

Summary of Meeting  
Colorado Radiation Advisory Committee (RAC)  
October 17, 2019

**Call to order**

Chair Riad Safadi called the Radiation Advisory Committee (RAC) meeting to order on October 17, 2019 at 1:05 p.m. in Room C1E, Building C at the Colorado Department of Public Health and Environment (CDPHE) main campus.

The agenda and supplemental information emailed on October 11, 2019 was used.

Members present: Steve Brown, Jennifer Kwak, Vicki LaRue, Selina Muccio, Riad Safadi and Jennifer Stickel.

The members present constituted a quorum\*.

(Members Stickel, and Brown departed at approximately 3:35 prior to the conclusion of the meeting due to other commitments resulting a lack of a quorum after this time. The committee did not take any formal actions or recommendations after this time.)

Members absent: Kelly Fulton, Tom Johnson, Craig Little.

No members declared any potential or actual conflict of interest based on the proposed agenda as emailed.

Radiation Control staff present: James Jarvis, Chrys Kelley, Kathy Liberman, Phill Peterson, and Nadine McClenathan.

**Program updates and activities**

**Radiation program update**

Phill Peterson provided an update on the activities of the Radiation Program on behalf of Jim Grice. Phill discussed:

- Six of the nine scheduled Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) stakeholder meetings have been held. Overall, the meetings and process has been successful in capturing the concerns and issues related to TENORM, which will help to shape the upcoming proposed rule. The next major step in the process is to provide a report on the stakeholder process and related topics to the general assembly, which is due at the end of the year.

RAC members and staff attending the recent international TENORM conference in Denver noted and discussed the fact that the U.S. focus is on TENORM materials, whereas many other countries focus more on the wider realm of Naturally Occurring Radioactive Material (NORM). It was discussed that in part, this differing focus is due to the U.S. regulatory structure for radioactive materials being based on the origin of materials and not necessarily the radiological risk.

**Radon unit update\*\***

Chrys Kelley provided an overview on the activities of the Radon Unit:

- Thirty-six State Indoor Radon Grant (SIRG) grants are in process.
- The Low Income Radon Mitigation Assistance (LIRMA) program has been ongoing for the past ~1.5 years. To date, 78 homes have been mitigated with an additional 10 that are in-process. There remains a need for additional qualified mitigation contractors, especially for those in the rural areas of the state.
- Recently, the Rocky Mountain chapter of the American Association of Radon Scientists and Technologists (AARST) requested a "sunrise review" to evaluate the need for regulation of radon mitigators. As a result, the Colorado Department of Regulatory Agencies (DORA) completed the sunrise review document which recommends that radon measurement and mitigation specialists be regulated. This and other sunrise reviews can be found online at <https://www.colorado.gov/pacific/dora-oprrr/node/143201>.

(\*\*Errata: The original agenda showed Chrys providing an update for the radioactive materials unit which was incorrect. The agenda should have instead indicated she was presenting the radon unit update. This error and change was verbally noted during the meeting.)

### Radioactive materials unit update

Phill Peterson provided an overview on the activities of the Radioactive Materials Unit.

- Phill discussed a few recent events involving radioactive material, including the theft of a moisture density gauge from a construction site in Golden. The gauge has not been located. Additionally, during a localization procedure, a single radioactive seed was inadvertently disposed of as biological waste in August and has not been recovered. Phill noted that our applications, forms, and licenses are in the process of being updated to meet the department branding and the Americans with Disability Act (ADA) requirements. This is an ongoing process. The ADA updates help website reader systems and software operate more effectively.
- In August, staff attended the annual Organization of Agreement States (OAS) meeting in Minneapolis. Information on new medical device changes, updates on NRC procedures and activities, and national radioactive materials events were presented and discussed. During the meeting, our division director Jennifer Opila transitioned from the OAS chair to past-chair.
- Although the NRC, Agreement States and various stakeholders have been discussing and meeting on possible additional (future) changes to training and experience requirements for radiopharmaceuticals, it is expected that these requirements will remain as-is with no changes.

Refer to the attachment for further details.

### X-ray unit update

Kathy Liberman provided an update on the current activities of the X-ray Certification Unit:

- The backlog of 59-1 certification evaluation (CE) forms was recently completed by staff - a great accomplishment.
- Staff recently made a presentation to the Colorado Mammography Society regarding new U.S. Food and Drug Administration (FDA) requirements for mammography facilities. The presentation was well received.
- Staff member Nadine McClenathan organized a department-wide "pink-out" day to recognize breast cancer and health which ultimately resulted in a Governor's proclamation.
- Certification inspection reminders to be sent to registrants in the near future.

It was discussed that some registrants have expressed concern with these notifications since it can result in facility staff being confused or spending time investigating the status of machines that have a current certification. Additionally, larger facilities are wondering if it is possible to opt out of such notifications since machines are continuously monitored and inspected, often by staff who are present in the facility.

Refer to the attachments for further details.

### Regulations and special projects update

James Jarvis provided an update on RAC and regulatory related activities:

- The originally scheduled hearing for the x-ray regulation amendments Part 2, 6, and 12 was postponed due to a stakeholder notification issue with our email marking system (mailchimp). As a result, stakeholders were provided with another 30 days to provide comments and the hearing was rescheduled to November 20. Staff are continuing to review comments.
- As required by statute for all state agencies who promulgate regulations, the proposed 2020 regulatory agenda and regulatory plan were reviewed and discussed. The final versions will be published on the department website on or before November 1, 2019. Refer to the attachments for additional information.

- The appointments for three current RAC members - Tom Johnson, Vicki LaRue, and Steve Brown end on January 1, 2020. However, two of the three are eligible to apply for reappointment to the RAC.
- Staff and RAC members reviewed the draft Part 7 proposed rule changes. The review included discussions regarding possible additional or clarifying requirements for nuclear medicine technologists and definition for nuclear medicine advanced associates; consistency of record retention requirements for associate radiation safety officers versus the primary radiation safety officer; and the requirement for instruments to be calibrated to 1000 mrem/hour. The review of this part of the draft rule was concluded at Section 7.21 and will be continued along with review of Part 3 during the next scheduled RAC meeting in December.

Refer to the attachments/presentation for further details.

#### **Suggestions for future meetings**

There were no specific suggestions for future meeting topics.

#### **Adjourn**

The meeting was adjourned at 4:08 p.m.

**2019 RAC meeting dates:** December 12.

#### **Attachments:**

1. Colorado Radiation Advisory Committee Agenda for as emailed October 11, 2019 (2 page).
2. Radioactive materials unit update (1 pages).
3. X-ray Unit update (1 page).
4. 2020 Regulatory agenda/regulatory plan summary (1 page)
5. Part 7 proposed draft rule (draft C, dated 10/11/2019) (112 pages).
6. Part 3 proposed draft rule (draft B, dated 10/11/2019) (10 pages).

Following incorporation of the applicable requested changes, and consistent with the RAC bylaws in-effect, the meeting minutes for October 17, 2019 were approved via email/google form between December 30, 2019 - January 15, 2020 by a quorum of RAC members in attendance.

## Colorado Radiation Advisory Committee meeting agenda

Thursday, October 17, 2019

1:00 pm, Building C - Room C1E

Colorado Dept. of Public Health and Environment  
4300 Cherry Creek Drive S., Denver, CO 80246

- 1:00 pm** Call to order, introductions, conflicts of interest, agenda additions or changes
- Declaration of potential or actual conflicts of interest based on agenda

### Program updates and activities

- 1:05 pm** Radiation program update -Phill Peterson for Jim Grice (15 min)
- TENORM rulemaking activities
  - NORM IX Conference
- 1:20 pm** Radioactive materials unit update - Chrys Kelley (20 min)
- 1:40 pm** Radioactive materials unit update - Phill Peterson (20 min)
- Americans with Disabilities Act (ADA) and license amendments
  - Recent Organization of Agreement States (OAS) Meeting
  - Discussion with NRC re training and experience requirements for radiopharmaceuticals
- 2:00 pm** X-ray unit update - Kathy Liberman (20 min)
- Presentation to Colorado Mammography Society
  - Facility reminder emails
  - "Pink out day" / Governor's proclamation
- 2:20 pm** -10 min break-
- 2:30 pm** RAC business / regulations update - James Jarvis (85 min)
- Updates re part 6, 2, and 12 rulemaking.
  - Proposed draft 2020 regulatory agenda / regulatory plan
  - RAC member terms; meeting days/times for 2020
  - Part 7 and 3 Draft rule review
- 3:50 pm** Suggestions for future topics (5 min)
- 4:00 pm** Adjourn

2019 RAC meetings: December 12;

2020 RAC meetings: TBD

Note: As all times, topics, and future meeting dates are subject to change, please refer to each specific meeting agenda for further details.



## MEMORANDUM

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To: Radiation Advisory Committee

From: Phillip Peterson, Radioactive Materials Unit Leader

Date: October 17, 2019

Subject: Update on Radiation Program and Radioactive Materials Unit

### Radiation Program Updates

Jim is at the annual Lincoln Park meeting with the EPA

TENORM rulemaking activities

- 6 of 9 public meetings have been conducted
  - Topics covered include drinking water treatment, waste water treatment, biosolids, oil & gas, landfill disposal, and setting exempt levels
- 3 more public meetings scheduled
  - Topics to be covered include composting, limits for specific licensing, and a summary meeting of all topics
- Next step after the public meetings is to prepare the final report to the state legislature

### Radioactive Materials Update

Events

- Lost portable gauge
  - Stolen from a construction site in Golden in August, gauge not recovered
  - 9 mCi cesium-137, 44 mCi americium-241:beryllium
- Lost iodine-125 seed
  - Radioactive seed localization procedure, tissue not identified as containing the seed
  - Seed was most likely disposed as biological waste in August
  - Activity was estimated as 67 uCi

License template revisions

- Rebranding and ADA compatibility

Annual Organization of Agreement State meeting (39 agreement states now)

- Discussions included new medical therapies and device changes, web-based licensing (WBL) changes, procedure changes implemented (and to be implemented) by the NRC, major events across the nation, and the election and introduction of the NRC and Agreement State Co-Champions

Training and experience requirements for radiopharmaceuticals

- NRC and some states explored changes but the status quo will most likely continue





# RAC Meeting X-ray Items

Date: Thursday, October 17<sup>th</sup>

Time: 1 – 4:30 p.m.

Location: CDPHE – C1E

- 1) Part 6, 2 and 12 update- I will defer this update to James Jarvis.
- 2) X-ray staff have entered all R59-1 certification forms in the QISC email queue. This backlog was cleared as of 10/4/19. Very proud of the staff and this accomplishment!
- 3) One permanent staff member was promoted to the open PAI position that was vacated on August 1. The promotion filled the vacant position as of September 1<sup>st</sup>. The promotion left an opening for the AAll position. New position posting went up September 25<sup>th</sup>. Interviews were scheduled October 9<sup>th</sup> -October 16<sup>th</sup>. Tentatively expect to have new staff member hired as of Nov. 15<sup>th</sup>.
- 4) The inspector team presented at the Colorado Mammography Society meeting on September 14<sup>th</sup>. The presentation focused on a newer component of the MQSA inspection requirements, EQUIP (Enhancing Quality Using the Inspection Program). The inspectors presented for 50 minutes and addressed the origination, evolution and main components of the program in an educational compliance session.
- 5) The unit is planning another newsletter to facilities before end of calendar year. Focus on highlights of new regulations if adopted.
- 6) Nadine McClenathan organized an official campus wide “Pink Out Day” resulting in the Governor’s proclamation. Her hard work and determination to bring this day to fruition was celebrated on October 15<sup>th</sup>. The events included a lecture from a radiologist specializing in breast health, lunch, and prizes all donated from community members. The color pink was worn campus wide. Her outreach and passion made this event possible.
- 7) Reminder emails to facilities will begin with the first communication the first week in November for machines expiring 12/31/19. This program had been discontinued due to a software change. Requests for reminders from qualified inspectors and facilities determined the need for the program to be re-ignited. The program currently sends registration renewal emails to facilities, service companies and qualified inspectors.
- 8) Updates to streamline the operator Access database are being developed to assist with tracking of current operator and potential future fluoroscopy operators.

# 2019 Reg status / 2020 Reg Agenda

Regulatory PART(s)	RAC Review	Stakeholder Process	BOH Request	BOH Hearing
<b>6, 2, &amp; 12</b>	2017 - 2019 	2017 - 2019 	3 <sup>RD</sup> QTR (JUL) 	4 <sup>TH</sup> QTR (NOV)
<b>7 &amp; 3</b> (Radionuclides in healing arts)	4 <sup>TH</sup> QTR (OCT)	4 <sup>TH</sup> QTR – 1 <sup>ST</sup> QTR (2020) (DEC-FEB)	2020 1 <sup>ST</sup> QTR (MAR)	2020 2 <sup>ND</sup> QTR (MAY)
<b>5, 17, 22</b> Misc. technical corrections	2020 2 <sup>ND</sup> QTR (APR)	2020 1 <sup>ST</sup> -2 <sup>ND</sup> QTR (FEB-APR)	2020 2 <sup>ND</sup> QTR (JUN)	2020 3 <sup>RD</sup> QTR (AUG)
<b>20, 12</b> (TENORM)	2020 2 <sup>ND</sup> QTR (APR)	2020 2 <sup>ND</sup> -3 <sup>RD</sup> QTR (APR-AUG)	2020 3 <sup>RD</sup> QTR (SEP)	2020 4 <sup>TH</sup> QTR (NOV)

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2 Hazardous Materials and Waste Management Division

3 RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS

4 6 CCR 1007-1 Part 07

5 [Editor's Notes follow the text of the rules at the end of this CCR Document.]

7 Adopted by the Board of Health May 20, 2020, effective date July 15, 2020

8 PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS

9 USE OF RADIONUCLIDES IN THE HEALING ARTS

10 Section A – General Information

11 7.1 Purpose and Scope. Purpose and scope.

12 7.1.1 Authority

13 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-  
14 108, 25-1.5-101(1)(l), and 25-11-104, CRS.

15 7.1.2 Basis and Purpose.

16 A statement of basis and purpose accompanies this part and changes to this part. A copy may be  
17 obtained from the Department.

18 7.1.3 Scope.

19 This part establishes requirements and provisions for the production, preparation, compounding  
20 and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical  
21 use of this material. These requirements and provisions provide for the protection of the public  
22 health and radiation safety of workers, the general public, patients, and human research subjects.  
23 The requirements and provisions of this part are in addition to, and not in substitution for, others  
24 in these regulations.

25 7.1.4 Applicability.

26 The requirements and provisions of these regulations apply to applicants and licensees subject to  
27 this part unless specifically exempted.

28 7.1.5 Published Material Incorporated by Reference.

29 7.1.5.1 Published material incorporated in Part 7 by reference is available in accord with 1.4. In  
30 accordance with Section 24-4-103(12.5)(c), CRS,  
31 <https://www.colorado.gov/cdphe/radregs> identifies where incorporated material is  
32 available to the public on the internet at no cost. If the incorporated material is not  
33 available on the internet at no cost to the public, copies of the incorporated  
34 material has been provided to the State Publications Depository and Distribution  
35 Center, also known as the State Publications Library. The State Librarian at the

Commented [JJ1]:  
EDITORIAL NOTE 1:  
These side margin comments as shown here are not part of the rule and are for information only, with the intent to aid the reader in understanding the proposed changes in the draft regulations. All side margin comments will be removed prior to publication as a final rule and are not part of the rule.

EDITORIAL NOTE 2:  
Most of the proposed changes in this draft rule are based on the 2018 changes to U.S. Nuclear Regulatory Commission (NRC) federal rules in 10 CFR Part 30, 32 and 35. Final NRC regulations may be found at: <https://www.nrc.gov/reading-rm/doc-collections/ctr/>. Links to specific sections are also provided in the side margin comments for the draft rule. Additionally, the changes to federal rule are summarized/consolidated in NRC Regulatory Action Tracking System (RATS) 2018-1 which is referenced in the side margin comments when applicable.

EDITORIAL NOTE 3:  
Throughout the side margin comments for select provisions, the NRC compatibility category may be listed. Information on NRC compatibility may be found on page 6 of NRC procedure SA-200 at: <https://scp.nrc.gov/impep/toolbox/impepcompatibility.html>.

Commented [JSJ2]: Note that adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule, and the Colorado Register publication dates.

Commented [JSJ3]: Here and throughout the rule, a new section headers are added for consistency with the format of 10 CFR 35. For example, 10 CFR 35 has "Subpart A". In Part 7, this is referred to as "Section A".

Commented [JJ4]: For consistency with other recent rule revisions, the following standard language is added.

36 State Publication Library retains a copy of the material and will make the copy  
37 available to the public.

38 **7.1.5.2 The materials incorporated by reference in this Part include only those versions**  
39 **that were in effect at the time of the most recent adoption of this Part, and not later**  
40 **amendments to the incorporated material, unless a prior version of the**  
41 **incorporated material is otherwise specifically noted, and in such case that prior**  
42 **version shall apply.**

Commented [JSJ5]: This provision is added for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS).

[NON-RATS ITEM]

43 **7.2 Definitions.**

44 As used in this part, these terms have the definitions set forth as follows:

45 "Address of use" means the building(s) identified on the license where radioactive material may  
46 be produced, prepared, received, used or stored.

47 "Area of use" means a portion of an address of use that has been set aside for the purpose of  
48 producing, preparing, receiving, using, or storing radioactive material.

49 **"Associate Radiation Safety Officer" means, for the purposes of Part 7, an individual who:**

- 50 (1) **Meets the requirements in Appendix 7A and 7.65; and**
- 51 (2) **Is currently identified as an Associate Radiation Safety Officer for the types**  
52 **of use of radioactive material for which the individual has been assigned**  
53 **duties and tasks by the Radiation Safety Officer on:**
- 54 a. **A specific medical use license issued by the Department, NRC or an**  
55 **Agreement State;**
- 56 b. **A medical use permit issued by an NRC master material licensee.**

Commented [JJ6]: Definition added, consistent with 2018 amendments to [10 CFR Part 35.2](#)

The addition of this definition will specifically permit the addition of one or more person(s) to serve as an associate to the primary radiation safety officer identified on a specific radioactive material license for medical use, provided they meet the applicable requirements of Part 7 or are already designated on another department, NRC or agreement state license as such.

NRC Compatibility B  
NRC [RATS 2018-1](#)

57 "Authorized medical physicist" (AMP) means an individual who meets the requirements of  
58 Appendix 7B; or

- 59 (1) Is identified as an authorized medical physicist or teletherapy physicist on:
- 60 a. A specific medical license issued by the Department, NRC, or  
61 Agreement State;
- 62 b. A medical use permit issued by an NRC master material license;
- 63 c. A permit issued by an NRC or Agreement State broad scope medical  
64 use licensee; or
- 65 d. A permit issued by an NRC master material license broad scope medical  
66 use license

67 "Authorized nuclear pharmacist" (ANP) means a pharmacist who meets the requirements of  
68 Appendix 7C; or

- 69 (1) Is identified as an authorized nuclear pharmacist on:
- 70 a. A specific license issued by the Department, NRC, or Agreement State  
71 that authorizes medical use or the practice of nuclear pharmacy;



110 "Diagnostic clinical procedures manual" means a collection of written procedures that describes  
111 each method (and other instructions and precautions) by which the licensee performs diagnostic  
112 clinical procedures; where each diagnostic clinical procedure has been approved by the  
113 authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in  
114 the case of sealed sources for diagnosis, the procedure.

115 "HDR", see high dose-rate remote afterloader.

116 "High dose-rate remote afterloader" (HDR) means a device that remotely delivers a dose rate in  
117 excess of 12 gray (1200 rad) per hour at the treatment site.

118 "LDR", see low dose-rate remote afterloader.

119 "Low dose-rate remote afterloader" (LDR) means a device that remotely delivers a dose rate of  
120 less than or equal to 2 gray (200 rad) per hour at the treatment site (at the specified distance).

121 "Management" means the chief executive officer, or other individual having the authority to  
122 manage, direct, or administer the licensee's activities, or such person's' delegate(s).

123 "Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually  
124 applied or inserted.

125 "MDR", see medium dose-rate remote afterloader".

126 "Medical institution" means an organization in which two or more medical disciplines are  
127 practiced.

128 **"Medical event" means an event that meets the criteria in 7.21.1 or 7.21.2.**

Commented [JSJ7]: For consistency with NRC language in 10 CFR Part 35, medical event replaces the current "misadministration" term here and throughout the rule.

129 "Medical use" means, for the purposes of Part 7, the intentional internal or external administration  
130 of radioactive material or the radiation from radioactive material to patients or human research  
131 subjects under the supervision of an authorized user.

132 "Medium dose-rate remote afterloader" (MDR) means a **brachytherapy** device that remotely  
133 delivers a dose rate of greater than 2 gray (200 rads) **per hour**, but less than, or equal to, 12 gray  
134 (1200 rads) per hour at the **treatment site (at the specified distance)point or surface where the**  
135 **dose is prescribed.**

Commented [JJ8]: Updated for consistency with same definition in [10 CFR 35.2](#).  
Compatibility D.

136 ~~"Misadministration" means an event that meets the criteria in 7.21.~~

Commented [JSJ9]: This term is deleted here and is replaced by "medical event", consistent with the terminology of 10 CFR 35.

137 "Mobile medical service" means the transportation of radioactive material to, or its medical use at,  
138 the client's address and/or a temporary job site.

139 "Nuclear medicine technologist" (NMT) means an individual who meets the requirements of  
140 Appendix 7N and who under the supervision of an authorized user prepares or administers  
141 radioactive drugs to patients or human research subjects, or performs *in vivo* or *in vitro*  
142 measurements for medical purposes.

143 "Nuclear medicine technology" means the science and art of in vivo and in vitro detection and  
144 measurement of radioactivity and the administration of radioactive drugs to patients or human  
145 research subjects for diagnostic and therapeutic purposes.

146 **"Ophthalmic physicist" means an individual who:**

Commented [JJ10]: Definition for "Ophthalmic physicist" added, consistent with 2018 amendments to [10 CFR Part 35.2](#).

The addition of this definition will specifically permit the addition of person(s) to serve as an ophthalmic physicist provided they meet the applicable requirements of Part 7 or are already designated on another department, NRC or agreement state license for such use.

147 **(1) Meets the requirements in 7.41.6.1(2) and 7.65; and**

NRC Compatibility B  
NRC [RATS 2018-1](#)

- 148 (2) Is identified as an ophthalmic physicist on a:
- 149 a. Specific medical use license issued by the Department, NRC or an  
150 Agreement State;
- 151 b. Permit issued by the Department, NRC or Agreement State broad  
152 scope medical use licensee;
- 153 c. Medical use permit issued by a NRC master material licensee; or
- 154 d. Permit issued by a NRC master material licensee broad scope  
155 medical use permittee.

156 "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these  
157 rates, from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic  
158 radiosurgery unit, for a specified set of exposure conditions.

159 "Patient intervention" means actions by the patient or human research subject, whether  
160 intentional or unintentional, such as dislodging or removing treatment devices or prematurely  
161 terminating the administration.

162 "PDR", see pulsed dose-rate remote afterloader.

163 "Pharmacist" means an individual licensed by a State or Territory of the United States, the District  
164 of Columbia or the Commonwealth of Puerto Rico to practice pharmacy. (See also Authorized  
165 nuclear pharmacist)

166 "Physician" means an individual licensed by a State or Territory of the United States, the District  
167 of Columbia or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

168 "Podiatrist" means an individual licensed by a State or Territory of the United States, the District  
169 of Columbia or the Commonwealth of Puerto Rico to practice podiatry.

170 "Preceptor" means an individual who provides, directs or verifies training and experience required  
171 for an individual to become **an authorized user, an authorized medical physicist, an**  
172 **authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety**  
173 **Officer** ~~radiation safety officer, an authorized user, an authorized medical physicist, an~~  
174 ~~authorized nuclear pharmacist, a nuclear medicine technologist, or a radiation therapy~~  
175 ~~technologist~~ (see appendices 7A through ~~7Q7M~~, and ~~7P~~).

**Commented [JJ11]:** Definition updated, consistent with 2018 amendments to 10 CFR Part 35.2.  
The changes to this definition incorporate the Associate Radiation Safety Officer term as defined earlier in this section.  
NRC Compatibility D  
NRC [RATS 2018-1](#)

176 "Prescribed dosage" means the specified activity or range of activity of a radioactive drug as  
177 documented in:

- 178 (1) A written directive as specified in 7.11; or
- 179 (2) Accordance with the directions of the authorized user for procedures performed  
180 pursuant to 7.30, 7.32, or 7.36.

181 "Prescribed dose" means:

- 182 (1) For gamma stereotactic radiosurgery, the total dose as documented in the written  
183 directive;
- 184 (2) For teletherapy, the total dose and dose per fraction as documented in the  
185 written directive;

186 (3) For manual brachytherapy, either the total source strength and exposure time or  
187 the total dose, as documented in the written directive; or

188 (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as  
189 documented in the written directive.

190 "Pulsed dose-rate remote afterloader" (PDR) means a special type of remote afterloading device  
191 that uses a single source capable of delivering dose rates (at the specified distance) in the "high  
192 dose-rate" range, but:

193 (1) Is approximately one-tenth of the activity of typical high dose-rate remote  
194 afterloader sources; and

195 (2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the  
196 source for a given fraction of each hour.

197 "Radiation safety officer" (RSO) means, for the purposes of Part 7, an individual who has  
198 demonstrated sufficient knowledge to apply radiation protection regulations appropriately, who in  
199 accord with 7.7 has been assigned such responsibility by the licensee, and who meets the  
200 requirements in Appendix 7A; or

201 (1) Is identified as a Radiation Safety Officer on:

202 a. A specific medical use license issued by the Department, NRC, or  
203 Agreement State; or

204 b. A medical use permit issued by an NRC master material licensee.

205 ~~"Radiation therapy technologist" (RTT) means an individual who meets the requirements of~~  
206 ~~Appendix 7O and is under the supervision of an authorized user to perform procedures and apply~~  
207 ~~radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.~~

208 ~~"Radiation therapy technology" means the science and art of applying radiation emitted from~~  
209 ~~sealed radioactive sources to patients or human research subjects for therapeutic purposes.~~

210 "Radioactive drug" means any chemical compound containing radioactive material that may be  
211 used on or administered to patients or human research subjects as an aid in the diagnosis,  
212 treatment, or prevention of disease or other abnormal condition.

213 "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or  
214 matrix designed to prevent release and dispersal of the radioactive material under the most  
215 severe conditions which are likely to be encountered in normal use and handling.

216 "Sealed Source and Device Registry" means the national registry that contains the registration  
217 certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation  
218 safety information for the sealed sources and devices and describe the licensing and use  
219 conditions approved for the product.

220 "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic  
221 guidance device to precisely deliver a dose to a treatment site.

222 "Structured educational program" means an accredited educational program designed to impart  
223 particular knowledge and practical education through interrelated studies and supervised training.

**Commented [JSJ12]:**

This definition is proposed for deletion as it is not used in the body of the rule, nor is it being used during licensing and compliance activities by the radiation program. The term is used in Appendix 7O, which is also proposed for deletion.

The term does not appear in 10 CFR 35.

(The term originated from [SSRCR Part Z](#) (2012).

**Commented [JSJ13]:**

This definition is not used in the body of the rule nor is it used in 10 CFR 35.

- 224 "Teletherapy", as used in this part, means a method of radiation therapy in which collimated  
225 gamma rays are delivered at a distance from the patient or human research subject.
- 226 "Temporary job site", as used in Part 7, means a location where mobile medical services are  
227 confined to the mobile unit not at a licensed address of use.
- 228 "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver  
229 a radiation dose to a patient or human research subject for palliative or curative treatment.
- 230 "Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive  
231 material to a patient or human research subject for palliative or curative treatment.
- 232 "Treatment site" means the anatomical description of the tissue intended to receive a radiation  
233 dose, as described in a written directive.
- 234 "Trunnion" means a support bar sometimes used as a bearing instead of a socket.
- 235 "Type of use" means use of radioactive material as specified under 7.30, 7.32, 7.36, 7.40, 7.42,  
236 7.48 or 7.62.
- 237 "Unit dosage" means a dosage that:
- 238 (1) Is obtained or prepared in accordance with the regulations for uses described in  
239 7.30, 7.32, or 7.36; and
- 240 (2) Is to be administered as a single dosage to a patient or human research subject  
241 without any further manipulation of the dosage after it is initially prepared.
- 242 "Written directive" means an authorized user's written order for the administration of radioactive  
243 material or radiation from radioactive material to a specific patient or human research subject, as  
244 specified in 7.11.

