to 15% of spheres went to spleen, gastric fundus and duodenum- potential permanent functional damage (SirSpheres)
- Incorrect positioning of the catheter- wrong treatment site put into right hepatic artery not left (SirSpheres)

20

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- Wrong patient – received dose for another patient – labeled with initials but tech given wrong vial –expected 143 mCi received 48 mCi (TheraSpheres)
- 2 incorrect doses prepared and delivered – 2 treatment sites one patient - did not follow protocol 40 and 27 % less than prescribed (TheraSphere)

21

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- 63% of activity remained in device – hemostat put on wrong tube deformed tubing restricted flow (TheraSphere)
- 77% delivered – think technician injecting microspheres failed to empty syringe (SirSpheres)
- 78% delivered – some adhered to the bottom of the septum (SirSpheres)

22

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- Received 36 % - small arteries – slow flush – too slow to keep microspheres from settling (TheraSpheres)
- 77% delivered low flush rate to prevent reflux to vessels to stomach –microspheres settled out in tubing before completion of administration (SirSpheres)

23

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- 71% delivered microspheres may have lodged in administration line at the stopcock (SirSpheres)
- 71% of prescribed activity – could not determine cause (TheraSpheres)

24

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- 78% of activity delivered – microspheres remained in delivery vial – harder to push plunger on three flushes (TheraSpheres)
- 76% and 56% delivered – low flow rate during delivery – indicated precipitation during low flow rate (TheraSpheres)

25

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- 71% delivered aggregate of microspheres in delivery vial and hub of micro catheter (TheraSpheres)
- 73% delivered flow clamp not fully opened position – microspheres plated out in the flow tube (Theraspheres)
- 60% delivered – think stasis occurred – vessel spasm small/fragile vessel, slow delivery stasis malfunction of system (TheraSphere)

26

## 35.1000 Medical Events

### Y-90 Microspheres (continued)

- 48% delivered (18% of first vial and 91% of second) – malfunction of delivery plunger –blood backed up into catheter on first vial – fluid ran into over-pressure vial (TheraSphere)
- 9% delivered – 90% remained in the catheter (TheraSphere)
- 2 patients – worksheets switched each got others dose – first reached stasis 35% above prescribed dose second 56% less than prescribed (SirSphere)

27

### Acronyms

- cGy (rad) –centiGray
- cm - centimeter
- FY – Fiscal Year
- GYN - gynaecological
- HDR – High Dose Rate Remote Afterloader

28

## Acronyms

- mCi - millicurie
- QA - Quality Assurance
- rem - roentgen equivalent in man
- Sr – Strontium
- Y- Yttrium

QUESTIONS?



**ThyCa 2012 Annual  
Conference:  
interviews with attendees  
about  
Outpatient RAI Experience**

**Laura Weil  
ACMUI Patients' Rights Advocate**

**ThyCa History**

- **Started in 1995 as informal grassroots association providing information and support for people with thyroid cancer**
- **In 1999 received IRS 501(c)(3) status as tax exempt organization**
- **Predominantly volunteer organization with a full time executive director**

2

**ThyCa services**

- **Email support groups include 14,000 participants**
- **Local in-person support groups**
- **Person-to-Person network**
- **Free online newsletters**
- **Free, downloadable Low-Iodine Cookbook in English and Spanish**
- **Annual Conference and periodic local informational workshops**

3

**Research Grants**

- **Research Fund Campaign grantees, partial list:**
  - **MSKCC**
  - **OSU**
  - **Johns Hopkins**
  - **Cochin Institute, Paris**
  - **MD Anderson**
  - **Rush-Presbyterian-St. Luke's MC**
  - **Harvard University**

4

### **ThyCa Annual Conference**

- **Over 500 attendees multiple days**
- **More than 100 separate sessions**
- **More than 50 speakers**
  - **predominantly physicians, many from leading cancer centers of excellence including Cleveland Clinic, MD Anderson, Mayo Clinic, MSKCC, Yale, Johns Hopkins**
  - **Also represented: attorneys, geneticists, nurses, Social Workers**