245 **GENERAL REGULATORY REQUIREMENTS**

246 **7.3 License Required.**~~License required.~~

247 **7.3.1**

248 7.3.1.1 A person ~~shall~~**may** manufacture, produce, ~~prepare,~~ acquire, receive, possess, **prepare,**  
249 use, or transfer radioactive material for medical use only in accordance with a specific  
250 license issued by the Department, an Agreement State or NRC, or as allowed in 7.3.1.1  
251 or 7.3.1.2.

252 **7.3.1.2 A specific license is not needed for an individual who:**

253 ~~7.3.1.(1) Unless prohibited by license condition, an individual may r~~**Receives,**  
254 possess, uses, or transfers radioactive material in accordance with the  
255 regulations ~~in this part~~ under the supervision of an authorized user as provided in  
256 7.10, **unless prohibited by license condition;** or

257 ~~7.3.1.(2) Unless prohibited by license condition, an individual may p~~**Prepares**  
258 unsealed radioactive material for medical use in accordance with the regulations ~~in this~~  
259 ~~part~~ under the supervision of an authorized nuclear pharmacist or authorized user as  
260 provided in 7.10, **unless prohibited by license condition.**

Commented [JSJ14]: 7.3.1 is updated/realigned for consistency with the format and content of [10 CFR 35.11](#).

[NON-RATS ITEM]

- 261 7.3.2 Provisions for the protection of Human Research Subjects.
- 262 A licensee may conduct research involving human subjects using radioactive material under the  
263 following conditions:
- 264 7.3.2.1 For research conducted, funded, supported, or regulated by a federal agency which has  
265 implemented The Federal Policy for the Protection of Human Subjects (Federal Policy),  
266 the licensee shall:
- 267 (1) Obtain prior informed consent from the human research subjects; and
- 268 (2) Obtain prior review and approval of the research activities by an "Institutional  
269 Review Board" in accordance with the meaning of these terms as defined and  
270 described in the Federal Policy; or
- 271 7.3.2.2 For research not conducted, funded, supported, or regulated by a federal agency which  
272 has implemented the Federal Policy, then:
- 273 (1) The licensee shall apply for and receive a specific amendment to its Department  
274 license before conducting such research. The amendment request shall include a  
275 written commitment that the licensee will, before conducting research:
- 276 (a) Obtain prior informed consent from the human research subjects; and
- 277 (b) Obtain prior review and approval of the research activities by an  
278 "Institutional Review Board" in accordance with the meaning of these  
279 terms as defined and described in the Federal Policy;
- 280 7.3.2.3 A licensee not authorized pursuant to 3.11 shall apply for and receive approval of a  
281 specific amendment to its Department license before conducting research involving  
282 human subjects;
- 283 7.3.2.4 The research involving human subjects authorized in 7.3.2 shall be conducted using  
284 radioactive material authorized for medical use in the license; and
- 285 7.3.2.5 Nothing in 7.3.2 relieves licensees from complying with the other requirements in Part 7.
- 286 7.3.3 Nothing in this part relieves the licensee from complying with applicable FDA, other federal, and  
287 state requirements governing radioactive drugs or devices.
- 288 **7.3.4** Application for ~~L~~icense, ~~A~~amendment, or ~~R~~enewal.
- 289 7.3.4.1 An application ~~shall~~**must** be signed by the applicant's or licensee's management.
- 290 7.3.4.2 An application for a new or renewal license for medical use of radioactive material as  
291 described in 7.30, 7.32, 7.36, 7.40, 7.42, 7.48 or 7.62 must be made by:
- 292 (1) Filing **an original a-completed-De**partment Form R-12 (7C) **that includes the**  
293 **facility diagram, equipment, and training and experience qualifications of**  
294 **the Radiation Safety Officer, Associate Radiation Safety Officer(s),**  
295 **authorized user(s), authorized medical physicist(s), ophthalmic**  
296 **physicist(s), and authorized nuclear pharmacist(s);** and

Commented [JSJ15]: 7.3.4 is updated for consistency with the wording of [10 CFR 35.12](#).

NRC Compatibility D (all provisions within 7.3.4)  
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297 (2) Submitting procedures required by Form R-12 (7C), and 7.12, 7.15, 7.51, 7.58,  
298 7.59, and 7.61, as applicable, and other procedures as requested by the  
299 Department.

300 7.3.4.3 A request for a license amendment must be made by:

301 (1) Submitting an original amendment request in letter format.

302 (2) Submitting procedures required by 7.12, 7.15, 7.51, 7.58, 7.59, and 7.61, as  
303 applicable, and other procedures as requested by the Department.

304 7.3.4.4 In addition to the requirements in 7.3.4.2 and 7.3.4.3, an application for a new license,  
305 renewal license, or amendment for medical use of radioactive material as described in  
306 7.62 must also include: ~~information regarding any radiation safety aspects of the medical~~  
307 ~~use of the material that is not addressed in 7.1 through 7.29, as well as any specific~~  
308 ~~information on:~~

309 (1) ~~Radiation safety precautions and instructions;~~ **Any additional aspects of the**  
310 **medical use of the material that are applicable to radiation safety that are**  
311 **not addressed in, or differ from, Sections A through C, 7.20, 7.21, 7.23, and**  
312 **7.35.5;**

313 ~~(2) Training and experience of proposed users;~~

314 (2) **Identification of and commitment to follow the applicable radiation safety**  
315 **program requirements in Sections D through H that are appropriate for the**  
316 **specific 7.62 medical use;**

317 (3) **Any additional specific information on:**

318 (a) **Radiation safety precautions and instructions;**

319 ~~(3) (b) Methodology for measurement of dosages or doses to be~~  
320 ~~administered to patients or human research subjects; and~~

321 ~~(4) (c) Calibration, maintenance, and repair of instruments and~~  
322 ~~equipment necessary for radiation safety; and~~

323 (4) **Any other information requested by the department in its review of the**  
324 **application.**

325 ~~7.3.4.5 The applicant or licensee shall also provide any other information requested by the~~  
326 ~~Department in its review of the application.~~

Commented [JSJ16]: Provision replaced by revised 7.3.4.4(4).

327

328 7.3.4.65 An applicant that satisfies the requirements specified in 3.11 may apply for a  
329 Type A specific license of broad scope.

330 7.3.5 Mobile Medical Service Administrative Requirements.

331 7.3.5.1 The Department shall license mobile medical services or clients of such services. The  
332 mobile medical service shall be licensed if the service receives, uses or possesses  
333 radioactive material. The client of the mobile medical service shall be licensed if the client  
334 receives or possesses radioactive material to be used by a mobile medical service.

- 335 7.3.5.2 Mobile medical service licensees shall obtain a letter signed by the management of each  
336 location where services are rendered that authorizes use of radioactive material at the  
337 client's address of use. This letter shall clearly delineate the authority and responsibility of  
338 both the client and the mobile medical service. If the client is licensed, the letter shall  
339 document procedures for notification, receipt, storage and documentation of transfer of  
340 radioactive material delivered to the client's address for use by the mobile medical  
341 service.
- 342 7.3.5.3 A mobile medical service shall not have radioactive material delivered directly from the  
343 manufacturer or the distributor to the client, unless the client has a license allowing  
344 possession of the radioactive material. Radioactive material delivered to the client shall  
345 be received and handled in conformance with the client's license.
- 346 7.3.5.4 A mobile medical service shall inform the client's management who is on site at each  
347 client's address of use at the time that radioactive material is being administered.
- 348 7.3.5.5 A licensee providing mobile medical services shall retain the letter required in 7.3.5.2 for  
349 3 years after the last provision of service.
- 350 7.3.5.6 A mobile medical service licensee shall, at a minimum, maintain the following documents  
351 on each mobile unit:
- 352 (1) The current operating and emergency procedures;
- 353 (2) A copy of the license;
- 354 (3) Copies of the letter required by 7.3.5.2;
- 355 (4) Current calibration records for each survey instrument and diagnostic equipment  
356 or dose delivery device in use; and
- 357 (5) Survey records covering uses associated with the mobile unit during, at a  
358 minimum, the preceding 30 calendar days.
- 359 7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's  
360 facility as a restricted area while radioactive material is present. For each location where  
361 radioactive materials will be routinely used, the licensee shall provide to the Department:
- 362 (1) A diagram of the location of use, including information about the placement of  
363 required postings; and
- 364 (2) Calculation(s) or survey(s) results that demonstrate compliance with applicable  
365 dose limits in 4.14 and 4.15 at the location of use.
- 366 7.3.5.8 The mobile medical service shall ensure that:
- 367 (1) Supervision by an authorized user is in accordance with 7.10.1;
- 368 (2) Radiation exposures to the client's personnel working in the client facility are:
- 369 (a) Below the dose limits to members of the public listed in 4.14; or
- 370 (b) The client's personnel are instructed as described in 10.3 and monitored  
371 for exposure in accordance with 4.18 unless the licensee can  
372 demonstrate that 4.18 does not apply.

373 7.3.5.9 A mobile medical service licensee shall maintain all records required by Parts 4 and 7 of  
374 these regulations at a location within the Department's jurisdiction that is:

375 (1) A single address of use:

376 (a) Identified as the records retention location; and

377 (b) Staffed at all reasonable hours by individual(s) authorized to provide the  
378 Department with access for purposes of inspection; or

379 (2) When no address of use is identified on the license for records retention, the  
380 mobile unit:

381 (a) Identified in the license; and

382 (b) Whose current client's address of use and area of use schedule is  
383 reported to the Department.

384 **7.3.6** A licensee possessing a Type A specific license of broad scope for medical use, **issued under**  
385 **Part 3 of these regulations** is exempt from:

**Commented [JJ17]:** Section updated for consistency with [10 CFR 35.15](#).

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386 7.3.6.1 The provisions of 7.3.4.4 regarding the need to file an amendment to the license for  
387 medical uses of radioactive material as described in 7.62;

388 7.3.6.2 The provisions of 7.4.2 regarding the need to file an amendment before permitting  
389 anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized  
390 medical physicist under the license;

391 **7.3.6.3** The provisions of 7.4.5 regarding additions to or changes in the areas of use at the  
392 addresses **specified identified in the application or on** the license;

**Commented [JJ18]:** Updated for consistency with 10 CFR 35.15(c).

393 7.3.6.4 The provisions of 7.5.1 regarding notification to the Department for new authorized users,  
394 new authorized nuclear pharmacists and new authorized medical physicists;

395 **7.3.6.5** **The provisions of 7.5.2.1 for an authorized user, an authorized nuclear pharmacist,**  
396 **an authorized medical physicist or an ophthalmic physicist;**

**Commented [JJ19]:** Added for consistency with 10 CFR 35.15(e).

397 **7.3.6.6** **The provisions of 7.5.2.5; and**

**Commented [JJ20]:** Added for consistency with 10 CFR 35.15(f).

398 **7.3.6.57** The provisions of 7.14 regarding suppliers for sealed sources.

399 7.3.7 The Department may, upon application of any interested person or upon its own initiative, grant  
400 such exemptions from the regulations in Part 7 as it determines are authorized by law and will not  
401 endanger life or property or the common defense and security and are otherwise in the public  
402 interest.

403 **7.4 License Amendments.**

**Commented [JSJ21]:** Language updates in this section are made consistent with 2018 changes to [10 CFR Part 35.13](#).

404 A licensee shall apply for and ~~shall have received~~ **must receive** a license amendment ~~before the~~  
405 ~~licensee:~~

The recent revisions to 10 CFR Part 35 and this section apply the ophthalmic physicist designation.

406 7.4.1 **Before it receives** ~~Receives~~, prepares, or uses radioactive material for a type of use that is  
407 permitted under this part but ~~that~~ is not authorized on the licensee's current license issued  
408 ~~pursuant to~~ **under** this part;

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- 409 7.4.2 ~~Before it permits~~Permits anyone to work as an authorized user, authorized medical physicist,  
410 **ophthalmic physicist**, or an authorized nuclear pharmacist under the license, **except: in**  
411 ~~accordance with the training and experience requirements specified in:~~
- 412 7.4.2.1 ~~Appendix 7D through Appendix 7M for an authorized user for a specific type of use of~~  
413 ~~radioactive material;~~**For an authorized user, an individual who meets the**  
414 **requirements in Appendix 7P and one or more of the following: Section 7D1 of**  
415 **Appendix D, Section 7E1 of Appendix E, Section 7F1 of Appendix F, Section 7G1 of**  
416 **Appendix G, Section 7H1 of Appendix 7H, Section 7K1 of Appendix K, Section 7J1**  
417 **of Appendix J, or Section 7M1 of Appendix M;**
- 418 7.4.2.2 ~~Appendix 7B for an authorized medical physicist;~~**For an authorized nuclear**  
419 **pharmacist, an individual who meets the requirements in Section 7C1 of Appendix**  
420 **7C and 7.65;**
- 421 7.4.2.3 ~~Appendix 7C for an authorized nuclear pharmacist; and~~**For an authorized medical**  
422 **physicist, an individual who meets the requirements in Section 7B1 of Appendix**  
423 **7B and 7.65;**
- 424 7.4.2.4 **An individual who is identified as an authorized user, an authorized nuclear**  
425 **pharmacist, authorized medical physicist, or an ophthalmic physicist on:**
- 426 (1) **A NRC or Agreement State license or other equivalent permit or license**  
427 **recognized by the Department that authorizes the use of radioactive**  
428 **material in medical use or in the practice of nuclear pharmacy;**
- 429 (2) **A permit issued by a NRC or Agreement State specific license of broad**  
430 **scope that is authorized to permit the use of radioactive material in medical**  
431 **use or in the practice of nuclear pharmacy;**
- 432 (3) **On a permit issued by a NRC master material licensee that is authorized to**  
433 **permit the use of radioactive material in medical use or in the practice of**  
434 **nuclear pharmacy; or**
- 435 (4) **By a commercial nuclear pharmacy that has been authorized to identify**  
436 **authorized nuclear pharmacists.**
- 437 7.4.2.5 **A physician, podiatrist, or dentist who used only accelerator-produced radioactive**  
438 **materials, discrete sources of radium-226, or both, for medical uses or a nuclear**  
439 **pharmacist who used only accelerator-produced radioactive materials in the**  
440 **practice of nuclear pharmacy at a Government agency or Federally recognized**  
441 **Indian Tribe before November 30, 2007 or at all other locations of use before**  
442 **August 8, 2009, or an earlier date as noticed by the NRC, and for only those**  
443 **materials and uses performed before these dates.**
- 444 7.4.3 ~~Before it C~~changes a Radiation Safety Officer, except as provided in ~~7.7.67.7.3~~;
- 445 **7.4.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the**  
446 **Radiation Safety Officer assigns duties to an Associate Radiation Safety Officer that differ**  
447 **from those for which this individual is authorized on the license;**
- 448 7.4.45 ~~Before it R~~receives radioactive material in excess of the amount or in a different physical or  
449 **chemical form, or receives a different radionuclide** than is authorized on the license;

Commented [JSJ22]: Added for consistency with [10 CFR 35.13\(d\)](#).

450 7.4.56 Adds to or changes the area(s) of use or address(es) of use identified in the application or on the  
451 license, except as specified in 7.5.2.4; and **Before it adds to or changes the areas of use**  
452 **identified in the application or on the license, including areas used in accordance with**  
453 **either 7.30 or 7.32 if the change includes addition or relocation of either an area where PET**  
454 **radionuclides are produced or a PET radioactive drug delivery line from the PET**  
455 **radionuclide/PET radioactive drug production area. Other areas of use where radioactive**  
456 **material is used only in accordance with either 7.30 or 7.32 are exempt;**

457 7.4.7 **Before it changes the address(es) of use identified in the application or on the license;**

458 7.4.68 **Before it C**changes statements, representations, and procedures which are incorporated into the  
459 license; or

460 7.4.79 **Before it R**releases licensed facilities for unrestricted use.

461 **7.4.10 Before it revises procedures required by 7.51, 7.58, 7.59, and 7.61, as applicable, where**  
462 **such revision reduces radiation safety; and**

463 7.4.11 **Before it receives a sealed source from a different manufacturer or of a different model**  
464 **number than authorized by its license unless the sealed source is used for manual**  
465 **brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and**  
466 **for an isotope authorized by the license.**

467 7.5 **Notifications and maintenance of records.**

468 **7.5.1 A licensee shall provide to the Department required documentation of adequate radiation safety**  
469 **training and experience under Appendix 7B for each authorized medical physicist pursuant to**  
470 **7.4.2, under Appendix 7C for each authorized nuclear pharmacist, and under the applicable**  
471 **appendix of Appendix 7D through Appendix 7M for each individual authorized user. A licensee**  
472 **shall provide the Department, no later than 30 days after the date that the licensee permits**  
473 **an individual to work under the provisions of 7.4.2 as an authorized user, authorized**  
474 **medical physicist, ophthalmic physicist, or authorized nuclear pharmacist:**

475 **7.5.1.1 A copy of the board certification and, as appropriate, verification of completion of:**

- 476 (1) **Training for the authorized medical physicist under 7B3 of Appendix 7B;**  
477 (2) **Any additional case experience required in 7F2.1(2)(f) of Appendix 7F for an**  
478 **authorized user under 7.36; or**  
479 (3) **Device specific training in 7M3 of Appendix 7M for the authorized user**  
480 **under 7.48; or**

481 **7.5.1.2 A copy of the NRC or Agreement State license, the permit issued by a NRC master**  
482 **material licensee, the permit issued by a NRC or Agreement State licensee of**  
483 **broad scope, the permit issued by a NRC master material license broad scope**  
484 **permittee, or documentation that only accelerator-produced radioactive materials,**  
485 **discrete sources of radium-226, or both, were used for medical use or in the**  
486 **practice of nuclear pharmacy at a Government agency or Federally recognized**  
487 **Indian Tribe before November 30, 2007, or at all other locations of use before**  
488 **August 8, 2009, or an earlier date as noticed by the NRC for each individual whom**  
489 **the licensee permits to work under the provisions of this section.**

490 7.5.2 A licensee shall notify the Department in writing ~~withi~~**no later than 30 days after:**

Commented [JSJ23]: 7.51 = 10 CFR 35.610  
7.58 = 10 CFR 35.642  
7.59 = 10 CFR 35.643  
7.61 = 10 CFR 35.645

Commented [JJ24]: Updated for consistency with [10 CFR 35.14\(a\)](#).

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Commented [JSJ25]: 7.4.2 = 10 CFR 35.13(b)

Commented [JJ26]: Added for consistency with [10 CFR 35.14\(a\)\(1\)](#).

7.5.1.1(1) = 35.14(a)(1)(i)  
7.5.1.1(2) = 35.14(a)(1)(ii)  
7.5.1.1(3) = 35.14(a)(1)(iii)

NRC Compatibility D

CROSS REFERENCES:  
7B3 = 10 CFR 35.51(c)  
7F2.1(2)(f) = 10 CFR 35.390(b)(1)(ii)(G)  
7.36 = 10 CFR 35.300  
7M3 = 10 CFR 35.690(c)  
7.48 = 10 CFR 35.600

Commented [JJ27]: Added for consistency with [10 CFR 35.14\(a\)\(2\)](#).

NRC Compatibility D

Commented [JJ28]: Updated for consistency with [10 CFR 35.14\(b\)](#).

NRC Compatibility D

491 7.5.2.1 An authorized user, ~~an authorized medical physicist~~ **authorized nuclear pharmacist, a**  
492 **Radiation Safety Officer, an Associate Radiation Safety Officer, an** authorized  
493 ~~nuclear pharmacist~~ **medical physicist, or Radiation Safety Officer** ~~ophthalmic physicist~~  
494 permanently discontinues performance of duties under the license or has a name  
495 change;

496 **7.5.2.2 The licensee permits an individual qualified to be a Radiation Safety Officer under**  
497 **Appendix 7A and 7.65 to function as a temporary Radiation Safety Officer and to**  
498 **perform the functions of a Radiation Safety Officer in accordance with 7.7.6.**

Commented [JSJ29]:  
CROSS REFERENCES:  
7A = 35.50  
7.65 = 35.59  
7.7.6 = 35.24(c)

499 7.5.2.23 The licensee's mailing address changes;

500 7.5.2.34 The licensee's name changes, but the name change does not constitute a  
501 transfer of control of the license as described in 3.15.2 of these regulations; or

502 7.5.2.45 The licensee has added to or changed the areas **of use identified in the**  
503 **application or on the license** where radioactive material is used in accordance  
504 with **either 7.30 and/or 7.32 if the change does not include addition or**  
505 **relocation of either an area where PET radionuclides are produced or a PET**  
506 **radioactive drug delivery line from the PET radionuclide/PET radioactive**  
507 **drug production area.; or**

508 **7.5.2.6 The licensee obtains a sealed source for use in manual brachytherapy from a**  
509 **different manufacturer or with a different model number than authorized by its**  
510 **license for which it did not require a license amendment as provided in 7.4.9. The**  
511 **notification must include the manufacturer and model number of the sealed**  
512 **source, the isotope, and the quantity per sealed source.**

Commented [JSJ30]: CROSS REFERENCE:  
7.4.9 = 10 CFR 35.13(i)

513 **7.5.3 The licensee shall submit the documents required in 7.5.1 and 7.5.2 to the department.**

514 7.5.34 Maintenance of Records.

515 Each record required by this part must be legible throughout the retention period specified by  
516 each Department regulation. The record may be the original, a reproduced copy, or a microform  
517 provided that the copy or microform is authenticated by authorized personnel and the microform  
518 is capable of producing a clear copy throughout the required retention period. The record may  
519 also be stored in electronic media with the capability for producing legible, accurate, and  
520 complete records during the required retention period. Records such as letters, drawings, and  
521 specifications must include all pertinent information such as stamps, initials, and signatures. The  
522 licensee shall maintain adequate safeguards against tampering with and loss of records.

523 **7.6 License Issuance.**

524 7.6.1 The Department shall issue a license for the medical use of radioactive material if:

525 7.6.1.1 The applicant has filed Department Form R-12 in accordance with the instructions in  
526 7.3.4;

527 7.6.1.2 The applicant has paid any applicable fee;

528 7.6.1.3 The applicant meets the requirements of Part 3 of these regulations; and

529 7.6.1.4 The Department finds the applicant equipped and committed to observe the safety  
530 standards established by the Department in these regulations for the protection of the  
531 public health and safety.

532 7.6.2 The Department shall issue a license for mobile services if the applicant:  
533 7.6.2.1 Meets the requirements in 7.6.1, and in particular 7.3.5; and  
534 7.6.2.2 Assures that individuals to whom radioactive drugs or radiation from implants containing  
535 radioactive material will be administered may be released following treatment in  
536 accordance with 7.26.

537 **ADDITIONAL OVERALL REQUIREMENTS**

538 **Section B – General Administrative Requirements**

539 **7.7 Authority and Responsibilities for the Radiation Protection Program**

540 7.7.1 In addition to the radiation protection program requirements of 4.5 of these regulations, a  
541 licensee's management ~~must~~ shall approve in writing:

542 7.7.1.1 Requests for license application, renewal, or amendments before submittal to the  
543 Department;

544 7.7.1.2 Any individual before allowing that individual to work as an authorized user, authorized  
545 nuclear pharmacist or authorized medical physicist; and

546 7.7.1.3 Radiation protection program changes that do not require a license amendment and are  
547 permitted under 7.7.

548 **7.7.2** A licensee's management shall appoint a Radiation Safety Officer (RSO), who agrees in writing to  
549 be responsible for implementing the radiation safety program. The licensee, through the RSO,  
550 shall ensure that radiation safety activities are being performed in accordance with licensee-  
551 approved procedures and regulatory requirements. **A licensee's management may appoint, in  
552 writing, one or more Associate Radiation Safety Officers (ARSO) to support the RSO. The  
553 RSO, with written agreement of the licensee's management, must assign the specific  
554 duties and tasks to each ARSO. These duties and tasks are restricted to the types of use  
555 for which the ARSO is listed on a license. The RSO may delegate duties and tasks to the  
556 ARSO but shall not delegate the authority or responsibilities for implementing the  
557 radiation protection program.**

558 **7.7.3** **For up to 60 days each year, a licensee may permit an individual qualified to be a  
559 Radiation Safety Officer, under Appendix 7A and 7.65, to function as a temporary  
560 Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as  
561 provided in 7.7.7, if the licensee takes the actions required in 7.7.2, 7.7.5, 7.7.6, and 7.7.7  
562 and notifies the department in accordance with 7.5.2.**

563 **7.7.4** **A licensee may simultaneously appoint more than one temporary Radiation Safety Officer  
564 in accordance with 7.7.3, if needed to ensure that the licensee has a temporary Radiation  
565 Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of  
566 the different types of uses of byproduct material permitted by the license.**

567 ~~7.7.35~~ ~~A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation~~  
568 ~~Safety Officer, and of the Alternate RSO, if required. A licensee shall establish the authority,~~  
569 ~~duties, and responsibilities of the Radiation Safety Officer in writing.~~

570 7.7.46 A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom,  
571 time, resources, and management prerogative, to:

Commented [JSJ31]: Section 7.7 is updated, consistent with updates to [10 CFR 35.24](#)  
NRC RATS 2018-1

Commented [JJ32]: Provision updated, consistent with updates to [10 CFR 35.24\(b\)](#)  
NRC RATS 2018-1  
NRC Compatibility: H&S

Commented [JSJ33]:  
CROSS REFERENCES:  
Appendix 7A = 10 CFR 35.50  
7.65 = 10 CFR 35.59  
7.7.7 = paragraph (g) of [10 CFR 35.24](#)  
7.7.2 = paragraph (b) of [10 CFR 35.24](#)  
7.7.5 = paragraph (e) of [10 CFR 35.24](#)  
7.7.6 = paragraph (g) of [10 CFR 35.24](#)  
7.5.2 = 10 CFR 35.35.14(b)

Commented [JSJ34]:  
CROSS REFERENCE:  
7.7.3 = paragraph (c) of [10 CFR 35.24](#)

Commented [JSJ35]: Language revised for consistency with [10 CFR 35.24\(e\)](#). No change in requirements.  
NRC Compatibility D

- 572 7.7.46.1 Identify radiation safety problems;
- 573 7.7.46.2 Initiate, recommend, or provide corrective actions;
- 574 7.7.46.3 Stop unsafe operations; and
- 575 7.7.46.4 Verify implementation of corrective actions.
- 576 ~~7.7.5 A license shall retain a record of actions taken pursuant to 7.7.1, 7.7.2 and 7.7.3 for 5 years,~~
- 577 ~~including:~~
- 578 ~~7.7.5.1 A summary of the actions taken (and a signature of licensee management) in accordance~~
- 579 ~~with 7.7.1;~~
- 580 ~~7.7.5.2 A signed copy of the RSO's agreement (including the signature of the RSO and licensee~~
- 581 ~~management) to be responsible for implementing the radiation safety program, as~~
- 582 ~~required by 7.7.2; and~~
- 583 ~~7.7.5.3 A current copy of the authorities, duties and responsibilities of the RSO as required by~~
- 584 ~~7.7.3.~~
- 585 **7.7.7 A licensee shall retain a record of actions taken under 7.7.1, 7.7.2, and 7.7.5 as follows:**
- 586 **Records of authority and responsibilities for radiation protection programs.**
- 587 **7.7.7.1 A licensee shall retain a record of actions taken by the licensee's management in**
- 588 **accordance with 7.7.1 for 5 years. The record must include a summary of the**
- 589 **actions taken and a signature of licensee management.**
- 590 **7.7.7.2 The licensee shall retain a copy of both authority, duties, and responsibilities of**
- 591 **the Radiation Safety Officer as required by 7.7.5, and a signed copy of each**
- 592 **Radiation Safety Officer's agreement to be responsible for implementing the**
- 593 **radiation safety program, as required by 7.7.2, for the duration of the license. The**
- 594 **records must include the signature of the Radiation Safety Officer and licensee**
- 595 **management.**
- 596 **7.7.7.3 For each Associate Radiation Safety Officer appointed under 7.7.2, the licensee**
- 597 **shall retain, for 5 years after the Associate Radiation Safety Officer is removed**
- 598 **from the license, a copy of the written document appointing the Associate**
- 599 **Radiation Safety Officer signed by the licensee's management.**
- 600 ~~7.7.6 For up to sixty days each year, a licensee may permit an authorized user or an individual qualified~~
- 601 ~~to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform~~
- 602 ~~the functions of a Radiation Safety Officer, as provided in 7.7.4, provided the licensee takes the~~
- 603 ~~actions required in 7.7.2, 7.7.3, 7.7.4 and 7.7.5.~~
- 604 ~~A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that~~
- 605 ~~the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the~~
- 606 ~~different uses of radioactive material permitted by the license.~~
- 607 **7.8 Radiation Safety Committee.**
- 608 7.8.1 Licensees that are authorized for one or more different types of radioactive material use under
- 609 7.36, 7.42, 7.48, or 7.62 shall establish a Radiation Safety Committee to oversee all uses of
- 610 radioactive material permitted by the license.

**Commented [JSJ36]:** This provision has been replaced by new 7.7.7.  
NRC Compatibility D

**Commented [JSJ37]:** This provision combines the requirements found in [10 CFR 35.24\(h\)](#) and [10 CFR 35.2024](#).  
Provision 7.7.7.3 is new to 10 CFR 35 as a result of 2018 CFR changes, to address the recordkeeping requirements pertaining to the (new) Associate Radiation Safety Officer position.  
NRC RATS 2018-1  
NRC Compatibility D  
**CROSS REFERENCES:**  
7.7.1 = paragraph (a) of 10 CFR 35.24  
7.7.2 = paragraph (b) of 10 CFR 35.24  
7.7.5 = paragraph (e) of 10 CFR 35.24

**Commented [JJ38]:** This provision is replaced by NEW 7.7.3 (above).

**Commented [JSJ39]:** This provision is replaced by NEW 7.7.4 (above).

- 611 7.8.2 The Committee shall:
- 612 7.8.2.1 Include:
- 613 (1) An authorized user of each type of use permitted by the license;
- 614 (2) The Radiation Safety Officer
- 615 (3) A representative of the nursing service
- 616 (4) A representative of management who is neither an authorized user nor a  
617 Radiation Safety Officer; and
- 618 (5) Other members as the licensee deems appropriate.
- 619 7.8.2.2 Meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months.
- 620 7.8.2.3 Maintain minutes of each meeting, including:
- 621 (1) The date of the meeting;
- 622 (2) Members present;
- 623 (3) Members absent; and
- 624 (4) Summary of deliberations and discussions.
- 625 **7.9 Radiation Protection Program Changes.**
- 626 7.9.1 A licensee may revise its radiation protection program without Department approval if:
- 627 7.9.1.1 The revision does not require an amendment under 7.4;
- 628 7.9.1.2 The revision is in compliance with the regulations and the license;
- 629 7.9.1.3 The revision has been reviewed and approved by the Radiation Safety Officer, licensee  
630 management and licensee's Radiation Safety Committee (if applicable); and
- 631 7.9.1.4 The affected individuals are instructed on the revised program before the changes are  
632 implemented.
- 633 7.9.2 A licensee shall retain a record of each change for 5 years, including
- 634 7.9.2.1 A copy of the old and new procedures;
- 635 7.9.2.2 The effective date of the change; and
- 636 7.9.2.2 The signature of the licensee management that reviewed and approved the change.
- 637 **7.10 Supervision.**
- 638 **7.10.1** A licensee that permits the receipt, possession, use, or transfer of radioactive material by an  
639 individual under the supervision of an authorized user as allowed by ~~7.3.27.3.1.2(1)~~ shall:

**Commented [JJ40]:** Updated to correct a prior cross-reference error and align with the renumbering of section 7.3.1. Formatting and alignment corrections are also made to this section.

640 7.10.1.1 In addition to the requirements of 10.3 of these regulations, instruct the  
641 supervised individual in the licensee's written radiation protection procedures,  
642 written directive procedures, regulations of Part 7, and license conditions with  
643 respect to the use of radioactive material; and;

644 7.10.1.2 Require the supervised individual to follow the instructions of the supervising  
645 authorized user for medical uses of radioactive material, written radiation  
646 protection procedures, written directive procedures, regulations of Part 7, and  
647 license conditions with respect to the medical use of radioactive material.

648 **7.10.2** A licensee that permits the preparation of radioactive material for medical use by an individual  
649 under the supervision of an authorized nuclear pharmacist or physician who is an authorized  
650 user, as allowed by ~~7.3-37.3.1.2(2)~~, shall:

**Commented [JJ41]:** Updated to correct a prior cross-reference error and align with the renumbering of section 7.3.1.

651 7.10.2.1 In addition to the requirements of 10.3, instruct the supervised individual in the  
652 preparation of radioactive material for medical use, as appropriate to that  
653 individual's use of radioactive material; and

654 7.10.2.2 Require the supervised individual to follow the instructions of the supervising  
655 authorized user or authorized nuclear pharmacist regarding the preparation of  
656 radioactive material for medical use, the written radiation protection procedures,  
657 the regulations of Part 7, and license conditions.

658 7.10.3 Unless physical presence as described in other sections of Part 7 is required, a licensee who  
659 permits supervised activities under 7.10.1 and 7.10.2 shall require an authorized user to be  
660 immediately available by telephone within ten minutes to communicate with the supervised  
661 individual, unless otherwise authorized by the Department with prior written approval.

662 7.10.4 A licensee who permits supervised activities under 7.10.1 and 7.10.2 is responsible for the acts  
663 and omissions of the supervising authorized user and supervised individual(s).

664 **7.10.5** A licensee who permits supervised activities under 7.10.1 and 7.10.2 shall require that the  
665 administration of radioactive material or radiation from radioactive material under the  
666 supervision of an authorized user be performed only by a physician or an individual who  
667 meets the requirements in Appendix 7B or 7N.

**Commented [JSJ42]:**  
This is a new proposed requirement intended to strengthen the requirements for persons who most often administer radioactive materials or radiation to patients while under the supervision of an authorized user physician that is named on the license. Such individuals may include physicians who may be undergoing additional training on a particular type of use and are not yet named as authorized users on a license; authorized medical physicists; and nuclear medicine technologists.

668 **7.11 Written Directives.**

669 **7.11.1** A written directive must be dated and signed by an authorized user, including the signatory's  
670 printed or typed name, ~~prior to~~ **before** the administration of:

This requirement is Colorado specific and is not found in 10 CFR 35.

671 7.11.1.1 I-131 sodium iodide greater than 1.11 MBq (30 µCi), or

672 7.11.1.2 Any therapeutic dosage of radioactive material, or

673 7.11.1.3 Any therapeutic dose of radiation from radioactive material.

**Commented [JJ43]:** Updated for consistency with [10 CFR 35.40\(a\)](#).

674 ~~If, because of the emergent nature of the patient's condition, a delay in order to provide a~~  
675 ~~written directive would jeopardize the patient's health, an oral directive is acceptable. The~~  
676 ~~information contained in the oral directive must be documented as soon as possible in~~  
677 ~~writing in the patient's record. A written directive must be prepared within 48 hours of the~~  
678 ~~oral directive.~~

**Commented [JJ44]:** This is not a new requirement but is relocated from prior Section 7.11.3 for consistency with the flow/format of [10 CFR 35.40](#).

679 **7.11.2** The written directive must contain the patient or human research subject's name and the  
680 following:

**Commented [JJ45]:** 35.40(b)

681 7.11.2.1 For an administration of a dosage of radioactive drug containing radioactive  
682 material, the name of the radioactive drug containing radioactive material, dosage, and  
683 route of administration;

684 7.11.2.2 For gamma stereotactic radiosurgery, the total dose, treatment site, and values  
685 for the target coordinate settings per treatment for each anatomically distinct treatment  
686 site;

687 7.11.2.3 For teletherapy, the total dose, dose per fraction, number of fractions, and  
688 treatment site;

689 7.11.2.4 For high dose rate remote afterloading brachytherapy, the radionuclide,  
690 treatment site, dose per fraction, number of fractions, and total dose; ~~or~~

691 ~~7.11.2.5~~ **For permanent implant brachytherapy:**

692 (1) **Before implantation: the treatment site, the radionuclide, and the total**  
693 **source strength; and**

694 (2) **After implantation but before the patient leaves the post treatment recovery**  
695 **area: the treatment site, the number of sources implanted, the total source**  
696 **strength implanted, and the date; or**

697 7.11.2.56 For all other brachytherapy, including LDR, MDR, and PDR:

698 (1) ~~Prior to~~ **Before** implantation: **the** treatment site, ~~the~~ radionuclide, and dose; and

699 (2) After implantation but ~~prior to~~ **before** completion of the procedure: the  
700 ~~radioisotope~~ **radionuclide**; treatment site; number of sources; ~~and~~ total source  
701 strength and exposure time (or the total dose); **and date.**

702 ~~7.11.3~~ **If, because of the emergent nature of the patient's condition, a delay in order to provide a written**  
703 **directive would jeopardize the patient's health, an oral directive will be acceptable, provided that**  
704 **the information contained in the oral directive is documented as soon as possible in writing in the**  
705 **patient's record and a written directive is prepared within 48 hours of the oral directive.**

706 ~~7.11.4~~ **A written revision to an existing written directive may be made provided that if the revision is dated**  
707 **and signed by an authorized user prior to **before** the administration of the dosage of ~~radioactive~~  
708 **drug containing unsealed** radioactive material, the brachytherapy dose, the gamma stereotactic  
709 radiosurgery dose, the teletherapy dose, or the next fractional dose.**

710 ~~7.11.5~~ **7.11.3.1** If, because of the patient's condition, a delay in order to provide a written revision  
711 to an existing written directive would jeopardize the patient's health, an oral revision to an  
712 existing written directive ~~will be~~ **is** acceptable, ~~provided that the~~ **The** oral revision ~~is~~ **must**  
713 **be** documented as soon as possible in the patient's record. ~~and a~~ **A** revised written  
714 directive ~~is~~ **must be** signed by the authorized user within 48 hours of the oral revision.

715 7.11.64 The licensee shall retain a copy of each written directive and/or written revision to an existing  
716 written directive for 3 years.

717 **7.12 Procedures for Administrations Requiring a Written Directive.**

718 7.12.1 For any administration requiring a written directive, the licensee shall develop, implement, and  
719 maintain written procedures to provide high confidence that:

**Commented [JJ46]:** Updated for consistency with 2018 amendments to [35.40\(b\)\(6\)](#).

The proposed language provides specific written directive requirements applicable to permanent implant brachytherapy consistent with federal rule. The proposed language primarily shifts the requirements from dose based criteria to radioactivity based criteria.

NRC RATS 2018-1  
NRC Compatibility H&S

**Commented [JJ47]:** For consistency with the flow/format of 10 CFR 35.40, this provision is relocated to 7.11.1.

**Commented [JJ48]:** Updated for consistency with language of [10 CFR 35.40\(c\)\(1\)](#).

NRC Compatibility H&S

**Commented [JJ49]:** Updated for consistency with [10 CFR 35.40\(c\)\(2\)](#).

NRC Compatibility H&S

- 720 7.12.1.1 The patient's or human research subject's identity is verified before each  
721 administration; and
- 722 7.12.1.2 Each administration is in accordance with the written directive.
- 723 ~~7.12.2 The procedures required by 7.12.1 must, at At a minimum, the procedures required by 7.12.1~~  
724 ~~must~~ address the following items that are applicable for the licensee's use of radioactive material:
- 725 7.12.2.1 Verifying the identity of the patient or human research subject;
- 726 ~~7.12.2.2~~ Verifying that the ~~specific details of the~~ administration ~~are~~is in accordance with  
727 the treatment plan, if applicable, and the written directive;
- 728 7.12.2.3 Checking both manual and computer-generated dose calculations; and
- 729 7.12.2.4 Verifying that any computer-generated dose calculations are correctly transferred  
730 into the consoles of therapeutic medical units authorized by 7.48
- 731 ~~7.12.2.5~~ **Determining if a medical event, as defined in 7.21, has occurred; and**
- 732 ~~7.12.2.6~~ **Determining, for a permanent implant brachytherapy, within 60 calendar**  
733 **days from the date the implant was performed, the total source strength**  
734 **administered outside of the treatment site compared to the total source**  
735 **strength documented in the post-implantation portion of the written**  
736 **directive, unless a written justification of patient unavailability is**  
737 **documented.**
- 738 **7.13 Duties of Aauthorized Uuser and Aauthorized Mmedical Pphysicist.**
- 739 7.13.1 A licensee shall assure that only authorized users for the type of radioactive material used:
- 740 7.13.1.1 Prescribe the radiopharmaceutical dosage and/or dose to be administered  
741 through the issuance of a written directive or reference to the diagnostic clinical  
742 procedures manual; and
- 743 7.13.1.2 Direct, as specified in 7.10 and 7.12, or in license conditions, the administration  
744 of radioactive material for medical use to patients or human research subjects;
- 745 ~~7.13.1.3~~ Prepare and administer, or supervise the preparation and administration of  
746 radioactive material for medical use, in accordance with ~~7.3.27.3.1.2(1), 7.3.37.3.1.2(2)~~  
747 and 7.10;
- 748 7.13.2 A licensee shall assure that only authorized medical physicists perform, as applicable:
- 749 7.13.2.1 Measurements and calculations as described in 7.41;
- 750 7.13.2.2 Full calibration measurements as described in 7.54, 7.55, and 7.56;
- 751 7.13.2.3 Periodic spot checks as described in 7.58, 7.59 and 7.61; and
- 752 7.13.2.4 Radiation surveys as described in 7.57.
- 753 ~~7.14 Suppliers for Sealed Sources or Devices for Medical Use. Suppliers for sealed sources or~~  
754 ~~devices for medical use.~~

Commented [JJ50]: Updated for consistency with wording of [10 CFR 35.41\(b\)](#).

Commented [JJ51]: Updated for consistency with wording of [10 CFR 35.41\(b\)\(2\)](#).

Commented [JJ52]: Updated for consistency with 2018 changes to [10 CFR 35.41\(b\)\(5\)](#).

NRC [RATS 2018-1](#)  
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CROSS REFERENCE:  
7.21 = 10 CFR 35.3045

Commented [JJ53]: Updated for consistency with 2018 changes to [10 CFR 35.41\(b\)\(6\)](#).

NRC [RATS 2018-1](#)  
NRC Compatibility H&S

Commented [JJ54]: Updated to correct prior cross-reference errors and align with the renumbering of section 7.3.1.

Commented [JSJ55]: Minor changes to this provision, consistent with [10 CFR 35.49](#).

NRC Compatibility C  
[NON-RATS ITEM]

755 **For medical use, a licensee may only use:**

756 7.14.1 Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with  
757 a license issued pursuant to Part 3 of these regulations or the equivalent regulations of another  
758 Agreement State, ~~a Licensing State~~ or the NRC;

759 7.14.2 Sealed source or devices non-commercially transferred from a Part 7 licensee or an Agreement  
760 State ~~or NRC~~ medical use licensee; or

761 7.14.3 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant  
762 to Part 3 of these regulations, or the equivalent regulations of another Agreement State, ~~a~~  
763 ~~Licensing State~~, or the NRC.

764 **SPECIFIC REQUIREMENTS Section C – General Technical Requirements**

765 **7.15 Quality Control of Diagnostic Equipment.**

766 7.15.1 Each licensee shall establish written quality control procedures for all diagnostic equipment used  
767 for radionuclide studies.

768 7.15.2 As a minimum, quality control procedures and frequencies shall be:

769 7.15.2.1 Those recommended by equipment manufacturers; or

770 7.15.2.2 Procedures which have been approved by the Department.

771 7.15.3 The licensee shall conduct quality control of diagnostic equipment in accordance with written  
772 procedures.

773 7.15.4 A licensee shall retain a record of each quality control test required by the written quality control  
774 procedures for 3 years.

775 **7.16 ~~Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed~~**  
776 **~~Radioactive Materials.~~ Possession, use, and calibration of instruments used to measure the**  
777 **activity of unsealed radioactive material.**

778 7.16.1 For direct measurements performed in accordance with 7.18, a licensee shall possess and use  
779 instrumentation to measure the activity of unsealed radioactive materials prior to administration to  
780 each patient or human research subject.

781 7.16.2 A licensee shall calibrate the instrumentation required in 7.16.1 in accordance with nationally  
782 recognized standards or the manufacturer's instructions.

783 7.16.3 In addition to the calibration required in 7.16.2, the licensee shall at a minimum also perform tests  
784 for constancy, linearity, and geometry dependence, as appropriate to demonstrate proper  
785 operation of the instrument.

786 7.16.4 A licensee shall retain a record of each instrument calibration and test required by 7.16 for 3  
787 years. The record shall include the:

788 7.16.4.1 Model and serial number of the instrument;

789 7.16.4.2 Date of the calibration and other tests;

790 7.16.4.3 Results of the calibration and other tests; and

- 791 7.16.4.4 Name of the individual who performed the calibration and other tests.
- 792 **7.17 Calibration of Survey Instruments.** ~~Calibration of survey instruments.~~
- 793 7.17.1 A licensee shall ~~ensure that~~**calibrate** the survey instruments used to show compliance with Part 4  
794 and Part 7 ~~have been calibrated~~ before first use, annually **at intervals not to exceed 12 months**,  
795 and following ~~any~~ repair that ~~will~~**affects** the calibration. **A licensee shall:**
- 796 **7.17.1.1 Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a**  
797 **radiation source;**
- 798 **7.17.1.2 Calibrate two separate readings on each scale or decade that will be used**  
799 **to show compliance; and**
- 800 **7.17.1.3 Conspicuously note on the instrument the date of calibration.**
- 801 ~~7.17.2 To satisfy the requirements of 7.17.1 the licensee shall:~~
- 802 ~~7.17.2.1 Calibrate all required scale readings up to 10 mSv (1 rem) per hour with a~~  
803 ~~radiation source;~~
- 804 ~~7.17.2.2 Have each radiation survey instrument calibrated as follows, or by acceptable~~  
805 ~~equivalent methods:~~
- 806 (1) ~~At energies appropriate for use and at intervals not to exceed 12 months or after~~  
807 ~~instrument servicing, except for battery changes;~~
- 808 (2) ~~For linear scale instruments, at 2 points located approximately one-third and two-~~  
809 ~~thirds of full-scale on each scale;~~
- 810 (3) ~~For logarithmic scale instruments, at mid-range of each decade and at 2 points of~~  
811 ~~at least one decade;~~
- 812 (4) ~~For digital instruments, at 3 points between 0.02 and 10 mSv (2 and 1000 mrem)~~  
813 ~~per hour; and~~
- 814 (5) ~~For dose rate instruments, so that an accuracy within plus or minus 20 percent of~~  
815 ~~the true radiation dose rate can be demonstrated at each point checked.~~
- 816 ~~7.17.2.3 Conspicuously note on the instrument the date of calibration.~~
- 817 7.17.32 ~~The~~**A** licensee ~~shall~~**may** not use survey instruments if the difference between the indicated  
818 exposure rate and the calculated exposure rate is ~~greater~~**more** than 20 percent.
- 819 7.17.43 ~~The~~**A** licensee shall retain a record of each survey instrument calibration required by 7.17 for 3  
820 years. The record shall include the:
- 821 7.17.43.1 Model and serial number of the instrument;
- 822 7.17.43.2 Date of the calibration;
- 823 7.17.43.3 Results of the calibration; and
- 824 7.17.43.4 Name of the individual who performed the calibration.

**Commented [JSJ56]:** Language and format/flow is updated for consistency with [10 CFR 35.61](#) except as indicated below.

Proposed 7.17.1.1 parallels the existing requirement in 7.17.2.1 (below).

Proposed 7.17.1.3 parallels the existing requirement in 7.17.2.3

Although not found in 10 CFR 35, the phrase "at intervals not to exceed 12 months" is retained from the current rule as the radiation program believes it adds clarity to the requirement.

NRC Compatibility H&S: 7.17.1.1, 7.17.1.2, 7.17.2  
NRC Compatibility D: 7.17.1.3, 7.17.3

**Commented [JSJ57]:** The requirement in 7.17.2.1 is replaced by 7.17.1.1 (above).

**Commented [JSJ58]:**  
The requirements of 7.17.2.2 are not found in Part 35 and are deleted. Due to the various makes, models and design configurations of modern survey instruments, calibration requirements are generally best determined by the facility performing the calibration. Licensed facilities typically perform calibrations in accordance with standard practices and nationally accepted standards appropriate for the specific instrument.

**Commented [JSJ59]:** The requirement in 7.17.2.3 is replaced by 7.17.1.3 (above).

- 825 **7.18 Determination of Dosages of Radioactive Material for Medical Use.**  
826 **Determination of dosages of unsealed radioactive material for medical use.**
- 827 7.18.1 A licensee shall determine and record the activity of each dosage prior to medical use.
- 828 7.18.1.1 For photon-emitting radioactive material, this determination shall be within 30  
829 minutes prior to medical use.
- 830 7.18.1.2 For all other radioactive material, this determination shall be within the period  
831 before medical use that is no greater than 10 percent of the physical half-life of  
832 the radioactive material.
- 833 7.18.2 For a unit dosage, the determination required by 7.18.1 shall be made by:
- 834 7.18.2.1 ~~d~~Direct measurement of radioactivity; or
- 835 7.18.2.2 ~~a~~A decay correction, based on the measurement made by:
- 836 (1) ~~a~~A manufacturer or preparer licensed pursuant to Part 3 of these regulations or  
837 equivalent provisions of another Agreement State, or NRC; or
- 838 (2) ~~a~~An NRC or Agreement State licensee for use in research in accordance with a  
839 Radioactive Drug Research Committee-approved protocol or an Investigational  
840 New Drug (IND) protocol accepted by FDA.
- 841 7.18.3 For other than a unit dosage, the determination by 7.18.1 shall be made by:
- 842 7.18.3.1 ~~d~~Direct measurement of radioactivity; or
- 843 7.18.3.2 ~~b~~By a combination of measurements of radioactivity and mathematical  
844 calculations; or
- 845
- 846 7.18.3.3 ~~b~~By a combination of volumetric measurements and mathematical calculations,  
847 based on the measurement made by:
- 848 (1) ~~a~~A manufacturer or preparer licensed pursuant to Part 3 of these regulations or  
849 equivalent provisions of another Agreement State, or NRC.
- 850 7.18.4 Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage  
851 differs from the prescribed dosage by more than 20 percent.
- 852 ~~7.18.5~~ A licensee shall retain a record of the each dosage determination required by 7.18.1 for 3 years.  
853 The record shall contain the:
- 854 7.18.5.1 Name of the radioactive drug;
- 855 7.18.5.2 Patient's or human research subject's name, and identification number if one has  
856 been assigned;
- 857 ~~7.18.3.35.3~~ Prescribed dosage;
- 858 ~~7.18.3.45.4~~ Determined dosage; or a notation that the total activity is less than 1.1 MBq (30  
859  $\mu$ Ci);

Commented [JJ60]:  
Correction of numbering errors made in this section.

- 860 7.18.3-55.5 Date and time of the dosage determination; and
- 861 7.18.3-65.6 Name of the individual who determined the dosage.
- 862 **7.19 Authorization for Calibration, Transmission and Reference Sources.**  
863 **Authorization for calibration, transmission and reference sources.**
- 864 **7.19.1** Any person authorized by 7.3 for medical use of radioactive material may receive, possess, and  
865 use **any of** the following radioactive material for check, calibration, **transmission** and reference  
866 use:
- 867 ~~7.19.17.19.1.1~~ **Sealed sources manufactured and distributed by persons specifically licensed**  
868 **pursuant to Part 3 of these regulations or equivalent provisions of the another**  
869 **Agreement State, a Licensing State, or NRC, and that do not exceed 1.1 GBq**  
870 **(30 mCi) each; Sealed sources, not exceeding 1.11 GBq (30 mCi) each,**  
871 **manufactured and distributed by a person licensed by NRC under 10 CFR**  
872 **32.74 or equivalent Agreement State regulations;**
- 873 **7.19.1.2** **Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a**  
874 **licensee authorized to redistribute the sealed sources manufactured and**  
875 **distributed by a person licensed by NRC under 10 CFR 32.74 or equivalent**  
876 **Agreement State regulations, providing the redistributed sealed sources**  
877 **are in the original packaging and shielding and are accompanied by the**  
878 **manufacturer's approved instructions;**
- 879 ~~7.19.27.19.1.3~~ Any radioactive material with a half-life not longer than 120 days or less in  
880 individual amounts not to exceed ~~0.550.56~~ GBq (15 mCi);
- 881 ~~7.19.37.19.1.4~~ Any radioactive material with a half life ~~greater~~ longer than 120 days in individual  
882 amounts not to exceed the smaller of **7.4 MBq (200 uCi) or 1000 times the**  
883 **quantities in Part 3 Schedule 3B; or**
- 884 ~~7.19.3.1~~ **7.4 MBq (200 µCi);**
- 885 ~~7.19.3.2~~ **1000 times the quantities in Part 3 Schedule 3B; and**
- 886 ~~7.19.47.19.1.5~~ Technetium-99m in amounts as needed.
- 887 **7.19.2 Radioactive material in sealed sources authorized by this provision shall not be:**
- 888 **7.19.2.1** **Used for medical use as defined in 7.2 except in accordance with the**  
889 **requirements in 7.40; or**
- 890 **7.19.2.1** **Combined (i.e., bundled or aggregated) to create an activity greater than**  
891 **the maximum activity of any single sealed source authorized under 7.19.**
- 892 **7.19.3 A licensee using calibration, transmission, and reference sources in accordance with the**  
893 **requirements in 7.19.1 or 7.19.2 need not list these sources on a specific medical use**  
894 **license.**
- 895 **7.20 Requirements for Possession of Sealed Sources and Brachytherapy**  
896 **Sources.** Requirements for possession of sealed sources and brachytherapy sources.
- 897 7.20.1 A licensee in possession of any sealed source or brachytherapy source shall follow the radiation  
898 safety and handling instructions supplied by the manufacturer or equivalent instructions approved

Commented [JSJ61]: Section 7.19 is revised for consistency with the 2018 amendments to [10 CFR 35.65](#).

Compatibility D  
NRC RATS 2018-1

Commented [JSJ62]: This is a new provision/requirement, added for consistency with the 2018 amendments to [10 CFR Part 35.65](#).

Compatibility D  
NRC RATS 2018-1

CROSS REFERENCES:  
7.2 = 10 CFR 35.2  
7.40 = 10 CFR 35.500

Commented [JSJ63]: This is a new provision/requirement, added for consistency with the 2018 amendments to [10 CFR Part 35.65](#).

Compatibility D  
NRC RATS 2018-1

CROSS REFERENCES:  
7.19.1 = 10 CFR 35.65(a)  
7.19.2 = 10 CFR 35.65(b)

- 899 by the Department and shall maintain the instructions for the duration of source use in a legible  
900 form convenient to users.
- 901 7.20.2 A licensee in possession of a sealed source shall test the source for leakage:
- 902 7.20.2.1 In accordance with Part 4 of these regulations; and
- 903 7.20.2.2 At intervals not to exceed 6 months or at intervals approved by the Department,  
904 another Agreement State, ~~a Licensing State~~ or the NRC in the Sealed Source and Device  
905 Registry.
- 906 7.20.3 To satisfy the leak test requirements of 7.20, the licensee shall measure the sample so that the  
907 leak test can detect the presence of 185 Bq (0.005 uCi) of radioactive material in the sample.
- 908 7.20.4 If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable  
909 contamination, the licensee shall:
- 910 7.20.4.1 Immediately withdraw the sealed source from use and store, dispose or cause it  
911 to be repaired in accordance with the requirements of these regulations; and
- 912 7.20.4.2 File a written report with the Department within 5 days of receiving the leak test  
913 result, including the model number and serial number, if assigned, of the leaking source,  
914 the radionuclide and its estimated activity, the date and results of the test, and the action  
915 taken.
- 916 7.20.5 A licensee in possession of a sealed source or brachytherapy source, except for a gamma  
917 stereotactic radiosurgery source, shall conduct a semi-annual physical inventory of all such  
918 sources. The licensee shall retain each inventory record for 3 years. The inventory records shall  
919 contain the model number of each source, and serial number if one has been assigned, the  
920 identity of each source radionuclide and its estimated activity, the location of each source, and  
921 the name of the individual who performed the inventory.
- 922 **7.21 Reports and Notifications of Misadministrations. Report and notification of a medical**  
923 **event.**
- 924 ~~7.21.1 Other than events that result from intervention by a patient or human research subject, a licensee~~  
925 ~~shall report any event in which the administration of radioactive material or radiation from~~  
926 ~~radioactive material results in:~~ **A licensee shall report any event as a medical event, except**  
927 **for an event that results from patient or human research subject intervention, in which:**
- 928 **7.21.1.1 The administration of radioactive material or radiation from radioactive**  
929 **material, except permanent implant brachytherapy, results in:**
- 930 ~~7.21.1.1~~ **(1) A dose that differs from the prescribed dose or dose that would have**  
931 **resulted from the prescribed dosage** by more than 0.05 Sv (5 rem) effective  
932 dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem)  
933 shallow dose equivalent to the skin; and ~~either~~
- 934 **(1) (a)** The total dose delivered differs from the prescribed dose by 20 percent  
935 or more;
- 936 **(2) (b)** The total dosage delivered differs from the prescribed dosage by 20  
937 percent or more or falls outside the prescribed dosage range; or

**Commented [JJ64]:** Consistent with current NRC language in 10 CFR 35, Part 7 is being modified to change the term "misadministration" to "medical event".