5

### **ThyCa Survey re Outpatient RAI Treatment (Iodine 131)**

- **2010 survey, 2424 respondents**
- **Release time: 67% within 30 min., 17% within 1 hr., 8% within 2 hrs.**
- **94% released to home or relative's home, 5% went to hotel/motel**
- **94% received oral instructions, 87% received written instructions on reducing radiation exposure to others**
- **Outpatient treatment setting: 89% hospital, 11% outpatient non-hospital**

6

### **Informal survey of ThyCa 2012 Conference attendees**

- **Goal: to collect anecdotal information about patients' experience with outpatient tx/release, specifically with regard to discharge instructions.**
- **>25 interviews**
- **Highly motivated, highly activated patient population**

7

### **Underlying Concern**

**RAI patients who are given d/c instructions at the time of treatment are no more likely to understand and follow d/c instructions than all other patients, indeed more likely to be like emergency department patients whose rate of understanding/following of instructions is in the 22-25% range.<sup>1,2</sup>**

1. K. Engel et al. "Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Don't Understand?" *Annals of Emergency Medicine*. Vol. 53, Issue 4, April 2009
2. [no authors listed] "Majority of emergency patients don't understand discharge instructions" *Emergency Department Management*. Vol. 20 No. 9, September 2008

8

### **Barriers to understanding**

- **Instructions may be given at time of treatment or release.**
- **Adequate time may not be provided for understanding and integration of information.**
- **Written instructions may be bundled in other administrative and financial materials.**
- **Patient's primary language may not be used.**

9

### **INTERVIEW ANECDOTES**

10

**Treated at a small community hospital, young woman was given final d/c instructions at the time of treatment. Stating she was extremely hypo-thyroid, she felt cognitively compromised. Remembers she received conflicting instructions from different members of clinical team. Felt nauseated, but no anti-emetics were offered. Was not offered instructions about travel home, not told to actively hydrate in post treatment period. Learned about these concerns at conference.**

11

**At a major university center, interviewee states she received contradictory d/c information. She stated she received no information about how to mitigate damage to salivary glands. She remained at the treatment site for 15 minutes post-administration, and travelled home alone. She was totally unaware of precautions relating to trash disposal, eating utensils. Learning some of this at the conference, she stated, "That stresses you out, not knowing what to do."**

12

**10 year old was treated at a university hospital. Mother was given virtually no instructions for post-treatment period, other than to stay far away from patient in the car on the long drive home. With a 6 year old sibling at home, mother was given no instructions: to isolate the patient from sibling, about solitary sleeping or bathroom use, eating utensils, and laundry. Suspicious re lack of precautions, mom accessed ThyCa for information. She sent her younger child to relatives for 3 days.**

13

**Woman states she was “sent to a hotel” after her RAI. She states she was given no other options or recommendation. Now a ThyCa volunteer who staffs the hotline, she receives many calls regarding hotel stays after treatment. Many patients tell her they get instructions only on the day of treatment, and she reports many patients state instructions were included “in a stack of discharge papers” and were not specifically identified as important instructions or verbally reviewed.**

14

**A young mother who has a 6 month old, is now 2 months post breastfeeding cessation in anticipation of I-131 treatment in near future. She feels she has had excellent instructions at a major medical center. She shared an email she had received from the center, listing specifics for her post treatment period. She stated that she has received some conflicting information from other clinical presentations at the conference.**

15

### **Representative concerns expressed repeatedly**

- **Conflicting instructions from members of the team**
- **Cursory to minimal discussion of precautions**
- **Missing information**
- **No effective contact information given for information after release.**
- **Lack of uniform agreement in medical community about appropriate precautions**

16

**Informal Conclusion based on anecdotal information:**

**People interviewed at the 2012 ThyCa conference, whether patient or caregiver, felt they had not received consistent and understandable discharge instructions to maximize safety to the patient and minimize harms to others.**

17

**Acronyms**

- **D/C – discharge**
- **IRS – Internal Revenue Service**
- **MSKCC – Memorial Sloan-Kettering Cancer Center**
- **OSU – Ohio State University**
- **RAI – Radioactive Iodine**
- **ThyCa – Thyroid Cancer Survivors' Association**