**Commented [JJ65]:** Reworded for consistency with [10 CFR 35.3045](#).

Due to the change in some requirements related to permanent implant brachytherapy, the requirements are also modified in 7.21.

NRC Compatibility C  
NRC RATS 2018-1

**Commented [JSJ66]:** Language pertaining to human research subject intervention is retained from the current rule although it is not found in 10 CFR 35.

- 938 (3) (c) The fractionated dose delivered differs from the prescribed dose, for a  
939 single fraction, by 50 percent or more.
- 940 7.21.1.2 (2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv  
941 (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the  
942 skin from any of the following:
- 943 (1) (a) An administration of a wrong radioactive drug **containing**  
944 **radioactive material or the wrong radionuclide for a brachytherapy**  
945 **procedures;**
- 946 (2) (b) An administration of a radioactive drug containing radioactive  
947 material by the wrong route of administration;
- 948 (3) (c) An administration of a dose or dosage to the wrong individual or  
949 human research subject;
- 950 (4) (d) An administration of a dose or dosage delivered by the wrong  
951 mode of treatment; or
- 952 (5) (e) A leaking sealed source.
- 953 7.21.1.3 (3) A dose to the skin or an organ or tissue other than the treatment site that  
954 exceeds by:
- 955 (a) ~~0.5 Sievert (50 rem) to an organ or tissue and~~ **0.5 Sievert (50**  
956 **rem) or more the expected dose to that site from the procedure if**  
957 **the administration had been given in accordance with the written**  
958 **directive prepared or revised before administration; and**
- 959 (b) ~~50 percent of the dose expected from the administration defined~~  
960 ~~in the written directive (excluding, for permanent implants, seeds that~~  
961 ~~were implanted in the correct site but migrated outside the treatment~~  
962 ~~site).~~ **50 percent or more the expected dose to that site from the**  
963 **procedure if the administration had been given in accordance with**  
964 **the written directive prepared or revised before administration.**
- 965 7.21.1.2 **For permanent implant brachytherapy, the administration of radioactive**  
966 **material or radiation from radioactive material (excluding sources that were**  
967 **implanted in the correct site but migrated outside the treatment site) that**  
968 **results in:**
- 969 (1) **The total source strength administered differing by 20 % or more**  
970 **from the total source strength documented in the post-implantation**  
971 **portion of the written directive;**
- 972 (2) **The total source strength administered outside of the treatment site**  
973 **exceeding 20 % of the total source strength documented in the**  
974 **post-implantation portion of the written directive; or**
- 975 (3) **An administration that includes any of the following:**
- 976 (a) **The wrong radionuclide;**
- 977 (b) **The wrong individual or human research subject;**
- 978
- 979

Commented [JSJ67]: 35.3045(a)(1)(ii)(A)  
NRC Compatibility C

Commented [JSJ68]: This is a new requirement added  
consistent with the 2018 amendments to [10 CFR](#)  
[35.3045\(a\)\(2\)](#) pertaining to permanent implant brachytherapy.  
NRC RATS 2018-1  
NRC Compatibility C

- 980  
981 (c) Sealed source(s) implanted directly into a location  
982 discontiguous from the treatment site, as documented in the  
983 post-implantation portion of the written directive; or  
984  
985 (d) A leaking sealed source resulting in a dose that exceeds 0.5  
986 Sv (50 rem) to an organ or tissue.
- 987 7.21.2 A licensee shall report any event resulting from intervention of a patient or human research  
988 subject in which the administration of radioactive material or radiation from radioactive material  
989 results, or will result in, unintended permanent functional damage to an organ or a physiological  
990 system, as determined by a physician.
- 991 7.21.3 The licensee shall notify ~~the Agency~~ by telephone **the department** no later than the next  
992 calendar day after discovery of the ~~misadministration~~**medical event**.
- 993 7.21.4 The licensee shall submit a written report to the ~~Agency~~**department** within 15 days after  
994 discovery of the ~~misadministration~~**medical event**.
- 995 7.21.4.1 The written report must include:
- 996 (1) The licensee's name;
- 997 (2) The name of the prescribing physician;
- 998 (3) A brief description of the event;
- 999 (4) Why the event occurred;
- 1000 (5) The effect, if any, on the individual(s) who received the administration;
- 1001 (6) ~~What actions~~**Actions**, if any, ~~that~~ have been taken, or are planned, to prevent  
1002 recurrence; **and**
- 1003 (7) Certification that the licensee notified the individual (or the individual's  
1004 responsible relative or guardian), and if not, why not.
- 1005 7.21.4.2 The report may not contain the individual's name or any other information that  
1006 could lead to identification of the individual.
- 1007 7.21.5 The licensee shall provide notification of the ~~misadministration~~**medical event** to the referring  
1008 physician and also notify the individual who is the subject of the ~~misadministration~~**medical event**  
1009 no later than 24 hours after its discovery, unless the referring physician personally informs the  
1010 licensee either that he or she will inform the individual or that, based on medical judgment, telling  
1011 the individual would be harmful. The licensee is not required to notify the individual without first  
1012 consulting the referring physician. If the referring physician or the affected individual cannot be  
1013 reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter.  
1014 The licensee may not delay any appropriate medical care for the individual, including any  
1015 necessary remedial care as a result of the ~~misadministration~~**medical event**, because of any  
1016 delay in notification. To meet the requirements of ~~this paragraph~~**7.21.5**, the notification of the  
1017 individual who is the subject of the ~~misadministration~~**medical event** may be made instead to that  
1018 individual's responsible relative or guardian. If a verbal notification is made, the licensee shall  
1019 inform the individual, or appropriate responsible relative or guardian, that a written description of  
1020 the event can be obtained from the licensee upon request. The licensee shall provide such a  
1021 written description if requested.

1022 7.21.6 Aside from the notification requirement, nothing in this section affects any rights or duties of  
1023 licensees and physicians in relation to each other, to individuals affected by the  
1024 ~~misadministration~~**medical event**, or to that individual's responsible relatives or guardians.

1025 ~~7.21.7 A licensee shall retain a record of a misadministration for 3 years. The record must contain:~~

**Commented [JSJ69]:** This provision is replaced by the revised requirements in new 7.21.7 (below).

1026 ~~7.21.7.1 The licensee's name;~~

1027 ~~7.21.7.1 Names of the individuals involved;~~

1028 ~~7.21.7.1 The social security number or other identification number if one has been~~  
1029 ~~assigned, of the individual who is the subject of the misadministration;~~

1030 ~~7.21.7.1 A brief description of the event and why it occurred;~~

1031 ~~7.21.7.1 The effect, if any, on the individual;~~

1032 ~~7.21.7.1 The actions, if any, taken, or planned, to prevent recurrence; and~~

1033 ~~7.21.7.1 Whether the licensee notified the individual (or the individual's responsible~~  
1034 ~~relative or guardian) and, if not, whether such failure to notify was based on guidance~~  
1035 ~~from the referring physician.~~

1036 ~~7.21.7 A licensee shall:~~

**Commented [JSJ70]:** In part, this provision replaces some requirements of the prior 7.21.7, consistent with 10 CFR 35.3045(g).

1037 ~~7.21.7.1 Annotate a copy of the report provided to the department with the:~~

1038 ~~(1) Name of the individual who is the subject of the event; and~~

1039 ~~(2) Social security number or other identification number, if one has been~~  
1040 ~~assigned, of the individual who is the subject of the event; and~~

1041 ~~7.21.7.2 Provide a copy of the annotated report to the referring physician, if other~~  
1042 ~~than the licensee, no later than 15 days after the discovery of the event.~~

1043 ~~7.21.8 A copy of the record required under 7.21.7 shall be provided to the referring physician if other~~  
1044 ~~than the licensee, within 15 days after discovery of the misadministration.~~

**Commented [JSJ71]:** This provision is replaced by new 7.21.7.2.

1045 **7.22 Notification to the Department of Deceased Patients or Human Research Subjects**  
1046 **Containing Radioactive Material.**Notification to the department of deceased patients or human  
1047 **research subjects containing radioactive material.**

1048 7.22.1 The licensee shall notify the Department by telephone immediately upon discovery that a patient  
1049 or human research subject containing radioactive material has died, and it is possible that any  
1050 individual could receive exposures in excess of 4.14 as a result of the deceased's body.

1051 7.22.2 The licensee shall submit a written report to the Department within 30 days after discovery that  
1052 the patient or human research subject referenced in 7.22.1 has died. The written report must  
1053 include the:

1054 7.22.2.1 Licensee's name;

1055 7.22.2.2 Date of death;

- 1056 7.22.2.3 Radionuclide, chemical and physical form and calculated activity at time of death;  
1057 and
- 1058 7.22.2.4 Names (or titles) and address(es) of known individuals who might have received  
1059 exposures exceeding 5 mSv (500 mrem).
- 1060 7.22.3 The licensee shall retain a record of each written report required by 7.22 for 3 years.
- 1061 **7.23 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child. Report and**  
1062 **notification of a dose to an embryo/fetus or a nursing child**
- 1063 7.23.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose  
1064 equivalent that is a result of an administration of radioactive material or radiation from radioactive  
1065 material to a pregnant individual unless the dose to the embryo/fetus was specifically approved,  
1066 in advance, by the authorized user.
- 1067 7.23.2 A licensee shall report any dose to a nursing child, that was not specifically approved, in advance,  
1068 by the authorized user, that is a result of an administration of radioactive material to a breast  
1069 feeding individual that:
- 1070 7.23.2.1 Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or
- 1071 7.23.2.2 Has resulted in unintended permanent functional damage to an organ or a  
1072 physiological system of the child, as determined by a physician.
- 1073 7.23.3 The licensee shall notify by telephone the **Agency department** no later than the next calendar day  
1074 after discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or  
1075 7.23.2.
- 1076 7.23.4 The licensee shall submit a written report to the **Agency department** within 15 days after  
1077 discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.
- 1078 7.23.4.1 The written report must include:
- 1079 (1) The licensee's name;
- 1080 (2) The name of the prescribing physician;
- 1081 (3) A brief description of the event;
- 1082 (4) Why the event occurred;
- 1083 (5) The effect on the embryo/fetus or the nursing child;
- 1084 (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and
- 1085 (7) Certification that the licensee notified the pregnant individual or mother (or the  
1086 mother's or child's responsible relative or guardian), and if not, why not.
- 1087 7.23.4.2 The report must not contain the individual's or child's name or any other  
1088 information that could lead to identification of the individual or child.
- 1089 7.23.5 The licensee shall ~~notify~~ **provide notification of the event to** the referring physician and also  
1090 notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24  
1091 hours after discovery of an event that would require reporting under 7.23.1 or 7.23.2, unless the

- 1092 referring physician personally informs the licensee either that he or she will inform the mother or  
1093 that, based on medical judgment, telling the mother would be harmful. The licensee is not  
1094 required to notify the mother without first consulting with the referring physician. If the referring  
1095 physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate  
1096 notifications as soon as possible thereafter. The licensee may not delay any appropriate medical  
1097 care for the embryo/fetus or for the nursing child, including any necessary remedial care as a  
1098 result of the event, because of any delay in notification. To meet the requirements of ~~this~~  
1099 ~~paragraph 7.23.5~~, the notification may be made to the mother's or child's responsible relative or  
1100 guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee  
1101 shall inform the mother, or the mother's or child's responsible relative or guardian, that a written  
1102 description of the event can be obtained from the licensee upon request. The licensee shall  
1103 provide such a written description if requested.
- 1104 7.23.6 A licensee shall retain a record of a dose to an embryo/fetus or a nursing child for 3 years. The  
1105 record must contain:
- 1106 7.23.6.1 The licensee's name;
- 1107 7.23.6.2 Names of all the individuals involved;
- 1108 7.23.6.3 Social security number or other identification number if one has been assigned to  
1109 the pregnant individual or nursing child who is the subject of the event;
- 1110 7.23.6.4 A brief description of the event and why it occurred;
- 1111 7.23.6.5 The effect, if any, on the embryo/fetus or nursing child;
- 1112 7.23.6.6 The actions, if any, taken, or planned, to prevent recurrence; and
- 1113 7.23.6.7 Whether the licensee notified the pregnant individual or mother (or the mother's  
1114 or child's responsible relative or guardian) and, if not, whether such failure to notify was  
1115 based on guidance from the referring physician.
- 1116 7.23.7 A copy of the record required under 7.23.6 shall be provided to the referring physician, if other  
1117 than the licensee, within 15 days after discovery of the event.
- 1118 **7.24 ~~Vial Shields and Labels.~~Labeling of vials and syringes.**
- 1119 7.24.1 A licensee shall require each individual preparing or handling a vial that contains a  
1120 radiopharmaceutical to keep the vial in a vial radiation shield.
- 1121 7.24.2 Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive  
1122 drug, to include the isotope and amount of radioactivity. Each syringe shield and vial shield shall  
1123 also be labeled unless the label on the syringe or vial is visible when shielded.
- 1124 **7.25 ~~Surveys for Contamination and Ambient Exposure Rate.~~Surveys for contamination and**  
1125 **ambient exposure rate.**
- 1126 7.25.1 Surveys required by 7.25.2 and 7.25.3 are in addition to surveys required by Part 4.
- 1127 7.25.2 Daily Survey Requirements
- 1128 7.25.2.1 At the end of each day of use, a licensee shall survey with an exposure rate  
1129 instrument, all areas where radioactive drugs containing radioactive material requiring a  
1130 written directive were prepared for use or administered.

- 1131 (1) A licensee does not need to perform the surveys required by 7.25.2.1 in an area  
1132 where patients or human research subjects are confined when they cannot be  
1133 released pursuant to 7.26.
- 1134 7.25.2.2 At the end of each day of use, a licensee shall survey for removable  
1135 contamination all areas where generators and bulk radioactive drugs are prepared for  
1136 use. An instrument capable of detecting 33.3 becquerels (2000 dpm) of contamination on  
1137 each wipe sample shall be used.
- 1138 7.25.3 Weekly Survey Requirements
- 1139 7.25.3.1 At least once each week, a licensee shall survey, with an exposure rate  
1140 instrument, all areas where radioactive drugs or radioactive wastes are stored.
- 1141 7.25.3.2 At least once each week, a licensee shall survey for removable contamination in  
1142 all areas where radioactive materials other than sealed sources as defined in Part 7 are  
1143 stored. An instrument capable of detecting 33.3 becquerels (2000 dpm) of contamination  
1144 on each wipe sample shall be used.
- 1145 7.25.4 A licensee shall establish action levels for the surveys required by 7.25.2 and 7.25.3 and shall  
1146 require that the individual performing the survey immediately notify the Radiation Safety Officer if  
1147 action levels are exceeded.
- 1148 7.25.5 A licensee shall retain a record of each survey required by 7.25.1, 7.25.2 and 7.25.3 for 3 years.  
1149 The record must include:
- 1150 7.25.5.1 The date of the survey;
- 1151 7.25.5.2 The results of the survey;
- 1152 7.25.5.3 The instrument used to make the survey (including, if applicable, that the  
1153 instrument was checked for consistent response with a dedicated check source prior to  
1154 each daily use); and
- 1155 7.25.5.4 The name of the individual who performed the survey.
- 1156 **7.26 Release of Individuals Containing Radioactive Drugs or Implants. Release of individuals**  
1157 **containing unsealed radioactive material or implants containing radioactive material.**
- 1158 7.26.1 A licensee may authorize the release from the licensee's control of any individual who has been  
1159 administered radioactive drugs or permanent implants containing radioactive material if the total  
1160 effective dose equivalent to any other individual from exposure to the released individual is not  
1161 likely to exceed 5 mSv (0.5 rem).<sup>1</sup>
- 1162 <sup>1</sup> Appendix U of U.S. Nuclear Regulatory Commission NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses:  
1163 Program Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains  
1164 tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).
- 1165 7.26.2 A licensee shall provide the released individual or the individual's parent or guardian with  
1166 instructions, including written instructions on the actions recommended to maintain doses to other  
1167 individuals as low as is reasonably achievable if the total effective dose equivalent to any other  
1168 individual is likely to exceed 1 mSv (0.1 rem).
- 1169 7.26.2.1 If the total effective dose equivalent to a nursing infant or child could exceed 1  
1170 mSv (0.1 rem) assuming there were no interruption in breast-feeding, the instructions  
1171 shall also include:

- 1172 (1) Guidance on the interruption or discontinuation of breast-feeding; and
- 1173 (2) Information on the potential consequences, if any, of failure to follow the  
1174 guidance.
- 1175 7.26.3 If the total effective dose equivalent to a nursing infant or child could exceed 5 mSv (0.5 rem)  
1176 from continued breast-feeding, the licensee shall maintain a record that the instructions required  
1177 by 7.26.2 were provided to a breast-feeding woman.
- 1178 7.26.4 The licensee shall maintain a record of the basis for authorizing the release of an individual in  
1179 accordance with 7.26, if the total effective dose equivalent is calculated by:
- 1180 7.26.4.1 Using the retained activity rather than the administered activity;
- 1181 7.26.4.2 Using an occupancy factor less than 0.25 at 1 meter;
- 1182 7.26.4.3 Using the biological or effective half-life; and
- 1183 7.26.4.4 Considering the shielding by tissue.
- 1184 7.26.5 The records required by 7.26.3 and 7.26.4 must be retained for 3 years after the date of release  
1185 of the individual.
- 1186 7.26.6 Reports of Patient Departure Prior to Authorized Release.
- 1187 7.26.6.1 The licensee shall notify the Department by telephone immediately upon  
1188 discovery that a patient or human research subject has departed from the licensee's  
1189 facility without authorization under 7.26.
- 1190 7.26.6.2 The licensee shall submit a written report to the Department within 30 days after  
1191 discovery of the unauthorized departure. The written report must include:
- 1192 (1) The licensee's name;
- 1193 (2) The date and time of the unauthorized departure;
- 1194 (3) The projected date and time when release would have occurred;
- 1195 (4) The address of the patient's or human research subject's home or anticipated  
1196 destination following departure;
- 1197 (5) The radionuclide, chemical and physical form and calculated activity at time of  
1198 release;
- 1199 (6) The apparent reason(s) for the departure prior to authorized release; and
- 1200 (7) A description of any changes in the licensee's patient release criteria or patient  
1201 instructions that are designed to avoid a recurrence of such an event.
- 1202 ~~7.27 Mobile Nuclear Medicine Service Technical Requirements.~~ **Mobile nuclear medicine service**  
1203 **technical requirements.**
- 1204 A licensee providing mobile nuclear medicine service shall:

- 1205 7.27.1 Transport to each client's address of use only syringes or vials containing prepared drugs or  
1206 radioactive materials that are intended for reconstitution of radioactive drug kits;
- 1207 7.27.2 Bring into each client's address of use all radioactive material to be used and, before leaving,  
1208 remove all unused radioactive material and associated radioactive waste;
- 1209 7.27.3 Secure or keep under constant surveillance and immediate control all radioactive material when  
1210 in transit or at a client's address of use;
- 1211 7.27.4 Check instruments used to measure the activity of unsealed radioactive material for proper  
1212 function before medical use at each client's address or on each day of use, whichever is more  
1213 frequent. At a minimum, the check for proper function shall include a constancy check;
- 1214 7.27.5 Check survey instruments for consistent response with a dedicated check source before use at  
1215 each client's address;
- 1216 7.27.6 Prior to leaving a client's address of use, perform area surveys and survey for removable  
1217 contamination in all areas of use, to ensure compliance with Part 4 of these regulations; and
- 1218 7.27.7 Retain a record of each survey required by 7.27.6 for 3 years. The record must include the date  
1219 of the survey, the results of the survey, the instrument used to make the survey, and the name of  
1220 the individual who performed the survey.
- 1221 **7.28 Storage of Volatiles and Gases.**
- 1222 7.28.1 A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and  
1223 container.
- 1224 7.28.2 A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- 1225 7.28.3 A licensee who administers radioactive aerosols or gases shall do so with a system that will keep  
1226 airborne concentrations within the limits prescribed in Part 4 of these regulations.
- 1227 7.28.3.1 The system shall either be directly vented to the atmosphere through an air  
1228 exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded  
1229 container.
- 1230 7.28.3.2 A licensee shall check the operation of collection systems monthly. Records of  
1231 these checks shall be maintained for 3 years.
- 1232 **7.29 Decay-In-Storage. Decay-in-storage.**
- 1233 7.29.1 A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days  
1234 for decay-in-storage before disposal without regard ~~for~~ its radioactivity if ~~the licensee~~ it:
- 1235 7.29.1.1 Monitors radioactive material at the ~~container~~ surface before disposal and  
1236 determines that its radioactivity cannot be distinguished from the background  
1237 radiation level with ~~an appropriate~~ radiation detection survey ~~instrument~~ meter  
1238 set on its most sensitive scale and with no interposed shielding; ~~and~~
- 1239 7.29.1.32 Removes or obliterates all radiation labels, except for ~~radiation labels on~~  
1240 materials ~~that are within containers and that~~ will be ~~handled~~ managed as  
1241 biomedical waste after ~~they have been released from the licensee~~; and

Commented [JSJ72]: Wording and formatting/alignment modifications were made for consistency with [10 CFR 35.92](#).

1242 7.29.1.4 Separates and monitors each generator column individually with all radiation  
1243 shielding removed to ensure that its contents have decayed to background  
1244 radiation level before disposal.

1245 7.29.2 Records of Decay-in-Storage.

1246 For radioactive material disposed in accordance with 7.29.1, the licensee shall retain a record of  
1247 each disposal for 3 years. A licensee shall retain a record of each disposal permitted under  
1248 7.29.1 as follows:

1249 7.29.2.1 A licensee shall maintain records of the disposal of licensed materials, as  
1250 required by 7.29, for 3 years. The record must include the date of the disposal,  
1251 the survey instrument used, the background radiation level, the radiation level  
1252 measured at the surface of each waste container, and the name of the individual  
1253 who performed the survey.

1254 **SPECIFIC REQUIREMENTS FOR THE USE OF RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION,  
1255 AND EXCRETION STUDIES**

1256 **Section D – Unsealed Radioactive Material – Written Directive Not Required**

1257 **7.30 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for which  
1258 a Written Directive is Not Required.** Use of unsealed radioactive material for uptake, dilution, and  
1259 excretion studies for which a written directive is not required.

1260 7.30.1 A licensee may use any unsealed radioactive material, in quantities that do not require a written  
1261 directive, as described in 7.11, for a diagnostic use involving measurements of uptake, dilution, or  
1262 excretion that: Except for quantities that require a written directive under 7.11.2, a licensee  
1263 may use any unsealed radioactive material prepared for medical use for uptake, dilution,  
1264 or excretion studies that is:

1265 7.30.1.1 Is obtained from Obtained from:

- 1266 (1) aA manufacturer or preparer licensed pursuant to licensed under Part 3,  
1267 Section 3.12.10 or equivalent regulations of another Agreement State, a  
1268 Licensing State, or NRC; or;
- 1269 (2) A PET radioactive drug producer licensed under Part 3, Section  
1270 3.8.10 or equivalent regulations of an Agreement State or NRC; or

1271 7.30.1.2 Excluding production of PET radioactive material, is prepared by an authorized  
1272 nuclear pharmacist, a physician who is an authorized user and who meets the  
1273 requirements specified in Appendix 7E, Appendix 7F, or Appendix 7E3.1(2)(g), or  
1274 an individual under the supervision of either as specified in 7.10;

1275 7.30.1.2 Excluding production of PET radionuclides, prepared by:

- 1276 (1) An authorized nuclear pharmacist;
- 1277 (2) A physician who is an authorized user and who meets the  
1278 requirements specified in Appendix 7E, or Appendix 7F and Section  
1279 7E3.1(2)(g) of Appendix 7E; or

**Commented [JSJ73]:**  
This provision combines the requirements found in [10 CFR 35.92\(b\)](#) and [10 CFR 35.2092](#).

The CFR (Part 35) structure retains recordkeeping requirements in one area of the rule, while in Part 7, the recordkeeping requirements are generally retained with the requirement that drives the record.

The proposed language does not change the requirement found in current rule.

**Commented [JSJ74]:** Modified format to "sentence case" for consistency with 10 CFR Part 35.

**Commented [JSJ75]:** Language updated for consistency with the flow and format of 10 CFR 35.100.

[Non-NRC RATS 2018-1 items]

CROSS REFERENCES USED IN THIS SECTION:  
7.11.2 = 10 CFR 35.40(b)  
3.8.10 = 10 CFR 30.32(j)

**Commented [JSJ76]:**  
CROSS REFERENCES:  
Appendix 7E = 10 CFR 35.290  
Appendix 7F = 10 CFR 35.390  
Section 7E3.1(2)(g) of App 7E = 35.290(c)(1)(ii)(G)  
7.10 = 10 CFR 35.27

- 1280 (3) An individual under the supervision, as specified in 7.10, of the  
1281 authorized nuclear pharmacist in 7.30.1.2(1) or the physician who is  
1282 an authorized user in 7.30.1.2(2); or
- 1283 7.30.1.3 ~~Is obtained from and prepared by a D~~ department, Agreement State, ~~Licensing~~  
1284 ~~State~~ or NRC licensee for use in research in accordance with a Radioactive Drug  
1285 Research Committee-approved protocol or an Investigational New Drug (IND)  
1286 protocol accepted by FDA; or
- 1287 7.30.1.4 ~~Is prepared by the licensee for use in research~~ prepared by the licensee **for use in research** in accordance with a  
1288 Radioactive Drug Research Committee-approved application or an  
1289 Investigational New Drug (IND) protocol accepted by FDA ~~for use in research~~.
- 1290 7.30.2 ~~Authorized User~~ Training For Uptake, Dilution, And Excretion Studies.
- 1291 The licensee shall require an authorized user of ~~an~~ unsealed radioactive material for the uses  
1292 authorized under 7.30 to meet the requirements of Appendix 7D.
- 1293 **7.31 Possession of Survey Instrument. Reserved**
- 1294 ~~A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall~~  
1295 ~~possess a portable radiation detection survey instrument capable of detecting dose rates over the~~  
1296 ~~range 1.0 μSv (0.1 mrem) per hour to 500 μSv (50 mrem) per hour. The instrument shall be~~  
1297 ~~operable and calibrated in accordance with 7.17.~~
- 1298 **SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL – WRITTEN**  
1299 **DIRECTIVE NOT REQUIRED**
- 1300 **7.32 Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a**  
1301 **Written Directive is Not Required. Use of unsealed radioactive material for imaging and**  
1302 **localizations studies for which a written directive is not required.**
- 1303 **Except for quantities that require a written directive under 7.11, a licensee may use any unsealed**  
1304 **radioactive material prepared for medical use for imaging and localization studies that is:**
- 1305 7.32.1 ~~A licensee may use, for imaging and localization studies, any radioactive material prepared for~~  
1306 ~~medical use, in quantities that do not require a written directive, as described in 7.11, that:~~
- 1307 **7.32.1 Obtained from:**
- 1308 7.32.1.1 ~~Is obtained from a A~~ manufacturer or preparer licensed pursuant to **Part 3,**  
1309 **Section 3.12.10** or equivalent regulations of another Agreement State, ~~a~~  
1310 ~~Licensing State,~~ or NRC; or;
- 1311 7.32.1.2 **A PET radioactive drug producer licensed under Part 3, Section 3.8.10; or**
- 1312 ~~7.32.1.2 Excluding production of PET radioactive material, is prepared by an authorized~~  
1313 ~~nuclear pharmacist, a physician who is an authorized user and who meets the~~  
1314 ~~requirements specified in Appendix 7E, or Appendix 7F and Appendix 7E3.1(2)(g), or an~~  
1315 ~~individual under the supervision of either as specified in 7.10.~~
- 1316 **7.32.2 Excluding production of PET radionuclides, prepared by:**
- 1317 7.32.2.1 **An authorized nuclear pharmacist;**

**Commented [JSJ77]:** This requirement does not appear in 10 CFR Part 35. The requirement originated from G.45 in SSR Part G (2003) and is believed to be unnecessary.

**Commented [JSJ78]:** Section 7.32 is modified for consistency with the format and content of 10 CFR 35.200.

**CROSS REFERENCES IN THIS SECTION:**  
7.11 = 10 CFR 35.40(b)  
3.8.10 = 10 CFR 30.32(j)

**Commented [JSJ79]:** This provision is replaced with the requirements of 7.32.2 below.

**Commented [JSJ80]:**  
**CROSS REFERENCES IN THIS SECTION:**  
Appendix 7E = 10 CFR 35.290  
Appendix 7F = 10 CFR 35.390  
7E3.1(2)(g) = 10 CFR 35.290(c)(1)(ii)(G)  
7.10 = 10 CFR 35.27  
7.32.2.1 = paragraph (b)(1) of 10 CFR 35.200  
7.32.2.2 = paragraph (b)(2) of 10 CFR 35.200

- 1318 **7.32.2.2** A physician who is an authorized user and who meets the requirements  
1319 specified in Appendix 7E, or Appendix 7F and 7E3.1(2)(g); or
- 1320 **7.32.2.3** An individual under the supervision, as specified in 7.10, of the authorized  
1321 nuclear pharmacist in 7.32.2.1 or the physician who is an authorized user in  
1322 7.32.2.2;
- 1323 ~~7.32.1.37.32.3~~ **7.32.3** ~~Is o~~Obtained from and prepared by a Department, Agreement State, ~~Licensing State~~ or  
1324 NRC licensee for use in research in accordance with a Radioactive Drug Research  
1325 Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by  
1326 FDA; or
- 1327 ~~7.32.1.47.32.4~~ **7.32.4** ~~Is p~~Prepared by the licensee in accordance with a Radioactive Drug Research  
1328 Committee-approved application or an Investigational New Drug (IND) protocol accepted  
1329 by FDA for use in research.
- 1330 7.32.2 Authorized User Training for Imaging and Localization Studies for which a Written Directive is Not  
1331 Required.
- 1332 The licensee shall require an authorized user of an unsealed radioactive material for the uses  
1333 authorized under 7.32 to meet the requirements of Appendix 7E.
- 1334 **7.33 Radionuclide Contaminants. Permissible molybdenum-99, strontium-82, and strontium-85**  
1335 **concentrations.**
- 1336 ~~7.33.1~~ A licensee ~~shall~~**may** not administer to humans a radioactive drug ~~containing~~**that contains**:
- 1337 7.33.1.1 More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15  $\mu$ Ci of  
1338 <sup>99</sup>Mo per mCi of <sup>99m</sup>Tc); **or**
- 1339 7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection  
1340 (0.02  $\mu$ Ci of <sup>82</sup>Sr per mCi of <sup>82</sup>Rb chloride); **or more than 0.2 kBq of strontium-85 per**  
1341 **MBq of rubidium-82 chloride injection (0.2  $\mu$ Ci of <sup>85</sup>Sr per mCi of <sup>82</sup>Rb).**
- 1342 ~~7.33.1.3~~ ~~More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2~~  
1343  ~~$\mu$ Ci of <sup>85</sup>Sr per mCi of <sup>82</sup>Rb).~~
- 1344 ~~7.33.2~~ ~~To demonstrate compliance with 7.33.1, the licensee preparing radioactive drugs from~~  
1345 ~~radionuclide generators shall measure the concentration of radionuclide contaminant in:~~
- 1346 ~~7.33.2.1~~ ~~Each eluate after receipt of a molybdenum-99/technetium-99m generator;~~
- 1347 ~~7.33.2.2~~ ~~Each eluate or extract, before the first patient use of the day, as appropriate for~~  
1348 ~~other than molybdenum-99/technetium-99m generator systems.~~
- 1349 **7.33.2** **A licensee that uses molybdenum-99/technetium-99m generators for preparing a**  
1350 **technetium-99m radioactive drug shall measure the molybdenum-99 concentration in each**  
1351 **eluate from a generator to demonstrate compliance with 7.33.1.**
- 1352 **7.33.3** **A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82**  
1353 **radioactive drug shall, before the first patient use of the day, measure the concentration of**  
1354 **radionuclides strontium-82 and strontium-85 to demonstrate compliance with 7.33.1.**
- 1355 ~~7.33.3~~ ~~Records of Radionuclide Purity.~~

**Commented [JSJ81]:**  
This provision is revised to follow the format of [10 CFR 35.204\(a\)](#). This is a change in formatting only and does not change the current requirement.

**Commented [JSJ82]:** This provision is combined with 7.33.1.2 (above) consistent with the formatting of [10 CFR 35.204\(a\)\(2\)](#).

**Commented [JSJ83]:** Revised language for consistency with [10 CFR 35.204\(b\)](#).

The revised language does not effectively change the requirement from the current Part 7 requirement – only the wording is changed.

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**Commented [JSJ84]:** Revised language for consistency with 10 CFR 35.204(c).

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RATS 2018-1

**Commented [JSJ85]:** This provision is replaced by 7.33.4.

A licensee who must measure radionuclide contaminant concentration shall retain a record of each radionuclide contaminant test for 3 years. The record shall include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kBq of contaminant per MBq of desired radionuclide ( $\mu\text{Ci}/\text{mCi}$ ), the time and date of the test, and the name of the individual who made the measurement.

**7.33.4 If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement as follows:**

**7.33.4.1 A licensee shall maintain a record of the molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by 7.33.2 and 7.33.3 for 3 years. The record must include:**

- (1) For each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement; or
- (2) For each measured elution of rubidium-82, the ratio of the measures expressed as kilobecquerel of strontium-82 per megabecquerel of rubidium-82 (or microcuries of strontium-82 per millicurie of rubidium), kilobecquerel of strontium-85 per megabecquerel of rubidium-82 (or microcuries of strontium-85 per millicurie of rubidium), the time and date of the measurement, and the name of the individual who made the measurement.

**7.33.5 The licensee shall report any measurement that exceeds the limits in 7.33.1 at the time of generator elution, as follows:**

**Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

**7.33.5.1 The licensee shall notify by telephone the department and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 7.33.1 at the time of generator elution. The telephone report to the department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.**

**7.33.5.2 The licensee shall submit a written report to the department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by 7.33.5.1.**

**7.33.4 – Immediate Report.**

**Commented [JSJ86]:** Recordkeeping requirement language is updated for consistency with the 2018 changes to [10 CFR 35.204\(d\)](#) and [10 CFR 35.2204](#).

This provision replaces (prior) 7.33.3. The proposed requirements are similar to those found in 7.33.3 with slight variation in wording. The proposed wording is specific to the type of generator rather than the more generic language of the current provision.

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CROSS REFERENCES IN THIS SECTION:  
7.33.2 = 10 CFR 35.204(b)  
7.33.3 = 10 CFR 35.204(c)

**Commented [JSJ87]:** Reporting language is updated for consistency with the 2018 changes to 10 CFR [35.204\(e\)](#).

This provision combines the requirements of [35.204\(e\)](#) for reporting/notification of an eluate that exceeds the specified limits, and the associated recordkeeping requirements of [10 CFR 35.3204](#).

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1406 A licensee shall report immediately to the Department each occurrence of radionuclide  
1407 contaminant concentration exceeding a limit specified in 7.33.1.

1408 **7.34 Aerosols and Gases.**

1409 Provided the conditions of 7.28 are met, a licensee shall use radioactive aerosols or gases only if  
1410 specific application is made to and approved by the Department.

1411 **7.35 Radiation Detection Capability. Reserved**

1412 A licensee authorized to use radioactive material pursuant to 7.32, 7.36, or 7.42 shall possess  
1413 portable radiation detection survey instrumentation capable of detecting dose rates over the  
1414 range 1.0 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour and over the range of 10 µSv  
1415 (1 mrem) per hour to 10 mSv (1 rem) per hour. Each instrument shall be operable and calibrated  
1416 in accordance with 7.17.

**Commented [JSJ88]:**  
Provision deleted as the general requirements of Part 4 apply. Licensees are required to possess instruments capable of performing measurements needed to demonstrate compliance with the license and regulations.

1417 **SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL – WRITTEN  
1418 DIRECTIVE REQUIRED**

1419 **Section E – Unsealed Radioactive Material – Written Directive Required**

**Commented [JSJ89]:** Section header added for consistency with 10 CFR Part 35.

1420 **7.36 Use of Unsealed Radioactive Material for Which A Written Directive Is Required. Use of  
1421 unsealed radioactive material for which a written directive is required.**

1422 **7.36.1** A licensee may use any unsealed radioactive material **identified in 7F2.1(2)(f) prepared for**  
1423 **diagnostic or therapeutic** medical use **and** for which a written directive is required that is:

**Commented [JSJ90]:** Section has been reformatted for alignment and consistency with [10 CFR 35.300](#).

1424 **7.36.1.1 Obtained from:**

Introductory text in 7.36.1 revised for consistency with 2018 changes to 35.300 per NRC [RATS 2018-1](#) (Compatibility B).

1425 **7.36.1.1 (1)** Is obtained from a manufacturer or preparer licensed pursuant to 3.12.10  
1426 or equivalent regulations of another Agreement State, a Licensing State,  
1427 or NRC; or **A manufacturer or preparer licensed under Part 3, Section**  
1428 **3.12.10 or equivalent regulations of NRC or an Agreement State; or**

Other changes in 7.36.1 and 7.36.2 are not associated with NRC RATS 2018-1.

1429 **(2)** **A PET radioactive drug producer licensed under Part 3, Section**  
1430 **3.8.10 or equivalent Agreement State or NRC regulations; or**

**CROSS REFERENCES:**  
7F2.1(2)(f) = 10 CFR 35.390(b)(1)(ii)(G)  
3.8.10 = 10 CFR 35.32(j)  
7.10 = 10 CFR 35.27  
7.36.1.2(1) = 10 CFR 35.300(b)(1)  
7.36.1.2(2) = 10 CFR 35.300(b)(2)

1431 **7.36.1.2** Excluding production of PET radioactive material, is prepared by: ~~an authorized~~  
1432 ~~nuclear pharmacist, a physician who is an authorized user and who meets the~~  
1433 ~~requirements specified in Appendix 7E, or Appendix 7F, or an individual under~~  
1434 ~~the supervision of either as specified in 7.10;~~

**Commented [JSJ91]:**  
This is a change in formatting only – no requirements are changing.

1435 **(1) An authorized nuclear pharmacist;**

1436 **(2) A physician who is an authorized user and who meets the**  
1437 **requirements specified in Appendix 7E, or Appendix 7F; or**

1438 **(3) An individual under the supervision, as specified in 7.10, of the**  
1439 **authorized nuclear pharmacist in 7.36.1.2(1) or the physician who is**  
1440 **authorized under 7.36.1.2(2); or**

1441 **7.36.1.3** ~~Is obtained~~**Obtained** from and prepared by a ~~D~~**d**epartment, Agreement State,  
1442 ~~Licensing State~~ or NRC licensee for use in research in accordance with a  
1443 Radioactive Drug Research Committee-approved protocol or an Investigational  
1444 New Drug (IND) protocol accepted by FDA; or

- 1445 7.36.1.4 ~~Is prepared by the licensee in accordance with a Radioactive Drug Research~~  
1446 ~~Committee approved application or an Investigational New Drug (IND) protocol~~  
1447 ~~accepted by FDA for use in research. Prepared by the licensee for use in~~  
1448 ~~research in accordance with an Investigational New Drug (IND) protocol~~  
1449 ~~accepted by FDA.~~
- 1450 7.36.2 ~~Authorized User~~ Training For Use Of Any Unsealed Radioactive Material For Diagnostic Or  
1451 Therapeutic Medical Use For Which A Written Directive Is Required.
- 1452 The licensee shall require an authorized user of an unsealed radioactive material for diagnostic or  
1453 therapeutic medical use for which a written directive is required under 7.36 to meet the  
1454 requirements of Appendix 7F.
- 1455 7.36.3 ~~Authorized User~~ Training For Oral Administration of  $\leq 1.22$  GBq  $^{131}\text{I}$  (33 mCi) Sodium Iodide  
1456 Requiring A Written Directive.
- 1457 The licensee shall require an authorized user of an unsealed radioactive material for oral  
1458 administration of  $\leq 1.22$  GBq  $^{131}\text{I}$  (33 mCi) sodium iodide requiring a written directive under  
1459 7.36 to meet the requirements of Appendix 7G.
- 1460 7.36.4 ~~Authorized User~~ Training For Oral Administration Of  $> 1.22$  GBq  $^{131}\text{I}$  (33 mCi) Sodium Iodide  
1461 Requiring A Written Directive.
- 1462 The licensee shall require an authorized user of an unsealed radioactive material for oral  
1463 administration of  $> 1.22$  GBq  $^{131}\text{I}$  (33 mCi) sodium iodide requiring a written directive under 7.36  
1464 to meet the requirements of Appendix 7H.
- 1465 7.36.5 ~~Authorized User~~ Training For Parenteral Administration Requiring A Written Directive.
- 1466 The licensee shall require an authorized user of an unsealed radioactive material for parenteral  
1467 administration requiring a written directive under 7.36 to meet the requirements of Appendix 7I.
- 1468 **7.37 Safety Instruction.**
- 1469 In addition to the requirements of Part 10 of these regulations:
- 1470 7.37.1 ~~The~~A licensee shall provide radiation safety instruction, initially and at least annually, to  
1471 personnel caring for patients or human research subjects that ~~have received therapy with a~~  
1472 ~~radioactive drug, and~~ cannot be released in accordance with 7.26. **To satisfy this requirement,**  
1473 **the instruction must be commensurate with the duties of the personnel and include:**
- 1474 ~~7.37.2 The instruction required by 7.37.1 shall be appropriate for the duties of the personnel and include:~~
- 1475 7.37.21.1 Patient or human research subject control;
- 1476 7.37.21.2 Visitor control, ~~to include the following;~~**including:**
- 1477 (1) Routine visitation to hospitalized individuals in accordance with Part 4, **Section**  
1478 **4.14.1.1** of these regulations; **and**
- 1479 (2) **Visitation authorized in accordance with Part 4, Section 4.14.2;**
- 1480 ~~7.37.1.3(2)~~ Contamination control;
- 1481 ~~7.37.1.4(3)~~ Waste control; and

**Commented [JSJ92]:** Section 7.37 is revised for consistency with the wording and formatting of [10 CFR 35.310](#).

These changes **are not** associated with RATS 2018-1.  
NRC Compatibility H&S (7.37.1)

**Commented [JSJ93]:** This requirement is incorporated into 7.37.1.

1482 **7.37.1.5(4)** Notification of the RSO, or his or her designee, and ~~the~~ authorized user if the  
1483 patient or the human research subject ~~dies or~~ has a medical emergency ~~or dies~~.

1484 ~~7.37.32~~ A licensee shall ~~keep~~**retain** a record of individuals receiving **safety** instructions required by  
1485 7.37.1 and maintain such records for 3 years. The record ~~shall~~**must** include a list of the topics  
1486 covered, the date of instruction, the name(s) of the attendee(s), and the name(s) of the  
1487 individual(s) who ~~gave~~**provided** the instruction.

**Commented [JSJ94]:** 7.37.2 combines the requirements of [10 CFR 35.310](#) and [10 CFR 35.2310](#).  
NRC Compatibility D

1488 **7.38 Safety Precautions.**

**Commented [JSJ95]:** 7.38 is revised for consistency with [10 CFR 35.315](#).

1489 7.38.1 For each patient or human research subject ~~receiving radiopharmaceutical therapy and~~  
1490 ~~hospitalized for compliance with 7.26 who cannot be released under 7.26~~, a licensee shall:

These changes **are not** associated with RATS 2018-1.

NRC Compatibility H&S (7.38)

CROSS REFERENCES:  
7.26 = 10 CFR 35.75

1491 7.38.1.1 Quarter the patient or the human research subject either in:

1492 (1) A private room with a private sanitary facility; or

1493 (2) A room, with a private sanitary facility, with another individual who also has  
1494 received ~~similar radiopharmaceutical~~ therapy **with unsealed radioactive**  
1495 **material** and who **also** cannot be released in accordance with 7.26; and

1496 7.38.1.2 Visibly post the patient's or the human research subject's ~~door~~**room** with a  
1497 "~~Caution:-~~"Radioactive Materials" sign. ~~and~~

1498 **7.38.1.3** ~~Note~~ on the door or ~~on~~**in** the patient's or the human research subject's chart  
1499 where and how long visitors may stay in the patient's or the human research  
1500 subject's room; **and**

1501 7.38.1.34 Either monitor material and items removed from the patient's or the human  
1502 research subject's room to determine that their radioactivity cannot be  
1503 distinguished from the natural background radiation level with a radiation  
1504 detection survey instrument set on its most sensitive scale and with no  
1505 interposed shielding, or handle ~~such~~**the** materials and items as radioactive  
1506 waste.

1507 7.38.2 A licensee shall notify the RSO, or his or her designee, and ~~the~~ authorized user ~~immediately if~~  
1508 ~~the hospitalized patient dies or has a medical emergency and notify the Department as required~~  
1509 ~~by 7.39 as soon as possible if the patient or human research subject has a medical~~  
1510 ~~emergency or dies~~.

**Commented [JSJ96]:** This provision is redundant with the requirements of 7.22 and is therefore deleted here.

1511 **7.39 Emergency Notification. Reserved.**

1512 ~~The licensee shall notify the Department in accordance with 7.22 if it is possible that any~~  
1513 ~~individual could receive exposures in excess of 4.14 as a result of a deceased's body.~~

1514 **SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS**

1515 **Section F – Sealed Sources for Diagnosis**

1516 **7.40 Use of Sealed Sources for Diagnosis. Use of sealed sources and medical devices for**  
1517 **diagnosis.**

**Commented [JSJ97]:** 7.40 is revised for consistency with [10 CFR 35.500](#) as a result of 2018 changes to 10 CFR 35 (RATS 2018-1).

NRC Compatibility C (7.40)

CROSS REFERENCES IN THIS SECTION:  
7.14.1 = 10 CFR 35.49(a)

1518 7.40.1 — A licensee shall use for diagnostic medical uses only sealed sources:

1519 7.40.1.1 — Approved in the Sealed Source and Device Registry; and

- 1520 ~~7.40.1.2~~ ——— Handled in accordance with the manufacturer's radiation safety and handling  
1521 instructions:
- 1522 **7.40.1** A licensee must use only sealed sources that are not in medical devices for diagnostic  
1523 medical uses if the sealed sources are approved in the Sealed Source and Device Registry  
1524 for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that  
1525 are not explicitly listed in the Sealed Source and Device Registry but must be used in  
1526 accordance with the radiation safety conditions and limitations described in the Sealed  
1527 Source and Device Registry.
- 1528 **7.40.2** A licensee must only use medical devices containing sealed sources for diagnostic  
1529 medical uses if both the sealed sources and medical devices are approved in the Sealed  
1530 Source and Device Registry for diagnostic medical uses. The diagnostic medical devices  
1531 may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source  
1532 and Device Registry but must be used in accordance with the radiation safety conditions  
1533 and limitations described in the Sealed Source and Device Registry.
- 1534 **7.40.3** Sealed sources and devices for diagnostic medical uses may be used in research in  
1535 accordance with and active Investigational Device Exemption (IDE) application accepted  
1536 by the U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.
- 1537 ~~7.40.24~~ Authorized User Training For Use Of Sealed Sources For Diagnosis: Training for use of sealed  
1538 sources and medical devices for diagnosis.
- 1539 The licensee shall require an authorized user under 7.40 to meet the requirements of Appendix  
1540 7J.
- 1541 **SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR MANUAL**  
1542 **BRACHYTHERAPY**
- 1543 **Section G – Manual Brachytherapy**
- 1544 ~~7.41~~ **Calibration Measurements of Brachytherapy Sealed Sources.** Calibration measurements of  
1545 brachytherapy sources.
- 1546 7.41.1 ~~Prior to~~Before the first medical use of a brachytherapy sealed source on or after October 25,  
1547 2005, a licensee shall ~~perform the following~~have:
- 1548 7.41.1.1 Determined the source output or activity using a dosimetry system that meets the  
1549 requirements of 7.53;
- 1550 7.41.1.2 Determined source positioning accuracy within applicators; and
- 1551 7.41.1.3 Used published protocols currently accepted by nationally recognized bodies to  
1552 meet the requirements of 7.41.1.1 and 7.41.1.2.
- 1553 7.41.2 ~~A- Instead of a licensee making its own measurements as required in 7.41.1, the~~ licensee  
1554 may use measurements provided by the source manufacturer or by a calibration laboratory  
1555 accredited by the American Association of Physicists in Medicine that are made in accordance  
1556 with 7.41.1.
- 1557 7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical  
1558 decay at intervals consistent with 1.0 percent physical decay.

Commented [JSJ98]: Section 7.41 is updated for consistency with the wording of [10 CFR 35.432](#). These changes are not associated with NRC RATS 2018-1.

CROSS REFERENCES:  
7.53 = 10 CFR 35.630(a)

1559 7.41.4 An authorized medical physicist shall perform or review the measurements and calculations made  
1560 pursuant to 7.41.1, 7.41.2, or 7.41.3.

1561 **7.41.5 A licensee shall retain a record of each calibration as follows:**

1562  
1563 **7.41.5.1 A licensee shall maintain a record of the calibrations of brachytherapy**  
1564 **sources required by 7.41.1 for 3 years after the last use of the source.**

1565  
1566 **7.41.5.2 The record must include:**

- 1567  
1568 (1) **The date of the calibration;**  
1569  
1570 (2) **The manufacturer's name, model number, and serial number for the**  
1571 **source and the instruments used to calibrate the source;**  
1572  
1573 (3) **The source output or activity;**  
1574  
1575 (4) **The source positioning accuracy within the applicators; and**  
1576  
1577 (5) **The name of the individual, the source manufacturer, or the**  
1578 **calibration laboratory that performed the calibration.**

1579 **7.41.6 Strontium-90 sources for ophthalmic treatments.**

1580 ~~7.41.5 Only an authorized medical physicist shall calculate the activity of each strontium-90 source that~~  
1581 ~~is used to determine the treatment times for ophthalmic treatments. The actual source output~~  
1582 ~~shall consider decay based on the activity determined in accordance with paragraphs 7.41.1,~~  
1583 ~~7.41.2, or 7.41.3.~~

1584 **7.41.6.1 Licensees who use strontium-90 for ophthalmic treatments must ensure**  
1585 **that certain activities as specified in 7.41.6.2 are performed by either:**

- 1586 (1) **An authorized medical physicist; or**  
1587  
1588 (2) **An individual who:**  
1589 (a) **Is identified as an ophthalmic physicist on a specific medical use**  
1590 **license issued by NRC or an Agreement State; permit issued by a**  
1591 **NRC or Agreement State broad scope medical use licensee;**  
1592 **medical use permit issued by a NRC master material licensee; or**  
1593 **permit issued by a NRC master material licensee broad scope**  
1594 **medical use permittee; and**  
1595 (b) **Holds a master's or doctor's degree in physics, medical physics,**  
1596 **other physical sciences, engineering, or applied mathematics from**  
1597 **an accredited college or university; and**  
1598 (c) **Has successfully completed 1 year full-time training in medical**  
1599 **physics and an additional year of full-time work experience under**  
1600 **the supervision of a medical physicist; and**  
1601 (d) **Has documented training in:**  
1602 (i) **The creation, modification, and completion of written**  
**directives;**

**Commented [JSJ99]:** Provision revised for consistency with [10 CFR 35.432\(d\)](#). This provision replaces (prior) 7.41.6.

10 CFR 35.432(d) references 35.2432 for the recordkeeping requirement. In Part 7, the recordkeeping requirement is incorporated into the section that mandates the requirement in the body of the rule.

NRC Compatibility D

CROSS REFERENCES:  
7.41.1 = 10 CFR 35.432

**Commented [JSJ100]:** Provision added to 7.41.6 for consistency with the 2018 amendments to [10 CFR 35.433](#).

7.41.6.1 (~10 CFR 35.433(a)) = NRC B Compatibility  
[Previously, this provision was a compatibility H&S]

7.41.6.3 (~10 CFR 35.433(c)) = NRC D Compatibility  
All remaining 10 CFR 35.433 provisions paralleled in 7.41.6 are NRC H&S Compatibility

NRC RATS 2018-1

CROSS REFERENCES:  
7.41.6.2 = 10 CFR 35.433(b)

**Commented [JSJ101]:** This provision is replaced by the added language in 7.41.6.2.

- 1603 (ii) Procedures for administrations requiring a written directive;  
1604 and
- 1605 (iii) Performing the calibration measurements of brachytherapy  
1606 sources as detailed in 7.41.1 through 7.41.5.
- 1607 **7.41.6.2** The individuals who are identified in 7.41.6.1 must:
- 1608 (1) Calculate the activity of each strontium-90 source that is used to determine  
1609 the treatment times for ophthalmic treatments. The decay must be based  
1610 on the activity determined under 7.41.1 through 7.41.5; and
- 1611 (2) Assist the licensee in developing, implementing, and maintaining written  
1612 procedures to provide high confidence that the administration is in  
1613 accordance with the written directive. These procedures must include the  
1614 frequencies that the individual meeting the requirements in 7.41.6.1 will  
1615 observe treatments, review the treatment methodology, calculate treatment  
1616 time for the prescribed dose, and review records to verify that the  
1617 administrations were in accordance with the written directives.
- 1618 **7.41.6.3** Licensees must retain a record of the activity of each strontium-90 source  
1619 as follows:
- 1620 (1) A licensee shall maintain a record of the activity of a strontium-90 source  
1621 required by 7.41.6 for the life of the source.
- 1622 (2) The record must include:
- 1623 (a) The date and initial activity of the source as determined under  
1624 7.41.1 through 7.41.5; and
- 1625 (b) For each decay calculation, the date and the source activity as  
1626 determined under 7.41.6.
- 1627
- 1628
- 1629
- 1630 ~~7.41.6~~ A licensee shall retain a record of each calibration on brachytherapy sources required by 7.41.1  
1631 for 3 years after the last use of the source. The record must include the date of the calibration; the  
1632 manufacturer's name, model number, and serial number for the source and the instruments used  
1633 to calibrate the source; the source output or activity; source positioning accuracy within  
1634 applicators; and the signature of the authorized medical physicist.
- 1635 ~~7.41.7~~ A licensee shall retain a record of decay calculations required by 7.41.5 for the life of the source.  
1636 The record must include the date and initial activity of the source as determined under 7.41, and  
1637 for each decay calculation, the date, the source activity and the signature of the authorized  
1638 medical physicist.
- 1639 **7.42 Use of Ssealed Ssources Ffor Mmanual Bbrachytherapy.**
- 1640 ~~7.42.1~~ A licensee shall use for manual brachytherapy only sealed sources: A licensee must use only  
1641 brachytherapy sources:
- 1642 7.42.1.1 Approved in the Sealed Source and Device Registry; ~~or for manual~~  
1643 brachytherapy use. The manual brachytherapy sources may be used for manual  
1644 brachytherapy uses that are not explicitly listed in the Sealed Source and Device  
1645 Registry, but must be used in accordance with the radiation safety conditions and  
1646 limitations described in the Sealed Source and Device Registry; or

**Commented [JSJ102]:** This provision is incorporated for consistency with [10 CFR 35.2433](#).

This provision replaces the current requirement found in (prior) 7.41.7 (below), although the Part 35 requirement does not explicitly require the medical physicist signature. It is implied however since a medical physicist is required to perform activity calculations.

NRC Compatibility D (35.2433).

**Commented [JSJ103]:** This provision is replaced by 7.41.5 (above) to better align with the format and wording of 10 CFR 35.