18



## Germanium-68/Gallium-68 Clinical Uses and Regulatory Issues

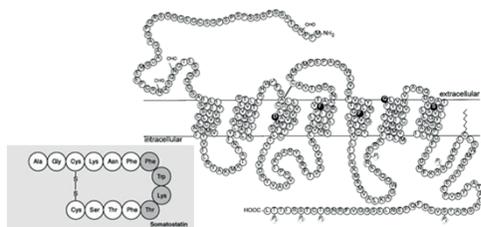
Steve Mattmuller  
Advisory Committee  
on the Medical Uses of Isotopes  
April 16, 2013

## Germanium-68/Gallium-68

- Receptor Imaging
- Ge-68/Ga-68 Generator
- Ga-68 Radiopharmaceuticals
- Regulatory Issues

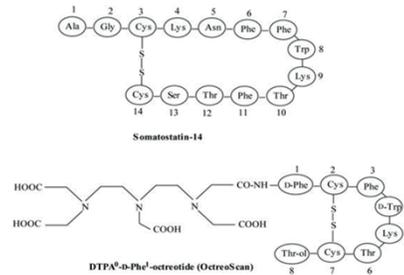
2

## Receptor Imaging



3

## Receptor Imaging



4



### Ge-68/Ga-68 Generator

- Ge-68 Breakthrough Test
  - Ga-68; minimum 99.9 percent of total radioactivity  
(Proposed Limit from the European Pharmacopeia)
  - Sr-82/Rb-82 generator  
Elute, assay, hold for decay, assay:  
Sr-82  $t_{1/2}$  = 25 day, Rb-82  $t_{1/2}$  = 75 sec  
Hold elution for one hour (48  $t_{1/2}$ )  
  
Ge-68  $t_{1/2}$  = 271 day, Ga-68  $t_{1/2}$  = 68 min  
Hold elution for two days (42  $t_{1/2}$ )

9

### Ga-68 Radiopharmaceuticals

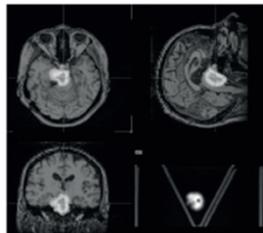
#### Radiochemical Synthesis Modules



10

### Ga-68 Radiopharmaceuticals

Somatostatin Receptor (SSTR) - Based agents  
DOTA-TOC  
-NOC  
-Tate



11

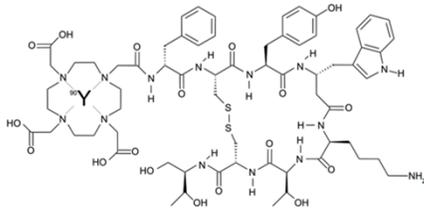
### Ga-68 Radiopharmaceuticals

- Somatostatin Receptor (SSTR)- Based agents  
DOTA-TOC, -NOC, -Tate
- Melanocyte-stimulating hormone (MSH)
- Arginine-glycine-aspartate (RGD)
- Bombesin

12

## Ga-68 Radiopharmaceuticals

Diagnostic versions with Ga-68 transition to therapy versions with Y-90 or Lu-177



13

## Ge-68/Ga-68 Regulatory Issues

### § 30.35 Financial assurance and recordkeeping for decommissioning.

(a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding  $10^5$  times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section.

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## Ge-68/Ga-68 Regulatory Issues

Appendix B to Part 30—Quantities of Licensed Material Requiring Labeling

Byproduct Material	Microcuries	Quantity $\times 10^5$ (Ci)	$T^{1/2}$	Decay
Fluorine 18	1,000	100	110 min	$\beta^+$
Iodine 131	1	0.1	8 days	$\beta^-$
Yttrium 90	10	1	2.7 days	$\beta^-$
Molybdenum 99	100	10	2.8 days	$\beta^-$
Germanium 68		0.01*	270 days	$\epsilon$

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## Ge-68/Ga-68 Regulatory Issues

30.35 (e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain (DFP)

(i) A detailed cost estimate for decommissioning, in an amount reflecting: (A) The cost of an independent contractor to perform all decommissioning activities; (B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria; (C) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and (D) An adequate contingency factor. (ii) Identification of and justification for using the key assumptions contained in the DCE; (iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility; (iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and (v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning). (2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs: (i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material; (ii) Waste inventory increasing above the amount previously estimated; (iii) Waste disposal costs increasing above the amount previously estimated; (iv) Facility modifications; (v) Changes in authorized possession limits; (vi) Actual remediation costs that exceed the previous cost estimate; (vii) Onsite disposal; and (viii) Use of a settling pond.