**Commented [JSJ104]:** This provision is replaced by 7.41.6.3 (above).

**Commented [JSJ105]:** This provision is updated for consistency with the 2018 amendments to [10 CFR 35.400](#).

NRC Compatibility C

- 1647 7.42.1.2 In research **to deliver therapeutic doses for medical use** in accordance with  
1648 an **effectiveactive** Investigational Device Exemption (IDE) application accepted by the  
1649 FDA provided the requirements of 7.14.1 are met.
- 1650 7.42.2 Authorized User Training For Use Of Sealed Sources For Manual Brachytherapy.  
1651 The licensee shall require an authorized user under 7.42 to meet the requirements of Appendix  
1652 7K.
- 1653 7.42.3 Authorized User Training For Use Of Strontium-90 Sealed Sources For Ophthalmic Uses.  
1654 The licensee shall require an authorized user of strontium-90 sealed sources for ophthalmic uses  
1655 under 7.42 to meet the requirements of Appendix 7L.
- 1656 **7.43 Safety Instruction.**
- 1657 **In addition to the requirements of Part 10 of these regulations:**
- 1658 7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel  
1659 caring for patients or human research subjects that are undergoing implant therapy and cannot  
1660 be released in accordance with 7.26.
- 1661 7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and  
1662 include:
- 1663 7.43.2.1 Size and appearance of the brachytherapy sources;
- 1664 7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;
- 1665 7.43.2.3 Patient or human research subject control;
- 1666 7.43.2.4 Visitor control, including both;
- 1667 (1) Routine visitation to hospitalized individuals in accordance with 4.14.1.1; and
- 1668 (2) Visitation authorized in accordance with 4.14.3; and
- 1669 7.43.2.5 Notification of the RSO, or his or her designee, and the authorized user if the  
1670 patient or the human research subject dies or has a medical emergency.
- 1671 **7.43.3** A licensee shall **keepretain** a record of individuals receiving **safety** instructions required by  
1672 7.43.1 and maintain such records for 3 years. The record **shallmust** include a list of the topics  
1673 covered, the date of instruction, the names(s) of the attendee(s), and the name(s) of the  
1674 individual(s) who **gaveprovided** the instruction.
- 1675 **7.44 Safety Precautions.**
- 1676 7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be  
1677 released in accordance with 7.26, a licensee shall:
- 1678 7.44.1.1 Not place the patient or the human research subject in the same room with a  
1679 patient who is not receiving radiation therapy;
- 1680 7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution:  
1681 Radioactive Material" sign and note on the door or on the patient's or human research

Commented [JSJ106]: 7.43.3 combines the requirements of [10 CFR 35.410](#) and [10 CFR 35.2310](#).  
NRC Compatibility D

- 1682 subject's chart where and how long visitors may stay in the patient's or human research  
1683 subject's room.
- 1684 7.44.2 A licensee shall have emergency response equipment available near each treatment room to  
1685 respond to a source that inadvertently becomes:
- 1686 7.44.2.1 Dislodged from the patient; or
- 1687 7.44.2.2 Lodged within the patient following removal of the source applicators.
- 1688 7.44.3 A licensee shall notify the RSO, or his or her designee, and ~~the~~ authorized user ~~immediately~~  
1689 ~~soon as possible~~ if the ~~hospitalized patient or human research subject dies or~~ has a medical  
1690 emergency ~~or dies and notify the Department as required by 7.39.~~
- 1691 **7.45 Brachytherapy Sources Inventory.**
- 1692 7.45.1 A licensee shall maintain accountability at all times for all brachytherapy sources in storage or  
1693 use.
- 1694 7.45.2 Promptly after removing brachytherapy sources from a patient, a licensee shall return  
1695 brachytherapy sources to a secure storage area and count or otherwise verify the number  
1696 returned to ensure that all sources taken from the storage area have been returned.
- 1697 7.45.3 A licensee shall maintain a record of brachytherapy source accountability for 3 years.
- 1698 7.45.3.1 For temporary implants, the record must include the number and activity of  
1699 sources:
- 1700 (1) Removed from storage, the time and date they were removed from storage, the  
1701 name of the individual who removed them from storage, and the location of use;  
1702 and
- 1703 (2) Not implanted, the time and date they were returned to storage, and the name of  
1704 the individual who returned them to storage.
- 1705 7.45.3.2 For permanent implants, the record must include the number and activity of  
1706 sources:
- 1707 (1) Removed from storage, the date they were removed from storage, and the name  
1708 of the individual who removed them from storage;
- 1709 (2) Returned to storage, the date they were returned to storage, and the name of the  
1710 individual who returned them to storage; and
- 1711 (3) Permanently implanted in the patient or human research subject.
- 1712 **7.46 ~~Surveys After Source Implant and Removal.~~ Surveys after source implant and removal.**
- 1713 7.46.1 Immediately after implanting sources in a patient or a human research subject, the licensee shall  
1714 perform a survey to locate and account for all sources that have not been implanted.
- 1715 7.46.2 Immediately after removing the last temporary implant source from a patient or a human research  
1716 subject, the licensee shall perform a radiation survey of the patient with a radiation detection  
1717 survey instrument to confirm that all sources have been removed. The licensee shall not release

Commented [JSJ107]: 7.39 is proposed for deletion due to overlap/redundancy with 7.22, so the reference to that section is deleted here.

1718 from confinement for medical care a patient treated by temporary implant until all sources have  
1719 been removed.

1720 ~~7.46.3~~ A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.46.1  
1721 and ~~7.6.27.46.2~~ for 3 years. Each record shall include the date and results of the survey, the  
1722 survey instrument used, and the name of the individual who made the survey.

1723 **7.47 Therapy-related Computer Systems. Therapy-related computer systems.**

1724 7.47.1 The licensee shall perform acceptance testing on the treatment planning system in accordance  
1725 with published protocols accepted by nationally recognized bodies.

1726 7.47.2 At a minimum, the acceptance testing required by 7.47.1 shall include, as applicable, verification  
1727 of:

1728 7.47.2.1 The source-specific input parameters required by the dose calculation algorithm;

1729 7.47.2.12 The accuracy of dose, dwell time, and treatment time calculations at  
1730 representative points;

1731 7.47.2.13 The accuracy of isodose plots and graphic displays; and

1732 7.47.2.14 The accuracy of the software used to determine radioactive source positions  
1733 from radiographic images.

1734 **Section H - Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma**  
1735 **Stereotactic Radiosurgery Units**

1736 **SPECIFIC REQUIREMENTS FOR PHOTON-EMITTING REMOTE AFTERLOADER UNITS,**  
1737 **TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS**

1738 **7.48 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma**  
1739 **Stereotactic Radiosurgery Unit. Use of a sealed source in a remote afterloader unit, teletherapy**  
1740 **unit, or gamma stereotactic radiosurgery unit.**

1741 ~~7.48.1~~ A licensee shall use sealed sources in remote afterloader units, teletherapy units, or gamma  
1742 stereotactic radiosurgery units for therapeutic medical uses:

1743 7.48.1.1 Approved in the Sealed Source and Device Registry; and

1744 7.48.1.2 In research in accordance with an active Investigational Device Exemption (IDE)  
1745 application accepted by the FDA provided the requirements of 7.14.1 are met.

1746 **7.48.1 A licensee must only use sealed sources:**

1747 7.48.1.1 Approved and as provided for in the Sealed Source and Device Registry in  
1748 photon emitting remote afterloader units, teletherapy units, or gamma  
1749 stereotactic radiosurgery units to deliver therapeutic doses for medical  
1750 uses; or

1751 7.48.1.2 In research involving photon-emitting remote afterloader units, teletherapy  
1752 units, or gamma stereotactic radiosurgery units in accordance with an  
1753 active Investigational Device Exemption (IDE) application accepted by the  
1754 U.S. Food and Drug Administration provided the requirements of 7.14.1 are  
1755 met.

Commented [JJ108]: Typo numbering correction.

Commented [JSJ109]: Due to changes in wording this provision is replaced in its entirety by new section 7.48.1.

Commented [JSJ110]: As a result of the 2018 amendment to [10 CFR 35.600](#), this provision is revised.

NRC RATS 2018-1  
NRC Compatibility C

CROSS REFERENCES:  
7.14.1 = 10 CFR 35.49(a)

- 1756  
1757 **7.48.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma**  
1758 **stereotactic radiosurgery units:**  
1759  
1760 **7.48.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic**  
1761 **dose for medical use. These devices may be used for therapeutic medical**  
1762 **treatments that are not explicitly provided for in the Sealed Source and**  
1763 **Device Registry, but must be used in accordance with radiation safety**  
1764 **conditions and limitations described in the Sealed Source and Device**  
1765 **Registry; or**  
1766  
1767 **7.48.2.2 In research in accordance with an active Investigational Device Exemption**  
1768 **(IDE) application accepted by the FDA provided the requirements of 7.14.1**  
1769 **are met.**
- 1770 ~~7.48.27.48.3~~ **Authorized User**-Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or  
1771 Gamma Stereotactic Radiosurgery Unit.
- 1772 The licensee shall require an authorized user under 7.48 to meet the requirements of Appendix  
1773 7M.
- 1774 **7.49 Installation, Maintenance, Adjustment, and Repair.**
- 1775 7.49.1 Only a person specifically licensed by the Department, another Agreement State, or the NRC  
1776 shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma  
1777 stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving  
1778 unit, or other electronic or mechanical component that could expose the source(s), reduce the  
1779 shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- 1780 7.49.2 Except for low dose-rate remote afterloader units, only a person specifically licensed by the  
1781 Department, another Agreement State, ~~a Licensing State,~~ or the NRC shall install, replace,  
1782 relocate, or remove a sealed source or source contained in other remote afterloader units,  
1783 teletherapy units, or gamma stereotactic radiosurgery units.
- 1784 7.49.3 For a low dose-rate remote afterloader unit, only a person specifically licensed by the  
1785 Department, another Agreement State, ~~a Licensing State,~~ or the NRC, or an authorized medical  
1786 physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.
- 1787 7.49.4 A licensee shall retain a record of the installation, maintenance, adjustment and repair done on  
1788 remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years.  
1789 The record shall include the date, description of the service, and name(s) of the individual(s) who  
1790 performed the work.
- 1791 **7.50 Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader**  
1792 **Unit. Surveys of patients and human research subjects treated with a remote afterloader.**
- 1793 7.50.1 Before releasing a patient or a human research subject from licensee control, a licensee shall  
1794 make a survey of the patient or the human research subject and the remote afterloader unit with a  
1795 portable radiation detection survey instrument to confirm that the source(s) has been removed  
1796 from the patient or human research subject and returned to the safe, shielded position.
- 1797 7.50.2 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.50.1  
1798 for 3 years. Each record shall include the date and results of the survey, the survey instrument  
1799 used, and the name of the individual who made the survey.

1800 **7.51 Safety Procedures and Instructions for a Remote Afterloader Unit, Teletherapy Unit, or**  
1801 **Gamma Stereotactic Radiosurgery Unit. Safety procedures and instructions for remote afterloader**  
1802 **units, teletherapy units, or gamma stereotactic radiosurgery units.**

Commented [JSJ111]: Reformatted to remove capitalization and for consistency with wording of 10 CFR 35.610.

1803 7.51.1 A licensee shall:

1804 7.51.1.1 Secure the unit, the console, the console keys, and the treatment room when not  
1805 in use or unattended;

1806 7.51.1.2 Permit only individuals approved by the authorized user, RSO, or authorized  
1807 medical physicist to be present in the treatment room during treatment with the source(s);  
1808 ~~if such presence is necessary and justified;~~

1809 7.51.1.3 Prevent dual operation of more than one radiation producing device in a  
1810 treatment room, if applicable; and

1811 7.51.1.4 Develop, implement, and maintain written procedures for responding to an  
1812 abnormal situation when the operator is unable to place the source(s) in the shielded  
1813 position, or remove the patient or human research subject from the radiation field with  
1814 controls from outside the treatment room. ~~This~~**These** procedures ~~s~~ must include:

1815 (1) Instructions for responding to equipment failures and the names of the individuals  
1816 responsible for implementing corrective actions;

1817 (2) The process for restricting access to and posting of the treatment area to  
1818 minimize the risk of inadvertent exposure; and

1819 (3) The names and telephone numbers of the authorized users, the authorized  
1820 medical physicist, and the RSO to be contacted if the unit or console operates  
1821 abnormally.

1822 7.51.2 A copy of the procedures required by 7.51.1.4 ~~shall~~**must** be physically located at the unit console.

1823 ~~7.51.3 A licensee shall conspicuously post instructions at the unit console to inform the operator of the~~  
1824 ~~names and telephone numbers of the authorized users, the authorized medical physicist, and the~~  
1825 ~~RSO to be contacted if the unit or console operates abnormally. A licensee shall post~~  
1826 ~~instructions at the unit console to inform the operator of:~~

Commented [JSJ112]: Provision revised to fit the format of 10 CFR 35.610(c).

1827 7.51.3.1 The location of the procedures required by 7.51.1.4; and

1828 7.51.3.2 The names and telephone numbers of the authorized users, the authorized  
1829 medical physicist, and the Radiation Safety Officer to be contacted if the  
1830 unit or console operates abnormally.

1831 **7.51.4 Operational and safety training.**

Commented [JSJ113]: This sub-section heading added to conform the formatting of the CFR to the Part 7 structure.

1832 **7.51.4.1**  
1833 **Prior to the first use for patient treatment of a new unit or an existing unit with a**  
1834 **manufacturer upgrade that affects the operation and safety of the unit, a licensee**  
1835 **shall ensure that vendor operational and safety training is provided to all**  
1836 **individuals who will operate the unit. The vendor operational and safety training**  
1837 **must be provided by the device manufacturer or by an individual certified by the**  
1838 **device manufacturer to provide the operational and safety training.**

Commented [JSJ114]: This is a new provision added for consistency with the 2018 amendments to 10 CFR 35.610(d). This specifies that training must be provided by the vendor or individual certified by the device manufacturer. See NRC FAQ #51, #52 for further information.

NRC RATS 2018-1  
NRC Compatibility H&S (for all but 35.610(f) / 7.51.6, which is compatibility D)

- 1839 7.51.4.2 A licensee shall provide **operational and safety** instructions, initially and at least  
1840 annually, to all individuals who operate **the unit at the facility**, as appropriate to the  
1841 individual's assigned duties.,~~in: The instructions shall include instruction in:~~
- 1842 ~~7.51.4.1(1)~~ The procedures identified in 7.51.1.4; and
- 1843 ~~7.51.4.2(2)~~ The operating procedures for the unit.
- 1844 7.51.5 A licensee shall ensure that operators, authorized medical physicists, and authorized users  
1845 participate in drills of the emergency procedures, initially and at least annually.
- 1846 ~~7.51.6~~ A licensee shall ~~keepretain~~ a record of individuals receiving instruction required by 7.51.4 **in**  
1847 **accordance with the following:**~~and maintain such records for 3 years. The record shall include~~  
1848 ~~a list of the topics covered, the date of instruction, the names(s) of the attendee(s), and the~~  
1849 ~~name(s) of the individual(s) who gave the instruction.~~
- 1850 **(1) A licensee shall maintain a record of the operational and safety instructions**  
1851 **required by 7.51.4 for 3 years. The record must include a list of the topics covered,**  
1852 **the date of instruction, the name(s) of the attendee(s), and the name(s) of the**  
1853 **individual(s) who provided the instruction.**
- 1854 ~~7.51.7~~ **A licensee shall retain a copy of the procedures required by 7.51.1.4 and 7.51.4.2(2) until**  
1855 **the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma**  
1856 **stereotactic radiosurgery unit.**
- 1857 ~~7.52~~ **Doors, Interlocks, and Warning Systems. Safety precautions for remote afterloader units,**  
1858 **teletherapy units, and gamma stereotactic radiosurgery units.**
- 1859 7.52.1 A licensee shall control access to the treatment room by a door at each entrance.
- 1860 7.52.2 A licensee shall equip each entrance to the treatment room with an electrical interlock system that  
1861 ~~shall~~**will:**
- 1862 7.52.2.1 Prevent the operator from initiating the treatment cycle unless each treatment  
1863 room entrance door is closed;
- 1864 7.52.2.2 Cause the source(s) to be shielded ~~promptly~~ when an entrance door is opened;  
1865 and
- 1866 7.52.2.3 Prevent the source(s) from being exposed following an interlock interruption until  
1867 all treatment room entrance doors are closed and the source(s)' on/off control is  
1868 reset at the console.
- 1869 7.52.3 A licensee shall require any individual entering the treatment room to assure, through the use of  
1870 appropriate radiation monitors, that radiation levels have returned to ambient levels.
- 1871 7.52.4 Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment  
1872 room with viewing and intercom systems to permit continuous observation of the patient or the  
1873 human research subject from the treatment console during irradiation.
- 1874 7.52.5 For licensed activities where sources are placed within the patient's or human research subject's  
1875 body, a licensee shall only conduct treatments which allow for expeditious removal of a  
1876 decoupled or jammed source.
- 1877 7.52.6 In addition to the requirements specified in 7.52.1 through 7.52.5, a licensee shall:

**Commented [JSJ115]:** This provision has been reformatted to better align with language in [10 CFR 35.610\(f\)](#) and [10 CFR 35.2310](#).

The proposed language does not significantly change the current requirements.

NRC RATS 2018-1  
NRC Compatibility D (for 35.610(f) and 35.2310)

**Commented [JSJ116]:** Added for consistency with [10 CFR 35.610\(g\)](#) and [10 CFR 35.2610](#). The proposed provision combines the requirements of these two provisions.

Provision (g) of 10 CFR 35.610 was revised as a result of the 2018 amendments.

NRC RATS 2018-1  
NRC Compatibility H&S

**Commented [JSJ117]:** Title of this section revised for consistency with [10 CFR 35.615](#).

Provisions in 7.52 have been formatted for alignment which is not indicated by strikeout/ revised text.

1878	7.52.6.1	For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:
1879		
1880	(1)	An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and
1881		
1882		
1883		
1884	(2)	An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
1885		
1886		
1887		
1888		
1889	7.52.6.2	For high dose-rate remote afterloader units, require:
1890	(1)	An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
1891		
1892	(2)	An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
1893		
1894		
1895		
1896	7.52.6.3	For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
1897		
1898		
1899	7.52.6.4	If a patient or research subject suffers a medical emergency during radiation therapy:
1900		
1901	(1)	Cease the therapy immediately;
1902	(2)	Remove the source(s); and
1903	(3)	Provide appropriate care to the patient or research subject.
1904	7.52.6.5	If the patient expires during treatment, remove the source(s) before further actions are taken.
1905		
1906	7.52.6.6	Notify the RSO, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.
1907		
1908		
1909	7.52.7	A licensee shall have <b>applicable</b> emergency response equipment available near each treatment room; to respond to a <del>situation in which a source inadvertently</del> <b>source</b> :
1910		
1911	7.52.7.1	<del>Remains</del> <b>Remaining</b> in the unshielded position; or
1912	7.52.7.2	Lodges <del>d</del> within the patient following completion of the treatment.
1913	7.53	<b>Dosimetry Eequipment.</b>

- 1914 7.53.1 Except for low dose-rate remote afterloader sources where the source output or activity is  
1915 determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for  
1916 use. To satisfy this requirement, one of the following two conditions ~~shall~~**must** be met:
- 1917 7.53.1.1 The system ~~shall~~**must** have been calibrated using a system or source traceable  
1918 to the National Institute of Standards and Technology and published protocols  
1919 accepted by nationally recognized bodies, or by a calibration laboratory  
1920 accredited by the American Association of Physicists in Medicine. The calibration  
1921 shall have been performed within the previous 2 years and after any servicing  
1922 that may have affected system calibration; or
- 1923 7.53.1.2 The system ~~shall~~**must** have been calibrated within the previous 4 years; 18 to 30  
1924 months after that calibration, the system shall have been intercompared with  
1925 another dosimetry system that was calibrated within the past 24 months by the  
1926 National Institute of Standards and Technology or by a calibration laboratory  
1927 accredited by the American Association of Physicists in Medicine. The results of  
1928 the intercomparison must have indicated that the calibration factor of the  
1929 licensee's system had not changed by more than 2 percent. The licensee shall  
1930 not use the intercomparison result to change the calibration factor. When  
1931 intercomparing dosimetry systems to be used for calibrating sealed sources for  
1932 therapeutic units, the licensee shall use a comparable unit with beam attenuators  
1933 or collimators, as applicable, and sources of the same radionuclide as the source  
1934 used at the licensee's facility.
- 1935 7.53.2 The licensee shall have available for use a dosimetry system for spot-check output  
1936 measurements. To meet this requirement, the system may be compared with a system that has  
1937 been calibrated in accordance with 7.53.1. This comparison shall have been performed within the  
1938 previous year and after each servicing that may have affected system calibration. The spot-check  
1939 system may be the same system used to meet the requirement in 7.53.1.
- 1940 7.53.3 The licensee shall ~~maintain~~**retain** a record of each calibration, intercomparison, and comparison  
1941 for the duration of the license. For each calibration, intercomparison, or comparison, the record  
1942 shall include:
- 1943 7.53.3.1 The date;
- 1944 7.53.3.2 The manufacturer's name, the model numbers and serial numbers of the  
1945 instruments that were calibrated, intercompared, or compared as required by  
1946 7.53.1 and 7.53.2;
- 1947 7.53.3.3 The correction factor that were determined from the calibration or comparison or  
1948 the apparent correction factor that was determined from an intercomparison;
- 1949 7.53.3.4 The names of the individuals who performed the calibration, intercomparison, or  
1950 comparison.
- 1951 **7.54 Full Calibration Measurements on Teletherapy Units.**
- 1952 7.54.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration  
1953 measurements on each teletherapy unit:
- 1954 7.54.1.1 Before the first medical use of the unit;
- 1955 7.54.1.2 Before medical use under the following conditions:

1956 1957 1958	(1)	Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
1959 1960	(2)	Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
1961 1962 1963	(3)	Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
1964	7.54.1.3	At intervals not exceeding 1 year.
1965	7.54.2	To satisfy the requirement of 7.54.1, full calibration measurements shall include determination of:
1966 1967	7.54.2.1	The output within +/- 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
1968 1969	7.54.2.2	The coincidence of the radiation field and the field indicated by the light beam localizing device;
1970 1971	7.54.2.3	The uniformity of the radiation field and its dependence on the orientation of the useful beam;
1972	7.54.2.4	Timer accuracy, constancy, and linearity;
1973	7.54.2.5	"On off" error; and
1974	7.54.2.6	The accuracy of all distance measuring and localization devices in medical use.
1975 1976 1977	7.54.3	A licensee shall use the dosimetry system described in 7.53 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 7.54.2.1 may then be made using a dosimetry system that indicates relative dose rates.
1978 1979	7.54.4	A licensee shall make full calibration measurements required by 7.54.1 in accordance with published protocols accepted by nationally recognized bodies.
1980 1981 1982	7.54.5	A licensee shall correct mathematically the outputs determined in 7.54.2.1 for physical decay for intervals not exceeding 1 month for cobalt 60, 6 months for cesium 137, or at intervals consistent with 1 percent decay for all other nuclides.
1983 1984	7.54.6	Full calibration measurements required by 7.54.1 and physical decay corrections required by 7.54.5 shall be performed by the authorized medical physicist.
1985 1986	7.54.7	A licensee shall maintain a record of each calibration for the duration of the license. The record shall include:
1987	7.54.7.1	The date of the calibration;
1988 1989	7.54.7.2	The manufacturer's name, model number, and serial number for the teletherapy unit, source(s), and instruments used to calibrate the teletherapy unit;
1990	7.54.7.3	The results and assessments of the full calibrations; and

1991 1992	7.54.7.4	The signature of the authorized medical physicist who performed the full calibration.
1993	<b>7.55</b>	<b>Full Calibration Measurements on Remote Afterloader Units.</b>
1994 1995	7.55.1	A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
1996	7.55.1.1	Before the first medical use of the unit;
1997	7.55.1.2	Before medical use under the following conditions:
1998 1999	(1)	Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
2000 2001	(2)	Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
2002 2003 2004	7.55.1.3	At intervals not exceeding one (1) calendar quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
2005	7.55.1.4	At intervals not exceeding 1 year for low dose-rate remote afterloader units.
2006 2007	7.55.2	To satisfy the requirement of 7.55.1, full calibration measurements must include, as applicable, determination of:
2008	7.55.2.1	The output within +/- 5 percent;
2009	7.55.2.2	Source positioning accuracy to within +/- 1 millimeter;
2010	7.55.2.3	Source retraction with backup battery upon power failure;
2011	7.55.2.4	Length of the source transfer tubes;
2012	7.55.2.5	Timer accuracy and linearity over the typical range of use;
2013	7.55.2.6	Length of the applicators; and
2014 2015	7.55.2.7	Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
2016 2017 2018	7.55.3	In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 7.55.2, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.
2019	7.55.4	A licensee shall use the dosimetry system described in 7.53 to measure the output.
2020 2021	7.55.5	A licensee shall make full calibration measurements required by 7.55.1 of this section in accordance with published protocols accepted by nationally recognized bodies.
2022 2023	7.55.6	For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 7.55.1 through 7.55.5.

2024 2025	7.55.7	A licensee shall mathematically correct the outputs determined in 7.55.2.1 for physical decay at intervals consistent with 1 percent physical decay.
2026 2027	7.55.8	Full calibration measurements required by 7.55.1 and physical decay corrections required by 7.55.7 must be performed by the authorized medical physicist.
2028 2029	7.55.9	A licensee shall retain a record of each calibration for the duration of the license. The record shall include:
2030	7.55.9.1	The date of the calibration;
2031 2032	7.55.9.2	The manufacturer's name, model number, and serial number for the remote afterloader unit, source(s), and instruments used to calibrate the remote afterloader unit;
2033	7.55.9.3	The results and assessments of the full calibrations;
2034 2035	7.55.9.4	The results of the autoradiograph required for low dose-rate remote afterloader units; and
2036 2037	7.55.9.5	The signature of the authorized medical physicist who performed the full calibration.
2038	<b>7.56</b>	<b>Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.</b>
2039 2040	7.56.1	A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
2041	7.56.1.1	Before the first medical use of the unit;
2042	7.56.1.2	Before medical use under the following conditions:
2043 2044 2045	(1)	Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
2046 2047	(2)	Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
2048 2049 2050	(3)	Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
2051 2052 2053	7.56.1.3	At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.
2054	7.56.2	To satisfy the requirement of 7.56.1, full calibration measurements must include determination of:
2055	7.56.2.1	The output within +/-3 percent;
2056	7.56.2.2	Relative helmet factors;
2057	7.56.2.3	Isocenter coincidence;
2058	7.56.2.4	Timer accuracy and linearity over the range of use;

2059	7.56.2.5	On-off error;
2060	7.56.2.6	Trunnion centricity;
2061 2062	7.56.2.7	Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
2063	7.56.2.8	Helmet microswitches;
2064	7.56.2.9	Emergency timing circuits; and
2065	7.56.2.10	Stereotactic frames and localizing devices (trunnions).
2066 2067 2068	7.56.3	A licensee shall use the dosimetry system described in 7.53 to measure the output for one set of exposure conditions. The remaining radiation measurements required in 7.56.2.1 may be made using a dosimetry system that indicates relative dose rates.
2069 2070	7.56.4	A licensee shall make full calibration measurements required by 7.56.1 in accordance with published protocols accepted by nationally recognized bodies.
2071 2072 2073	7.56.5	A licensee shall mathematically correct the outputs determined in 7.56.2.1 at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.
2074 2075	7.56.6	Full calibration measurements required by 7.56.1 and physical decay corrections required by 7.56.5 must be performed by the authorized medical physicist.
2076 2077	7.56.7	A licensee shall retain a record of each calibration for the duration of the license. The record shall include:
2078	7.56.7.1	The date of the calibration;
2079 2080 2081	7.56.7.2	The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source(s), and instruments used to calibrate the gamma stereotactic radiosurgery unit;
2082	7.56.7.3	The results and assessments of the full calibrations;
2083 2084	7.56.7.4	The signature of the authorized medical physicist who performed the full calibration.
2085	<b>7.57</b>	<b>Radiation Surveys of Therapeutic Treatment Units.</b>
2086 2087 2088 2089 2090 2091	7.57.1	A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 $\mu$ Sv (0.1 mrem) per hour to 500 $\mu$ Sv (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 $\mu$ Sv (1 mrem) per hour to 10 mSv (1 rem) per hour. The instruments shall be operable and calibrated in accordance with 7.17.
2092 2093 2094 2095	7.57.2	In addition to the survey requirements in Part 4 of these regulations, a person licensed pursuant to Part 7 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

2096 7.57.3 The licensee shall make the survey required by 7.57.2 at installation of a new source and  
2097 following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or  
2098 mechanical component that could expose the source, reduce the shielding around the source(s),  
2099 or compromise the radiation safety of the unit or the source(s).

2100 **Records of surveys of therapeutic treatment units**

2101 7.57.4 A licensee shall retain a record of the radiation surveys required by 7.57.2 for the duration of use  
2102 of the unit. The record must include:

2103 7.57.4.1 The date of the measurements;

2104 7.57.4.2 The manufacturer's name, model number and serial number of the treatment  
2105 unit, source, and instrument used to measure radiation levels;

2106 7.57.4.3 Each dose rate measured around the source while the unit is in the off position  
2107 and the average of all measurements; and

2108 ~~7.57.4.4~~ The signature of the ~~authorized medical physicist~~ individual who performed the  
2109 test.

Commented [JSJ118]: 35.2652(b)(4)

2110 **7.58 Periodic sSpot Cchecks for Tteletherapy Uunits.**

2111 7.58.1 A licensee authorized to use teletherapy units for medical use shall perform output spot checks  
2112 on each teletherapy unit once in each calendar month, including determination of:

2113 7.58.1.1 Timer accuracy and timer linearity over the range of use;

2114 7.58.1.2 "On off" error;

2115 7.58.1.3 The coincidence of the radiation field and the field indicated by the light beam  
2116 localizing device;

2117 7.58.1.4 The accuracy of all distance measuring and localization devices used for medical  
2118 use;

2119 7.58.1.5 The output for one typical set of operating conditions measured with the  
2120 dosimetry system described in 7.53; and

2121 7.58.1.6 The difference between the measurement made in 7.58.1.5 and the anticipated  
2122 output, expressed as a percentage of the anticipated output (i.e., the value obtained at  
2123 last full calibration corrected mathematically for physical decay).

2124 7.58.2 A licensee shall perform spot checks required by 7.58.1 in accordance with procedures  
2125 established by the authorized medical physicist. That individual need not actually perform the  
2126 output spot-check measurements.

2127 7.58.3 A licensee shall have the authorized medical physicist review the results of each spot check  
2128 within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the  
2129 results of each spot check.

2130 7.58.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks  
2131 of each teletherapy facility once in each calendar month and after each source installation to  
2132 assure proper operation of:

2133	7.58.4.1	Electrical interlocks at each teletherapy room entrance;
2134	7.58.4.2	Electrical or mechanical stops installed for the purpose of limiting use of the
2135		primary beam of radiation restriction of source housing angulation or elevation, carriage
2136		or stand travel, and operation of the beam "on off" mechanism;
2137	7.58.4.3	Source exposure indicator lights on the teletherapy unit, on the control console,
2138		and in the facility;
2139	7.58.4.4	Viewing and intercom systems;
2140	7.58.4.5	Treatment room doors from inside and outside the treatment room; and
2141	7.58.4.6	Electrically assisted treatment room doors with the teletherapy unit electrical
2142		power turned "off".
2143	7.58.5	If the results of the checks required in 7.58.4 indicate the malfunction of any system, a licensee
2144		shall lock the control console in the "off" position and not use the unit except as may be
2145		necessary to repair, replace, or check the malfunctioning system.
2146	7.58.6	A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.5 for 3 years.
2147		The record shall include:
2148	7.58.6.1	The date of the spot check;
2149	7.58.6.2	The manufacturer's name, model number, and serial number for the teletherapy
2150		unit, source, and instrument used to measure the output of the teletherapy unit;
2151	7.58.6.3	An assessment of timer linearity and constancy;
2152	7.58.6.4	The calculated "on off" error;
2153	7.58.6.5	A determination of the coincidence of the radiation field and the field indicated by
2154		the light beam localizing device
2155	7.58.6.6	The determined accuracy of each distance measuring or localization device;
2156	7.58.6.7	The difference between the anticipated output and the measured output;
2157	7.58.6.8	Notations indicating the operability of each entrance door electrical interlock,
2158		each electrical or mechanical stop, each source exposure indicator light, and the viewing
2159		and intercom system and doors; and
2160	7.58.6.9	The name of the individual who performed the periodic spot check and the
2161		signature of the authorized medical physicist who reviewed the record of the spot check.
2162	<b>7.59</b>	<b>Periodic Sspot Cchecks for Rremote Aafterloader Uunits.</b>
2163	7.59.1	A licensee authorized to use remote afterloader units for medical use shall perform spot checks of
2164		each remote afterloader facility and on each unit:
2165	7.59.1.1	At the beginning of each day of use of a high dose-rate, medium dose-rate or
2166		pulsed dose-rate remote afterloader unit;
2167	7.59.1.2	Prior to each patient treatment with a low dose-rate remote afterloader unit; and

2168	7.59.1.3	After each source installation.
2169	7.59.2	The licensee shall have the authorized medical physicist establish written procedures for performing the spot checks required in 7.59.1. The authorized medical physicist need not actually perform the spot-check measurements.
2170		
2171		
2172	7.59.3	A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.
2173		
2174		
2175	7.59.4	To satisfy the requirements of 7.59.1, spot checks must, at a minimum, assure proper operation of:
2176		
2177	7.59.4.1	Emergency response equipment;
2178	7.59.4.2	Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
2179		
2180	7.59.4.3	Radiation monitors used to indicate the source position;
2181	7.59.4.4	Electrical interlocks at each remote afterloader unit room entrance;
2182	7.59.4.5	Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
2183		
2184	7.59.4.6	Timer accuracy;
2185	7.59.4.7	Clock (date and time) in the unit's computer; and
2186	7.59.4.8	Decayed source(s) activity in the unit's computer.
2187	7.59.5	If the results of the checks required in 7.59.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
2188		
2189		
2190	7.59.6	A licensee shall retain a record of each check required by 7.59.4 for 3 years. The record must include, as applicable:
2191		
2192	7.59.6.1	The date of the spot check;
2193	7.59.6.2	The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
2194		
2195	7.59.6.3	An assessment of timer accuracy;
2196	7.59.6.4	Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
2197		
2198		
2199	7.59.6.5	The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.
2200		
2201	<b>7.60</b>	<b>Additional Technical Requirements for Mobile Remote Afterloader Units.</b>
2202	7.60.1	A licensee providing mobile remote afterloader service shall:

Commented [JSJ119]: Select provisions in 7.60 have been formatted for alignment purposes which are not easily reflected by text changes/redlines.

2203 2204	7.60.1.1	Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
2205	7.60.1.2	Account for all sources before departure from a client's address of use.
2206 2207 2208	7.60.2	In addition to the periodic spot checks required by 7.59, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:
2209	7.60.2.1	Electrical interlocks on treatment area access points;
2210 2211	7.60.2.2	Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
2212	7.60.2.3	Viewing and intercom systems;
2213	7.60.2.4	Applicators, source transfer tubes, and transfer tube-applicator interfaces;
2214	7.60.2.5	Radiation monitors used to indicate room exposures;
2215	7.60.2.6	Source positioning (accuracy); and
2216 2217	7.60.2.7	Radiation monitors used to indicate whether the source has returned to a safe shielded position.
2218 2219 2220	7.60.3	In addition to the requirements for checks in 7.60.2, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
2221 2222 2223	7.60.4	If the results of the checks required in 7.60.2 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
2224 2225	7.60.5	A licensee shall retain a record of each check required by 7.60.2 for 3 years. The record must include:
2226	7.60.5.1	The date of the check;
2227 2228	7.60.5.2	The manufacturer's name, model number, and serial number of the remote afterloader unit;
2229	7.60.5.3	Notations accounting for all sources before the licensee departs from a facility;
2230 2231 2232 2233	7.60.5.4	Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
2234	7.60.5.5	The signature of the individual who performed the check.
2235	<b>7.61</b>	<b>Periodic Sspot Cchecks for Ggamma Sstereotactic Rradiosurgery Uunits.</b>
2236 2237	7.61.1	A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

2238	7.61.1.1	Monthly;
2239	7.61.1.2	<del>At the beginning of each day of use</del> Before the first use on a given day; and
2240	7.61.1.3	After each source installation.
2241	<b>7.61.2</b>	<del>The licensee shall have the authorized medical physicist:</del> <b>A licensee shall:</b>
2242	7.61.2.1	<del>Establish written procedures for performing the spot checks required in 7.61.1;</del> <del>and</del> <b>Perform the measurements required by 7.61.1 in accordance with</b> <del>written procedures established by the authorized medical physicist. That</del> <del>individual need not actually perform the spot check measurements.</del> <b>written procedures established by the authorized medical physicist. That</b> <b>individual need not actually perform the spot check measurements.</b>
2246	<b>7.61.2.2</b>	<del>Have the authorized medical physicist R</del> <b>review the results of each spot-check</b> <del>required by 7.61.1.1 within 15 days. of the check. The authorized medical</del> <del>physicist need not actually perform the spot-check measurements. The</del> <del>authorized medical physicist shall notify the licensee as soon as possible, in</del> <del>writing, of the results of the</del> <del>each</del> spot-check.
2251	7.61.3	To satisfy the requirements of 7.61.1.1-4 spot checks must, at a minimum:
2252	7.61.3.1	Assure proper operation of:
2253	(1)	Treatment table retraction mechanism, using backup battery power or hydraulic
2254		backups with the unit off;
2255	(2)	Helmet microswitches;
2256	(3)	Emergency timing circuits; and
2257	(4)	Stereotactic frames and localizing devices (trunnions).
2258	7.61.3.2	Determine:
2259	(1)	The output for one typical set of operating conditions measured with the
2260		dosimetry system described in 7.53.2;
2261	(2)	The difference between the measurement made in 7.61.3.2(1) and the
2262		anticipated output, expressed as a percentage of the anticipated output (i.e., the
2263		value obtained at last full calibration corrected mathematically for physical
2264		decay);
2265	(3)	Source output against computer calculation;
2266	(4)	Timer accuracy and linearity over the range of use;
2267	(5)	On-off error; and
2268	(6)	Trunnion centricity.
2269	7.61.4	To satisfy the requirements of 7.61.1.2 and 7.61.1.3, spot-checks must assure proper operation
2270		of:
2271	7.61.4.1	Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

Commented [JSJ120]: Section 7.61.2 revised for consistency with [10 CFR 35.645](#).

Commented [JSJ121]: The language regarding the AMP not being required to perform the spot check is incorporated into 7.61.2.1 (above).

2272	7.61.4.2	Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
2273		
2274	7.61.4.3	Viewing and intercom systems;
2275	7.61.4.4	Timer termination;
2276	7.61.4.5	Radiation monitors used to indicate room exposures; and
2277	7.61.4.6	Emergency off buttons.
2278	7.61.5	A licensee shall arrange for prompt repair of any system identified in 7.61.3 that is not operating properly.
2279		
2280	7.61.6	If the results of the checks required in 7.61.4 indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
2281		
2282		
2283	7.61.7	A licensee shall retain a record of each check required by 7.61.3 and 7.61.4 and a copy of the procedures required by 7.61.2 for 3 years. The record must include:
2284		
2285	7.61.7.1	The date of the spot check;
2286	7.61.7.2	The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
2287		
2288		
2289	7.61.7.3	An assessment of timer linearity and accuracy;
2290	7.61.7.4	The calculated on-off error;
2291	7.61.7.5	A determination of trunnion centricity;
2292	7.61.7.6	The difference between the anticipated output and the measured output;
2293	7.61.7.7	An assessment of source output against computer calculations;
2294	7.61.7.8	Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
2295		
2296		
2297		
2298		
2299	7.61.7.9	The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.
2300		
2301		
2302	<b>7.62 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.</b>	
2303		
2304	7.62.1	A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Part 7 if:
2305		
2306	7.62.1.1	The applicant or licensee has submitted the information required by 7.3.4.2, 7.3.4.3, and 7.3.4.4; and
2307		

Commented [JSJ122]: This section has been formatted/aligned for appearance. Alignment corrections may not appear as strike out/changed text.

2308 7.62.1.2 The applicant or licensee has received written approval from the **department**, an  
2309 Agreement State, ~~Licensing State~~, or NRC in a license and uses the material in  
2310 accordance with the regulations and specific conditions that the **department**, Agreement  
2311 State, ~~Licensing State~~, or NRC considers necessary for the medical use of the material.

2312 **7.63 Five Year Inspection. Full-inspection servicing for teletherapy and gamma stereotactic**  
2313 **radiosurgery units**

**Commented [JJ123]:** Updated for consistency with changes to [10 CFR 35.655\(a\)](#).

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2314 7.63.1 ~~A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully~~  
2315 ~~inspected and serviced during source replacement or at intervals not to exceed 5 years,~~  
2316 ~~whichever comes first, to assure proper functioning of the source exposure mechanism. A~~  
2317 ~~licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully~~  
2318 ~~inspected and serviced during each source replacement to assure proper functioning of~~  
2319 ~~the source exposure mechanism and other safety components. The interval between each~~  
2320 ~~full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not~~  
2321 ~~exceed 7 years for each gamma stereotactic radiosurgery unit.~~

2322 7.63.2 This inspection and servicing shall only be performed by persons specifically licensed to do so by  
2323 the ~~D~~department, another Agreement State, ~~a~~ ~~Licensing State~~, or the NRC.

2324 **Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.**

2325 ~~7.63.3 A licensee shall keep maintain a record of the full-inspection and servicing for teletherapy and~~  
2326 ~~gamma stereotactic radiosurgery units required by 7.63 for the duration of the licensee use of~~  
2327 ~~the unit. The record shall contain:~~

**Commented [JSJ124]:** Updated for consistency with [10 CFR 35.2655](#).

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CROSS REFERENCE:  
7.63 = 10 CFR 35.655

2328 **7.63.4 The record required by 7.63.3 must contain:**

2329 7.63.~~3~~.4.1 The inspector's radioactive materials license number;

2330 7.63.~~3~~.4.2 The date of inspection;

2331 7.63.~~3~~.4.3 The manufacturer's name and model number and serial number of both the  
2332 treatment unit and source;

2333 ~~7.63.3.4 A list of components inspected and serviced;~~

**Commented [JSJ125]:** Prior provisions 7.63.3.4 and 7.63.3.5 are replaced by an equivalent requirement in 7.63.4.4.

2334 7.63.~~3~~.~~5~~.4.4 A list of components inspected and serviced, and the type of service; **and**

2335 ~~7.63.3.6 A list of components replaced; and~~

**Commented [JSJ126]:** There is no equivalent provision in 10 CFR 35.

2336 ~~7.63.3.7 The signature of the inspector.~~

**Commented [JSJ127]:** Prior provision 7.63.3.7 is replaced by an equivalent requirement in 7.63.4.5.

2337 **7.63.4.5 The signature of the inspector.**

2338 **7.64 Therapy-related computer systems.**

**Commented [JSJ128]:** Provision added for consistency with [10 CFR 35.657](#).

2339 **7.64.1 The licensee shall perform acceptance testing on the treatment planning system in**  
2340 **accordance with published protocols accepted by nationally recognized bodies.**

With the exception of 7.64.2.5, these requirements are equivalent to those found in the current 7.47.

2341 **7.64.2 At a minimum, the acceptance testing required by 7.64.1 shall include, as applicable,**  
2342 **verification of:**

2343 **7.64.2.1 The source-specific input parameters required by the dose calculation**  
2344 **algorithm;**



**PART 7, APPENDIX 7A: TRAINING FOR RADIATION SAFETY OFFICER (RSO) AND ASSOCIATE RADIATION SAFETY OFFICER (ARSO)**

**Except as provided in Appendix 7P, the licensee shall require the individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer (ARSO) as provided in 7.7 to be an individual who:**

**7A1 Is certified by a specialty board whose certification process has been recognized by NRC or an Agreement State and who meets the requirements in paragraphs 7A4 and 7A5 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. Is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in 7A4 of this Appendix. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:**

**To have its certification process recognized, a specialty board shall require all candidates for certification to:**

**7A1.1**

- (1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

and

- (2) Have 5 or more years of professional experience in health physics (**graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics;** provided:

(a) ~~At least 3 years are in applied health physics;~~

and

(b) ~~Graduate training may substitute for no more than 2 years of the required 5 years of experience;~~

and

- (3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry;

or

**7A1.2**

- (1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

Commented [JJ136]: For final publication, insert a page break to ensure each new appendices begins at the top of the page.

Commented [JJ137]: Introductory text modified, consistent with 2018 revision to [10 CFR 35.50](#).

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Commented [JJ138]: Wording and format updated for consistency and alignment of 10 CFR 35.50(a).

There is no change to the requirement. Only the formatting is changed to better align with CFR.

- 2402 and
- 2403 (2) Have 2 years of full-time practical training and/or supervised experience in  
2404 medical physics: ~~that is:~~
- 2405 (a) Under the supervision of a medical physicist who is certified in medical  
2406 physics by a specialty board recognized by an Agreement State or NRC;
- 2407 or
- 2408 (b) In clinical nuclear medicine facilities providing diagnostic ~~and/or~~ or  
2409 therapeutic services under the ~~general supervision direction~~ of  
2410 physicians who meet the requirements for Authorized Users in  
2411 ~~7A7~~Appendix 7P, Appendix 7E or Appendix 7F;
- 2412 and
- 2413 (3) Pass an examination administered by diplomates of the specialty board, that  
2414 assesses knowledge and competence in clinical diagnostic radiological or  
2415 nuclear medicine physics and in radiation safety.
- 2416 or
- 2417 **7A2** ~~Has satisfied the following criteria:~~
- 2418 7A2.1 Has completed a structured educational program consisting of **both**:
- 2419 (1) 200 hours of classroom and laboratory training in the following areas:
- 2420 (a) Radiation physics and instrumentation;
- 2421 (b) Radiation protection;
- 2422 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2423 (d) Radiation biology; and
- 2424 (e) Radiation dosimetry;
- 2425 and
- 2426 (2) ~~One~~ **One** year of full-time radiation safety experience, under the supervision of the  
2427 individual identified as ~~an~~ **the RSO or Alternate RSO**, on an **NRC or an**  
2428 Agreement State **license** or **NRC license** or permit issued by a NRC master  
2429 material licensee that authorizes similar type(s) of use(s) of radioactive material,  
2430 ~~involving the following: An Associate Radiation Safety Officer may provide~~  
2431 **supervision for those areas for which the Associate Radiation Safety**  
2432 **Officer is authorized on a NRC or an Agreement State license or permit**  
2433 **issued by a NRC master material licensee. The full-time radiation safety**  
2434 **experience must involve the following:**
- 2435 (a) Shipping, receiving, and performing related radiation surveys;
- 2436 (b) Using and performing checks for proper operation of ~~dose~~  
2437 **calibrators instruments used to determine the activity of dosages,**

**Commented [JSJ139]:** This provision is revised for consistency with the 2018 amendments to [10 CFR 35.50\(b\)\(1\)\(ii\)](#).

With the introduction of the concept of an Associate RSO (as defined in Section 7.2) arising from the 2018 amendments to Part 35, the revised language in this requirement clarifies that for an individual who is in the process of becoming a RSO for a medical licensee, the experience gained while under the supervision of an Associate RSO is acceptable for those areas for which the Associate RSO is authorized on the license.

- 2438 survey meters, and, ~~if appropriate,~~ instruments used to measure  
2439 radionuclides;
- 2440 (c) Securing and controlling radioactive material;
- 2441 (d) Using administrative controls to avoid mistakes in the administration of  
2442 radioactive material;
- 2443 (e) Using procedures to prevent or minimize radioactive contamination and  
2444 using proper decontamination procedures;
- 2445 (f) Using emergency procedures to control radioactive material; and
- 2446 (g) Disposing of radioactive material;

2447 and

2448 **7A2.2 This individual must obtain a written attestation, signed by a preceptor RSO or**  
2449 **ARSO who has experience with the radiation safety aspects of similar types of use**  
2450 **of radioactive material for which the individual is seeking approval as a RSO or an**  
2451 **ARSO. The written attestation must state that the individual has satisfactorily**  
2452 **completed the requirements in 7A2.1 and 7A4 of Appendix 7A and is able to**  
2453 **independently fulfill the radiation safety related duties as a RSO or as an ARSO for**  
2454 **a medical use license;**

2455 or

2456 **7A3 Meets the following requirements:**

Commented [JJ140]: 35.50(c)

2457 7A3.1 Is a medical physicist who has been certified by a specialty board whose certification  
2458 process has been recognized by the NRC or an Agreement State under Appendix 7B,  
2459 **Section 7B1, and** has experience ~~in~~**with the** radiation safety ~~aspects for~~ **aspects** of similar types  
2460 of use of radioactive material for which the licensee ~~is seeking~~**seeks** the approval of the  
2461 individual as ~~Radiation Safety Officer~~**RSO or an ARSO**, and ~~who~~ meets the requirements  
2462 in 7A4 ~~and~~ 7A5.

2463 or

2464 7A3.2 ~~Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist~~  
2465 ~~identified on the licensee's license and has experience with the radiation safety aspects~~  
2466 ~~of similar types of use of radioactive materials for which the individual has RSO~~  
2467 ~~responsibilities;~~**Is an authorized user, authorized medical physicist, or authorized**  
2468 **nuclear pharmacist identified on a NRC or an Agreement State license, a permit**  
2469 **issued by a NRC master material license, a permit issued by a NRC or an**  
2470 **Agreement State licensee of broad scope, or a permit issued by a NRC master**  
2471 **material broad scope permittee, has experience with the radiation safety aspects of**  
2472 **similar types of use of radioactive material for which the licensee seeks the**  
2473 **approval of the individual as the RSO or ARSO, and meets the requirements in**  
2474 **7A4;**

2475 or

2476 **7A3.3 Has experience with the radiation safety aspects of the types of use of radioactive**  
2477 **material for which the individual is seeking simultaneous approval both as the**  
2478 **Radiation Safety Officer and the authorized user on the same new medical use**

Commented [JJ141]: 35.50(c)(3).

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2479 permit issued by a NRC master material license. The individual must also meet the  
2480 requirements in 7A4.

2481 and

2482 ~~7A4~~ Has provided written attestation(s), signed by a preceptor RSO, that the individual has  
2483 satisfactorily completed the requirements in 7A5 and in 7A1.1(1) and 7A1.1(2) or 7A1.2(1) and  
2484 7A1.2(2) or 7A2.1 or 7A3.1 or 7A3.2, and has achieved a level of radiation safety knowledge  
2485 sufficient to function independently as an RSO for a medical use licensee;

2486 and

2487 ~~7A5~~~~7A4~~ Has training in the radiation safety, regulatory issues, and emergency procedures for the  
2488 types(s) of use for which a licensee seeks approval. This training requirement may be satisfied by  
2489 completing training that is supervised by an RSO, ~~Alternate RSO, an Associate RSO~~, authorized  
2490 medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is  
2491 authorized ~~on an Agreement State or NRC license~~ for the type(s) of use ~~of radioactive material~~ for  
2492 which the licensee is seeking approval.

Commented [JJ142]: This provision is updated for consistency with the 2018 amendment to 10 CFR 35.50(d).

2493 and

2494 ~~7A6~~ Meets the following recentness of training requirements:

Commented [JJ143]: Here and in multiple subsequent Appendices, the requirements for recentness of training have been relocated to new provision 7.65 in order to consolidate the requirements in one location in the rule. (The requirements of 7.65 parallel the requirements of 10 CFR 35.59.)

2495 ~~7A6.1~~ The training and experience required by Appendix 7A shall have been obtained within the  
2496 7 years preceding the date of license application or amendment request;

2497 or

2498 ~~7A6.2~~ The individual must have had related, documented continuing education and experience  
2499 since the required training and experience was obtained.

2500 or

2501 ~~7A7~~ Meets the following requirements for an experienced Radiation Safety Officer:

Commented [JJ144]: Here and in multiple subsequent Appendices, the requirements for an experienced authorized "individual" is replaced with the requirements contained in (new) Appendix 7P in order to consolidate the requirements in one location.

2502 ~~7A7.1~~ An individual identified as a Radiation Safety Officer on a license issued by the NRC or  
2503 Agreement State, a permit issued under an NRC or Agreement State broad scope  
2504 license before October 25, 2005, are not required to comply with the training  
2505 requirements of 7A1 through 7A6. ~~7A7.2~~ Individuals not required to comply with the  
2506 training requirements of 7A1 through 7A6 may serve as preceptors for, and supervisors  
2507 of, applicants seeking authorization on licenses for the same uses for which these  
2508 individuals are authorized.  
2509  
2510

The requirements of Appendix 7P parallel the requirements of 10 CFR 35.57.

2511 PART 7, ~~APPENDIX 7B~~: TRAINING FOR AN AUTHORIZED MEDICAL PHYSICIST (AMP)

Commented [JJ145]: For final publication, insert a page break to ensure each new appendices begins at the top of the page.

2512 The licensee shall require each authorized medical physicist to be an individual who: Except as  
2513 provided in Appendix 7P, the licensee shall require the authorized medical physicist to be an  
2514 individual who:

2515 ~~7B1~~ ~~Is certified by a medical specialty board whose certification process has been recognized by the~~  
2516 ~~NRC or an Agreement State and who meets the requirements in paragraph 7B2.3 and 7B3 of this~~  
2517 ~~Appendix. NRC recognized specialty boards are posted on the NRC website at~~  
2518 ~~http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.~~ ~~Is certified by a~~  
2519 ~~specialty board whose certification process has been recognized by the NRC or an~~  
2520 ~~Agreement State and who meets the requirements in 7B3 of this Appendix. The names of~~  
2521 ~~board certifications that have been recognized by the NRC or an Agreement State are~~  
2522 ~~posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification~~  
2523 ~~process recognized, a specialty board shall require all candidates for certification to:~~

Commented [JJ146]: Appendix 7B is updated for consistency with the 2018 amendments to [10 CFR 35.51](#).

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2524 ~~7B1.1~~ ~~To have its certification process recognized, a specialty board shall require all candidates~~  
2525 ~~for certification to:~~

2526 ~~(1)7B1.1~~ Hold a master's or doctor's degree in physics, medical physics, other physical  
2527 science, engineering, or applied mathematics from an accredited college or university;

2528 and

2529 ~~(2)7B1.2~~ Have 2 years of full-time practical training and/or supervised experience in  
2530 medical physics:

2531 ~~(a1)~~ Under the supervision of a medical physicist who is certified in medical physics  
2532 by a specialty board **whose certification process has been recognized under**  
2533 **7B1 by the NRC or an Agreement State** ~~or NRC~~;

2534 or

2535 ~~(b2)~~ In clinical radiation facilities providing high energy, external beam therapy  
2536 (photons and electrons with energies greater than or equal to 1 million electron  
2537 volts) and brachytherapy services under the direction of physicians who meet the  
2538 requirements ~~for authorized users in 7B5~~ **Appendix 7P**, Appendix 7K or Appendix  
2539 7M;

2540 and

2541 ~~(3)7B1.3~~ Pass an examination administered by diplomates of the specialty board, that  
2542 assesses knowledge and competence in clinical radiation therapy, radiation safety,  
2543 calibration, quality assurance, and treatment planning for external beam therapy,  
2544 brachytherapy, and stereotactic radiosurgery;

2545 or

2546 **7B2** ~~Has satisfied the following criteria:~~

2547 7B2.1 Holds a master's or doctor's degree in physics, medical physics, other physical science,  
2548 engineering, or applied mathematics from an accredited college or university; **and has**  
2549 **completed 1 year of full-time training in medical physics and an additional year of**  
2550 **full-time work experience under the supervision of an individual who meets the**

2551 requirements for an authorized medical physicist for the type(s) of use for which  
2552 the individual is seeking authorization. This training and work experience must be  
2553 conducted in clinical radiation facilities that provide high-energy, external beam  
2554 therapy (photons and electrons with energies greater than or equal to 1 million  
2555 electron volts) and brachytherapy services and must include:

2556 and

2557 ~~7B2.2~~ Has completed 1 year of full-time training in medical physics and an additional year of  
2558 full-time work experience under the supervision of an individual who meets the  
2559 requirements for an authorized medical physicist for the type(s) of use for which the  
2560 individual is seeking authorization.

Commented [JSJ147]: This provision is replaced by the prior updated provision in 7B2.1 in keeping with the format and flow of [10 CFR 35.51](#).

2561 (1) The training and work experience of ~~7B2.2~~ must be:

2562 — Conducted in clinical radiation facilities that provide high-energy, external beam  
2563 therapy (photons or electrons with energies greater than or equal to 1 MeV) and  
2564 brachytherapy services and must include:

2565 (a1) Performing sealed source leak tests and inventories;

2566 (b2) Performing decay corrections;

2567 (c3) Performing full calibration and periodic spot checks of external beam treatment  
2568 units, stereotactic radiosurgery units, and remote afterloading units as applicable;

2569 and

2570 (d4) Conducting radiation surveys around external beam treatment units, stereotactic  
2571 radiosurgery units, and remote afterloading units as applicable;

2572 and

2573 ~~7B2.32~~ Has obtained written attestation that the individual has satisfactorily completed the  
2574 requirements in: **7B2.1 and 7B3, and is able to independently fulfill the radiation**  
2575 **safety-related duties as an authorized medical physicist for each type of**  
2576 **therapeutic medical unit for which the individual is requesting authorized medical**  
2577 **physicist status. The written attestation must be signed by a preceptor authorized**  
2578 **medical physicist who meets the requirements in Appendix 7B, Appendix 7P, or**  
2579 **equivalent NRC or Agreement State requirements for an authorized medical**  
2580 **physicist for each type of therapeutic medical unit for which the individual is**  
2581 **requesting authorized medical physicist status.**

Commented [JJ148]: Updated for consistency with [10 CFR 35.51\(b\)\(2\)](#).

2582 (1) ~~7B3 and 7B1.1(1) and 7B1.1(2);~~

2583 or

2584 (2) ~~7B2 and 7B3;~~

2585 and

2586 (3) ~~Has achieved a level of competency sufficient to function independently as an~~  
2587 ~~authorized medical physicist for each type of therapeutic medical unit for which~~  
2588 ~~the individual is requesting authorized medical physicist status. The written~~  
2589 ~~attestation must be signed by a preceptor authorized medical physicist who~~

2590 meets the requirements in this Appendix (7B), 7B5, or equivalent NRC or  
2591 Agreement State requirements for an authorized medical physicist for each type  
2592 of therapeutic medical unit for which the individual is requesting authorized  
2593 medical physicist status;

2594 and

2595 ~~7B3~~ Has met the following requirements:

2596 ~~7B3.1~~ Has training for the type(s) of use for which authorization is sought that includes:

2597 (1) ~~Hands-on device operation,~~

2598 (2) ~~Safety procedures,~~

2599 (3) ~~Clinical use,~~

2600 and

2601 (4) ~~The operation of a treatment planning system.~~

2602 ~~7B3.2~~ The training required by ~~7B3.1~~ may be satisfied by:

2603 (1) ~~Satisfactorily completing a training program provided by the vendor;~~

2604 or

2605 Through training supervised by an authorized medical physicist authorized for the type(s)  
2606 of use for which the individual is seeking authorization.