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## Ge-68/Ga-68 Regulatory Issues

Appendix C to Part 30—Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of Funds for Decommissioning, and

Appendix D to Part 30—Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds

II. Financial Test A. To pass the financial test a company must meet all of the criteria set forth in this section....

(1) Tangible net worth of at least \$21 million, and total net worth at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

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## Ge-68/Ga-68 Regulatory Issues

Appendix E to Part 30—Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. Introduction

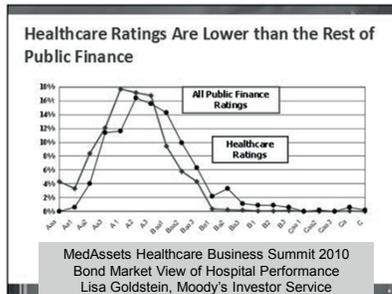
II. Financial Test

A. For colleges and universities, to pass the financial test ...

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

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## Ge-68/Ga-68 Regulatory Issues



19

## Ge-68/Ga-68 Regulatory Issues

- Current regulatory status of Ge-68 is hampering its use.
  - ◆ Unintentional, as Ge-68 fell through the regulatory cracks in 2005.
  - ◆ Missing from Appendix B to Part 30
  - ◆ DFP is a very onerous, expensive process
- Wide range of experiences by licensees
  - ◆ Some who already have a DFP or meet financial test, no problem
  - ◆ But those who don't have a DFP or can't meet financial test; a real barrier to being licensed for Ge-68.

20

## Ge-68 **Lost In Translation?**



21

## Lost in Translation; Schedules vs. Appendixes ?

Byproduct Material	30.71 Schedule B to Part 30 (μCi)	Appendix C to Part 20 (μCi)	Appendix B To Part 30 (μCi)
Fluorine-18 T <sub>1/2</sub> 110 min	1,000	1,000	1,000
Iodine-131 T <sub>1/2</sub> 8 days	1	1	1
Yttrium-90 T <sub>1/2</sub> 2.7 days	10	10	10
Molybdenum-99 T <sub>1/2</sub> 2.8 days	100	100	100
Germanium-68 T <sub>1/2</sub> 271 days	10	10	

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## Regulatory Relief is Needed...

ACMUI recommends that the NRC provide regulatory relief from the DFP requirements for the use of a Ge-68/Ga-68 generator.

- given that there is a good possibility that all of this was unintentional...
- given that licensee's return their Ge-68/Ga-68 generator back to the manufacturer...
- given the burden of a DFP is stifling the use of an important radionuclide in nuclear medicine...



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## Germanium-68/Gallium-68: Acronyms 1/5

Advisory Committee for the Medical Uses of Isotopes	ACMUI
Amino Acids	a.a.
Glycine	Gly
Alanine	Ala
Valine	Val
Leucine	Leu
Isoleucine	Iso
Serine	Ser
Threonine	Thr
Aspartic acid	Asp
Glutamic acid	Glu
Lysine	Lys

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### Germanium-68/Gallium-68: Acronyms 2/5

Amino Acids, continued	a.a.
Arginine	Arg
Cysteine	CySH
Cystine	CySSCy
Methionine	Met
Phenylalanine	Phe
Tyrosine	Tyr
Tryptophan	Try
Histidine	His
Proline	Pro
Hydroxyproline	Hypro
Anterior	ANT

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### Germanium-68/Gallium-68: Acronyms 3/5

Arginine-glycine-aspartate	RGD
Beta Positive Decay (Positron)	$\beta^+$
Beta Negative Decay (Beta)	$\beta^-$
Code of Federal Regulations	CFR
Curie	Ci
Decommissioning Financial Plan	DFFP
Electron Capture Decay	$\epsilon$
1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid	DOTA
DOTA-[NaI3]-Octreotide	DOTA-NOC
DOTA-[Tyr3]-Octreotate	DOTA-TATE
DOTA-[Tyr3]-Octreotide	DOTA-TOC

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### Germanium-68/Gallium-68: Acronyms 4/5

EZAG	Eckert-Ziegler
Gallium-68	Ga-68
Germanium-68	Ge-68
Half life	T1/2 or t1/2
Hydrochloric	HCl
Indium-111	In-111
Lutetium-177	Lu-177
Melanocyte-Stimulating Hormone	MSH
Microcurie	$\mu\text{Ci}$
Micrometer	$\mu\text{m}$
Posterior	POST
Rubidium-82	Rb-82

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### Germanium-68/Gallium-68: Acronyms 5/5

Rubidium Chloride	RbCl
Somatostatin Receptor	SSTR
Strontium-82	Sr-82
Yttrium-90	Y-90

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## **Status of Licensing Guidance for ViewRay™**

**Sandra Gabriel, Ph.D.**  
**Sophie Holiday**  
**Medical Radiation Safety Team**  
**April 16, 2013**

### **Outline**

- **Description**
- **Sealed Source and Device Registry**
- **Working Group**
- **Progress and Current Status**
- **Communication**
- **Summary**

2

### **Description**

#### **The ViewRay™ System for Radiation Therapy Features:**

- **Rotating Gantry with 3 Co-60 radiation  
therapy heads and 3 MLCs**
- **MRI System**
- **Integrated treatment planning and  
delivery software**

3

### **Sealed Source and Device Registry (SSDR)**

- **Ohio approved the SSDR on  
August 17, 2012**
- **SSDR No.: OH-1346-D-101-S**

4

### **Working Group (WG)**

- **NRC Management Directive 8.3**
- **Joint NRC/OAS WG**
- **NRC – (2) HQ, (1) RIII**
- **A/S – (1) CA, (1) OH, (1) WI**

5

### **Progress and Current Status**

- **Formation of WG**
- **Initial Draft**
- **Currently Undergoing Review**  
**[PRE-DECISIONAL INFORMATION]**

6

### **Communication**

- **Medical List Server**  
**[Med-Listserverquestions@nrc.gov](mailto:Med-Listserverquestions@nrc.gov)**
- **Memo to NRC Regions and OAS Board**
- **NRC Medical Toolkit**  
**<http://www.nrc.gov/materials/miau/med-use-toolkit.html>**

7

### **Summary**

- **The WG completed its initial draft.**
- **This draft is undergoing review.**
- **Upon approval, the guidance will be shared via multiple routes.**

8

## **Acronyms**

- **A/S – Agreement States**
- **Co-60 – Cobalt-60**
- **MLCs – Multi-Leaf Collimators**
- **MRI – Magnetic Resonance Imaging**
- **OAS – Organization of Agreement States**

9

## **Acronyms (cont'd)**

- **SSDR – Sealed Source and Device Registry**
- **WG – Working Group**

10

**Questions?**

11

Outgoing Remarks

NO HANDOUT

# September 2013

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1 X	2 LABOR DAY	3 X	4 X	5 Rosh Hashana	6 Rosh Hashana	7
8 X	9	10	11	12	13 Yom Kippur	14 Yom Kippur
15 X	16	17	18 X	19 Sukkot	20 Sukkot	21
22 ASTRO	23 ASTRO	24 ASTRO	25 ASTRO	26 Shmini Atzeret	27 Simchat Torah	28
29 X	30 X					

# October 2013

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1 X	2 X	3 X	4 X	5 X
6 X	7 X	8 X	9 X	10 X	11 X	12 X
13 X	14 COLUMBUS DAY	15 X	16 X	17 X	18 X	19 X
20 X	21	22	23 X	24 ABS Brachytherapy School	25 ABS Brachytherapy School	26 X
27 X	28 X	29 X	30 X	31 ?	?	