2607 **7B3** Has training for the type(s) of use for which authorization is sought that includes hands-on  
2608 device operation, safety procedures, clinical use, and the operation of a treatment  
2609 planning system. This training requirement may be satisfied by satisfactorily completing  
2610 either a training program provided by the vendor or by training supervised by an  
2611 authorized medical physicist authorized for the type(s) of use for which the individual is  
2612 seeking authorization.

2613 **7B4** Meets the following recentness of training requirements:

2614 ~~7B4.1~~ Training and experience required by Appendix 7B shall have been obtained within the 7  
2615 years preceding the date of license application or amendment request;

2616 or

2617 ~~7B4.2~~ The individual must have had related, documented, continuing education and experience  
2618 since the required training and experience was obtained.

2619 or

2620 **7B5** Meets the following requirements for an experienced authorized medical physicist:

2621 ~~7B5.1~~ An individual identified as an authorized medical physicist on a license issued by the  
2622 NRC or Agreement State, a permit issued under an NRC or Agreement State broad  
2623 scope license before October 25, 2005, are not required to comply with the training  
2624 requirements of ~~7B1~~ through ~~7B4~~.

**Commented [JSJ149]:** This provision is replaced by revised 7B3 (below) to maintain the flow and format of [10 CFR 35.51\(c\)](#).

The requirements remain the same. Only the numbering and some phrasing has changed.

2625           or

2626

2627           ~~7B5.2—An experienced medical physicist who has demonstrated to the Department experience~~  
2628           ~~in the type(s) of use for which the individual is requesting authorized medical physicist~~  
2629           ~~status (and thus need not comply with the specific training and experience requirements~~  
2630           ~~of 7B1 through 7B4):~~

2631           ~~(1)—— Having been certified before October 25, 2005 by the American Board of~~  
2632           ~~Radiology in:~~

2633                     ~~(a)—— Therapeutic radiological physics;~~

2634                     ~~(b)—— Roentgen ray and gamma ray physics;~~

2635                     ~~(c)—— X ray and radium physics;~~

2636           or

2637                     ~~(d)—— Radiological physics;~~

2638           or

2639           ~~(2)—— Having been certified before October 25, 2005 by the American Board of Medical~~  
2640           ~~Physics in radiation oncology physics;~~

2641           and

2642           ~~(3)—— Has sufficient work experience that includes the tasks listed in 7.13.2 and/or~~  
2643           ~~other sections of these regulations related to medical physics, as applicable~~  
2644           ~~(having also satisfied 7B2.1 and being trained in therapeutic radiological~~  
2645           ~~physics).~~

2646           ~~7B5.3—Individuals not required to comply with the training requirements of 7B1 through 7B4 may~~  
2647           ~~serve as preceptors for, and supervisors of, applicants seeking authorization on licenses~~  
2648           ~~for the same uses for which these individuals are authorized.~~  
2649

2650 PART 7, APPENDIX 7C: TRAINING FOR AND AUTHORIZED NUCLEAR PHARMACIST (ANP)

2651 ~~The licensee shall require each authorized nuclear pharmacist to be a pharmacist who has a~~  
2652 ~~current active Colorado State Board of Pharmacy license and who:~~ Except as provided in  
2653 Appendix 7P, the licensee shall require the authorized nuclear pharmacist to be a pharmacist  
2654 who:

2655 **7C1** ~~Is certified by a medical specialty board whose certification process has been recognized by the~~  
2656 ~~NRC or an Agreement State and who meets the requirements in paragraph 7C2.2 of this~~  
2657 ~~Appendix. NRC recognized specialty boards are posted on the NRC website at~~  
2658 ~~http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.~~ Is certified by a  
2659 specialty board whose certification process has been recognized by the NRC or an  
2660 Agreement State. The names of board certifications that have been recognized by the NRC  
2661 or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page.  
2662 To have its certification process recognized, a specialty board shall require all candidates  
2663 for certification to:

2664 7C1.1 ~~To have its certification process recognized, a specialty board shall require all candidates~~  
2665 ~~for certification to:~~

2666 (1) **7C1.1** Have graduated from a pharmacy program accredited by the American Council  
2667 on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy  
2668 Graduate Examination Committee (FPGEC) examination;

2669 (2) **7C1.2** Hold a current, active license to practice pharmacy;

2670 (3) **7C1.3** Provide evidence of having acquired at least 4000 hours of training/experience in  
2671 nuclear pharmacy practice. ~~(a)~~ Academic training may be substituted for no more  
2672 than 2000 hours of the required training and experience);

2673 and

2674 (4) **7C1.3** Pass an examination, in nuclear pharmacy administered by diplomates of the  
2675 specialty board, ~~which~~ that assesses knowledge and competency in  
2676 procurement, compounding, quality assurance, dispensing, distribution, health  
2677 and safety, radiation safety, provision of information and consultation, monitoring  
2678 patient outcomes, and research and development;

2679 or

2680 **7C2** ~~Has satisfied the following criteria:~~

2681 7C2.1 Has completed 700 hours in a structured educational program ~~that includes~~ consisting of  
2682 both:

2683 (1) 200 hours of classroom and laboratory training in the following areas:

- 2684 (a) Radiation physics and instrumentation;
- 2685 (b) Radiation protection;
- 2686 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2687 (d) Chemistry of radioactive material for medical use; and

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Appendix 7C is amended, consistent with the 2018 revisions to 10 CFR 35.55.

NRC RATS 2018-1  
NRC Compatibility B

Commented [JJ151]: 35.55(b)(1)(i)(A) – (E)

(a) = 35.55(b)(1)(i)(A)  
(b) = 35.55(b)(1)(i)(B)  
(c) = 35.55(b)(1)(i)(C)  
(d) = 35.55(b)(1)(i)(D)  
(e) = 35.55(b)(1)(i)(E)

- 2688 (e) Radiation biology;
- 2689 and
- 2690 (2) Supervised practical experience in nuclear pharmacy involving:
- 2691 (a) Shipping, receiving, and performing related radiation surveys;
- 2692 (b) Using and performing checks for proper operation of instruments to  
2693 determine the activity of dosages, survey meters, and, if appropriate,  
2694 instruments used to measure alpha- or beta-emitting radionuclides;
- 2695 (c) Calculating, assaying, and safely preparing dosages for patients or  
2696 human research subjects;
- 2697 (d) Using administrative controls to avoid ~~misadministrations~~ **medical events**  
2698 in the administration of radioactive material;
- 2699 and
- 2700 (e) Using procedures to prevent or minimize radioactive contamination and  
2701 using proper decontamination procedures;
- 2702 and
- 2703 ~~7C2.2~~ Has ~~provided~~ **obtained** written attestation(s), signed by a preceptor authorized nuclear  
2704 pharmacist, that the individual has satisfactorily completed the requirements in ~~7C1.1(1),~~  
2705 ~~7C1.1(2), and 7C1.1(3) or 7C2.1,~~ and ~~has achieved a level of competency sufficient~~  
2706 ~~to function independently is able to independently fulfill the radiation safety related~~  
2707 ~~duties~~ as an authorized nuclear pharmacist.
- 2708 and
- 2709 ~~7C3~~ — ~~Meets the following recentness of training requirements:~~
- 2710 ~~7C3.1~~ — ~~The training and experience required by Appendix 7C shall have been obtained within the~~  
2711 ~~7 years preceding the date of license application or amendment request;~~
- 2712 or
- 2713 ~~7C3.2~~ — ~~The individual must have had related, documented, continuing education and experience~~  
2714 ~~since the required training and experience was obtained.~~
- 2715 or
- 2716 ~~7C4~~ — ~~Meets the following requirements for an experienced authorized nuclear pharmacist.~~
- 2717 ~~7C4.1~~ — ~~An individual identified as an authorized nuclear pharmacist on a license issued by the~~  
2718 ~~NRC or Agreement State, a permit issued under an NRC or Agreement State broad~~  
2719 ~~scope license before October 25, 2005, are not required to comply with the training~~  
2720 ~~requirements of 7C1 through 7C3.~~
- 2721 ~~7C4.2~~ — ~~Individuals not required to comply with the training requirements of 7C1 through 7C3 may~~  
2722 ~~serve as preceptors for, and supervisors of, applicants seeking authorization on licenses~~  
2723 ~~for the same uses for which these individuals are authorized.~~  
2724

Commented [JJ152]: 35.55(b)(1)(ii)(A) – (E)  
= (a) through (e)

Commented [JJ153]: Updated for consistency with  
35.55(b)(2).

NRC Compatibility B  
RATS 2018-1

2725 PART 7, APPENDIX 7D: ~~AUTHORIZED USER TRAINING FOR UPTAKE, DILUTION AND EXCRETION~~  
2726 ~~STUDIES (7.30 USES)~~

2727 ~~The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized~~  
2728 ~~under 7.30 to be a physician who has a current active State of Colorado license and: Except as~~  
2729 ~~provided in Appendix 7P, the licensee shall require an authorized user of unsealed~~  
2730 ~~radioactive material for the uses authorized under 7.30 to be a physician who:~~

2731 7D1 Is certified by a medical specialty board whose certification process has been recognized by the  
2732 NRC or an Agreement State. ~~and who meets the requirements in paragraph 7D3.2 of this~~  
2733 ~~Appendix. NRC recognized specialty boards are posted on the NRC website at~~  
2734 ~~<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. The names of board~~  
2735 ~~certifications that have been recognized by the NRC or an Agreement State are posted on~~  
2736 ~~the NRC's Medical Uses Licensee Toolkit web page. To have its certification process~~  
2737 ~~recognized, a specialty board shall require all candidates for certification to:~~

2738 7D1.1 ~~To have its certification process recognized, a specialty board shall require that all~~  
2739 ~~candidates for certification to:~~ (1) Complete 60 hours of training and experience in basic  
2740 radionuclide handling techniques and radiation safety applicable to the medical use of  
2741 unsealed radioactive materials for uptake, dilution, and excretion studies as described in  
2742 7D3.1(1) through 7D3.1(2)(f);

2743 and

2744 ~~(2)~~ 7D1.2 Pass an examination, administered by diplomates of the specialty board, that  
2745 assesses knowledge and competence in radiation safety, radionuclide handling, and  
2746 quality control;

2747 or

2748 7D2 Is an authorized user under Appendix 7E, Appendix 7F, or equivalent Agreement State or NRC  
2749 requirements; ~~or 7D3~~

2750 or

2751 ~~7D3~~ Has satisfied the following criteria:

2752 7D3.1 Has ~~satisfactorily~~ completed 60 hours of training and experience, including a minimum of  
2753 8 hours of classroom and laboratory training, in basic radionuclide handling techniques  
2754 applicable to the medical use of unsealed radioactive materials for uptake, dilution, and  
2755 excretion studies. The training and experience must include:

2756 (1) Classroom and laboratory training in the following areas:

2757 (a) Radiation physics and instrumentation;

2758 (b) Radiation protection;

2759 (c) Mathematics pertaining to the use and measurement of radioactivity;

2760 (d) Chemistry of radioactive material for medical use; and

2761 (e) Radiation biology;

Commented [JJ154]:

For final publication, insert a page break to ensure each new appendices begins at the top of the page.

Appendix 7D is updated for consistency with the 2018 changes to [10 CFR 35.190](#).

Appendix 7D has been realigned/formatted for consistency with the formatting of other sections of Part 7 and with the flow and format of 10 CFR 35.

Compatibility B  
NRC RATS 2018-1

Commented [JSJ155]: Section 7D3 has been realigned/formatted for consistency with other sections of Part 7 and the flow and format of 10 CFR 35.

- 2762 and
- 2763 (2) Work experience under the supervision of an authorized user who meets the  
2764 requirements ~~of 7D5~~ in **Appendix 7P**, 7D, 7E, 7F, or equivalent Agreement State  
2765 or NRC requirements, involving:
- 2766 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2767 performing the related radiation surveys;
- 2768 (b) Performing quality control procedures on instruments used to determine  
2769 the activity of dosages and performing checks for proper operation of  
2770 survey meters;
- 2771 (c) Calculating, measuring, and safely preparing patient or human research  
2772 subject dosages;
- 2773 (d) Using administrative controls to prevent a ~~misadministration~~**medical**  
2774 **event** involving the use of unsealed radioactive material;
- 2775 (e) Using procedures to contain spilled radioactive material safely and using  
2776 proper decontamination procedures; and
- 2777 (f) Administering dosages to patients or human research subjects;

2778 And

- 2779 7D3.2 ~~Has provided written attestation(s), signed by a preceptor authorized user who meets the~~  
2780 ~~requirements of 7D5, Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent Agreement State~~  
2781 ~~or NRC requirements, that the individual has satisfactorily completed the requirements in~~  
2782 ~~7D1.1(1) or 7D3.1, and has achieved a level of competency sufficient to function independently~~  
2783 ~~as an authorized user for the medical uses authorized under 7.30. Has obtained written~~  
2784 ~~attestation that the individual has satisfactorily completed the requirements in 7D3.1 and~~  
2785 ~~is able to independently fulfill the radiation safety-related duties as an authorized user for~~  
2786 ~~the medical uses authorized under 7.30. The attestation must be obtained from either:~~
- 2787
- 2788
- 2789 (1) **A preceptor authorized user who meets the requirements in Appendix 7P,**  
2790 **Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent NRC or Agreement State**  
2791 **requirements; or**
- 2792
- 2793 (2) **A residency program director who affirms in writing that the attestation represents**  
2794 **the consensus of the residency program faculty where at least one faculty member**  
2795 **is an authorized user who meets the requirements in Appendix 7P, Appendix 7D,**  
2796 **Appendix 7E, Appendix 7F, or equivalent NRC or Agreement State requirements,**  
2797 **and concurs with the attestation provided by the residency program director. The**  
2798 **residency training program must be approved by the Residency Review Committee**  
2799 **of the Accreditation Council for Graduate Medical Education or the Royal College**  
2800 **of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of**  
2801 **the American Osteopathic Association and must include training and experience**  
2802 **specified in 7D3.1.**

2803 and

2804 ~~7D4~~ —Meets the following recentness of training requirements:

- 2805 ~~7D4.1 — The training and experience required by Appendix 7D shall have been obtained within the 7 years~~  
2806 ~~preceding the date of license application or amendment request; or~~
- 2807 ~~7D4.2 — The individual must have had related, documented, continuing education and experience since~~  
2808 ~~the required training and experience was obtained.~~
- 2809 ~~or~~
- 2810 ~~7D5 — Meets the following requirements for an experienced authorized user for 7.30 uses:~~
- 2811 ~~7D5.1 — An individual identified as an authorized user for the medical use of radioactive material on a~~  
2812 ~~license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement~~  
2813 ~~State broad scope license that authorizes medical use before October 25, 2005, who perform~~  
2814 ~~only those medical uses for which they were authorized on that date are not required to comply~~  
2815 ~~with the training requirements of 7D1 through 7D4.~~
- 2816 ~~7D5.2 — Individuals not required to comply with the training requirements of 7D1 through 7D4 may serve~~  
2817 ~~as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same~~  
2818 ~~uses for which these individuals are authorized.~~  
2819

2820 PART 7, ~~APPENDIX 7E: AUTHORIZED USER TRAINING FOR IMAGING AND LOCALIZATION~~  
2821 ~~STUDIES (7.32 USES)~~

2822 ~~The licensee shall require an authorized user of an unsealed radioactive material for the uses~~  
2823 ~~authorized under 7.32 to be a physician who has a current active State of Colorado license~~  
2824 ~~and: Except as provided in Appendix 7P, the licensee shall require an authorized user of unsealed~~  
2825 ~~radioactive material for the uses authorized under 7.32 to be a physician who:~~

2826 7E1 ~~Is certified by a medical specialty board whose certification process has been recognized by the~~  
2827 ~~NRC or an Agreement State and who meets the requirements in paragraph 7E3.2 of this~~  
2828 ~~Appendix. NRC recognized specialty boards are posted on the NRC website at~~  
2829 ~~http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html. Is certified by a~~  
2830 ~~medical specialty board whose certification process has been recognized by the NRC or~~  
2831 ~~an Agreement State. The names of board certifications that have been recognized by the~~  
2832 ~~NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web~~  
2833 ~~page. To have its certification process recognized, a specialty board shall require all~~  
2834 ~~candidates for certification to:~~

2835 ~~7E1.1 To have its certification process recognized, a specialty board shall require all candidates~~  
2836 ~~for certification to:~~

2837 ~~(1)~~

2838 **7E1.1** Complete 700 hours of training and experience in basic radionuclide handling techniques  
2839 and radiation safety applicable to the medical use of unsealed radioactive materials for  
2840 imaging and localization studies as described in 7E3.1(1) through 7E3.1(2)(g);

2841 and

2842 ~~(2)~~

2843 **7E1.2** Pass an examination, administered by diplomates of the specialty board, which assesses  
2844 knowledge and competence in radiation safety, radionuclide handling, and quality control;

2845 or

2846 7E2 Is an authorized user under Appendix 7F and meets the requirements in 7E3.1(2)(g), or  
2847 equivalent Agreement State or NRC requirements;

2848 or

2849 7E3 ~~Has satisfied the following criteria:~~

2850 7E3.1 Has satisfactorily completed 700 hours, including a minimum of 80 hours of classroom  
2851 and laboratory training in basic radionuclide handling techniques applicable to the  
2852 medical use of unsealed radioactive materials for imaging and localization studies. The  
2853 training **and experience** must include at a minimum:

2854 (1) Classroom and laboratory training in the following areas:

2855 (a) Radiation physics and instrumentation;

2856 (b) Radiation protection;

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This appendix is updated for format and content, consistent with the 2018 amendments to [10 CFR 35.290](#).

- 2857 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 2858 (d) Chemistry of radioactive material for medical use; and
- 2859 (e) Radiation biology;
- 2860 and
- ~~2861 (2) Work experience under the supervision of an authorized user who meets the~~  
~~2862 requirements of 7E5, 7E, or 7F and 7E3.1(2)(g), or equivalent Agreement State~~  
~~2863 or NRC requirements, involving:~~
- (2) Work experience, under the supervision of an authorized user who meets**  
**the requirements in Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent**  
**NRC or Agreement State requirements. An authorized nuclear pharmacist**  
**who meets the requirements in Appendix 7C or Appendix 7P may provide**  
**the supervised work experience for 7E3.1(2)(g). Work experience must**  
**involve:**
- 2871 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2872 performing the related radiation surveys;
- 2873 (b) Performing quality control procedures on instruments used to determine  
2874 the activity of dosages and performing checks for proper operation of  
2875 survey meters;
- 2876 (c) Calculating, measuring, and safely preparing patient or human research  
2877 subject dosages;
- 2878 (d) Using administrative controls to prevent a ~~misadministration~~**medical**  
2879 **event** involving the use of unsealed radioactive material;
- 2880 (e) Using procedures to **safely** contain spilled radioactive material **safely**  
2881 and using proper decontamination procedures; ~~and~~
- 2882 (f) Administering dosages to patients or human research subjects; **and**
- 2883 (g) Eluting generator systems appropriate for preparation of radioactive  
2884 drugs for imaging and localization studies, measuring and testing the  
2885 eluate for radiochemical purity, and processing the eluate with reagent  
2886 kits to prepare labeled radioactive drugs;
- 2887 and
- 2888 **7E3.2 Has provided written attestation(s), signed by a preceptor authorized user who meets the**  
2889 **requirements of 7E5, Appendix 7E, or Appendix 7F and 7E3.1(2)(g), or equivalent**  
2890 **Agreement State or NRC requirements, that the individual has satisfactorily completed**  
2891 **the requirements in 7E1.1(1) or 7E3, and has achieved a level of competency sufficient to**  
2892 **function independently as an authorized user for the medical uses authorized under 7.30**  
2893 **and 7.32. Has obtained written attestation that the individual has satisfactorily**  
2894 **completed the requirements in 7E3.1 and is able to independently fulfill the**  
2895 **radiation safety-related duties as an authorized user for the medical uses**  
2896 **authorized under 7.30 and 7.32. The attestation must be obtained from either:**  
2897

- 2898 (1) A preceptor authorized user who meets the requirements in Appendix 7P,  
2899 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement State  
2900 requirements;  
2901  
2902 or  
2903  
2904 (2) A residency program director who affirms in writing that the attestation  
2905 represents the consensus of the residency program faculty where at least  
2906 one faculty member is an authorized user who meets the requirements in  
2907 Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement  
2908 State requirements, and concurs with the attestation provided by the  
2909 residency program director. The residency training program must be  
2910 approved by the Residency Review Committee of the Accreditation Council  
2911 for Graduate Medical Education or the Royal College of Physicians and  
2912 Surgeons of Canada or the Council on Postdoctoral Training of the  
2913 American Osteopathic Association and must include training and  
2914 experience specified in 7E3.1.

2915 and

2916 ~~7E4~~ Meets the following recentness of training requirements:

2917 ~~7E4.1~~ The training and experience required by Appendix 7E shall have been obtained within the  
2918 7 years preceding the date of license application or amendment request;

2919 or

2920 ~~7E4.2~~ The individual must have had related, documented, continuing education and experience  
2921 since the required training and experience was obtained.

2922 or

2923 ~~7E5~~ Meets the following requirements for an experienced authorized user for 7.32 uses:

2924 ~~7E5.1~~ An individual identified as an authorized user for the medical use of radioactive material  
2925 on a license issued by the NRC or Agreement State, a permit issued under an NRC or  
2926 Agreement State broad scope license that authorizes medical use before October 25,  
2927 2005, who perform only those medical uses for which they were authorized on that date  
2928 are not required to comply with the training requirements of 7E1 through 7E4. ~~7E5.2~~  
2929 Individuals not required to comply with the training requirements of 7E1 through 7E4 may  
2930 serve as preceptors for, and supervisors of, applicants seeking authorization on licenses  
2931 for the same uses for which these individuals are authorized.  
2932  
2933

Commented [JSJ157]: Requirements for recentness of training is now addressed in 7.65

Commented [JSJ158]: Training for experienced individuals is now addressed in Appendix 7P.

**PART 7, APPENDIX 7F: AUTHORIZED USER TRAINING FOR DIAGNOSTIC OR THERAPEUTIC USE OF UNSEALED RADIOACTIVE MATERIAL REQUIRING FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED (7.36.2-USES)**

**The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.36.2 to be a physician who has a current active State of Colorado license and: Except as provided in Appendix 7P, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 7.36 to be a physician who:**

~~7F4~~ — ~~Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in paragraph 7F2.1(2)(f) and 7F2.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.~~

**7F1** — **Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in 7F2.1(2)(f). The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To be recognized, a specialty board shall require all candidates for certification to:**

7F1.1 ~~To have its certification process recognized, a specialty board shall require all candidates for certification to:~~

~~(1)~~ — Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 7F2.1(1) through 7F2.1(2)(e). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association;

and

~~(2)7F1.2~~ Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required;

or

**7F2** ~~Has satisfied the following criteria:~~

7F2.1 Has ~~satisfactorily~~ completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training must include:

(1) Classroom and laboratory training in the following areas:

(a) Radiation physics and instrumentation;

(b) Radiation protection;

(c) Mathematics pertaining to the use and measurement of radioactivity;

Commented [JJ159]: For final publication, insert a page break such that each appendix begins on a new page.

Changes to this appendix are based on the 2018 amendments to [10 CFR 35.390](#).

NRC RATS 2018-1  
All of 10 CFR 35.390 is NRC compatibility B

Commented [JSJ160]:

Consistent with federal rule, this provision is amended to eliminate the requirement for a preceptor statement for individuals who have a board certification identified on NRC's medical toolkit web page for the applicable use. The board certification combined with the recentness of training requirements (found in 7.65) are deemed acceptable to demonstrate adequate training and experience for regulatory purposes.

- 2976 (d) Chemistry of radioactive material for medical use; and
- 2977 (e) Radiation biology;
- 2978 and
- 2979 (2) Work experience, under the supervision of an authorized user who meets the  
2980 requirements of ~~7F4~~**Appendix 7P**, ~~or 7F~~, or equivalent Agreement State or NRC  
2981 requirements. A supervising authorized user, who meets the requirements in  
2982 ~~7F2.1~~, must also have experience in administering dosages in the same dosage  
2983 category or categories (i.e., 7F2.1(2)(f)) as the individual requesting authorized  
2984 user status. The work experience must involve:
- 2985 (a) Ordering, receiving, and unpacking radioactive materials safely and  
2986 performing the related radiation surveys;
- 2987 (b) Performing quality control procedures on instruments used to determine  
2988 the activity of dosages and performing checks for proper operation of  
2989 survey meters;
- 2990 (c) Calculating, measuring, and safely preparing patient or human research  
2991 subject dosages;
- 2992 (d) Using administrative controls to prevent a ~~misadministration~~**medical**  
2993 **event** involving the use of unsealed radioactive material;
- 2994 (e) Using procedures to contain spilled radioactive material safely and using  
2995 proper decontamination procedures;
- 2996 and
- 2997 (f) ~~Administering dosages of radioactive drugs to patients or human~~  
2998 ~~research subjects involving a minimum of 3 cases in each of the~~  
2999 ~~following categories for which the individual is requesting authorized user~~  
3000 ~~status:~~**Administering dosages of radioactive drugs to patients or**  
3001 **human research subjects from the three categories in 7F2.1(2)(f).**  
3002 **Radioactive drugs containing radionuclides in categories not**  
3003 **included in 7F2 are regulated under 7.62. This work experience**  
3004 **must involve a minimum of three cases in each of the following**  
3005 **categories for which the individual is requesting authorized user**  
3006 **status:**
- 3007 (i) Oral administration of less than or equal to 1.22  
3008 ~~GBq~~**gigabecquerels (33 mCi)** of ~~Nasodium iodide I-~~  
3009 ~~131~~, for which a written directive is required;
- 3010 (ii) ~~Oral administration of greater than 1.22 GBq (33 mCi) of Na I-~~  
3011 ~~131 for which a written directive is required [experience with at~~  
3012 ~~least 3 cases in 7F2.1(2)(f)(ii) also satisfies the requirement in~~  
3013 ~~category 7F2.1(2)(f)(i)];~~**Oral administration of greater than**  
3014 **1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;<sup>2</sup>**
- 3015 (iii) Parenteral administration of any **radioactive drug that contains**  
3016 **a radionuclide that is primarily used for its electron**  
3017 **emission, beta emitter radiation characteristics, alpha**

Commented [JJ161]: Updated for consistency with 10 CFR 35.390(b)(1)(ii)(G).  
NRC Compatibility B

Commented [JSJ162]: Note that footnote "2" is associated with this provision.

3018 radiation characteristics, or a photon-emitting radionuclide with  
3019 a photon energy less than 150 keV, for which a written directive  
3020 is required;

3021 and/or

3022 (iv) ~~Parenteral administration of any other radionuclide for which a~~  
3023 ~~written directive is required;~~

3024 and

3025 7F2.2 Has provided written attestation(s), that the individual has satisfactorily completed the  
3026 requirements in 7F4.1(1) and 7F2.1(2)(f) or 7F2.1, and has achieved a level of  
3027 competency sufficient to function independently as an authorized user for the medical  
3028 uses authorized under 7.36. ~~The written attestation must be signed by a preceptor~~  
3029 ~~authorized user who:~~ **Has obtained written attestation that the individual has**  
3030 **satisfactorily completed the requirements in 7F2.1 and is able to independently**  
3031 **fulfill the radiation safety-related duties as an authorized user for the medical uses**  
3032 **authorized under 7.36. The attestation must be obtained from either:**

3033 (1) ~~Meets the requirements in 7F4, Appendix 7F, or equivalent NRC or Agreement~~  
3034 ~~State requirements; and~~ **A preceptor authorized user who meets the**  
3035 **requirements in 7P, 7F, or equivalent Agreement State requirements and**  
3036 **has experience in administering dosages in the same dosage category or**  
3037 **categories as the individual requesting authorized user status; or**

3038 (2) ~~The preceptor authorized user, who meets the requirements in 7F2.1 must have~~  
3039 ~~experience in administering dosages in the same dosage category or categories~~  
3040 ~~(i.e., 7F2.1(2)(f)) as the individual requesting authorized user status. A~~  
3041 ~~residency program director who affirms in writing that the attestation~~  
3042 ~~represents the consensus of the residency program faculty where at least~~  
3043 ~~one faculty member is an authorized user who meets the requirements in~~  
3044 ~~7P, 7F, or equivalent Agreement State requirements, has experience in~~  
3045 ~~administering dosages in the same dosage category or categories as the~~  
3046 ~~individual requesting authorized user status, and concurs with the~~  
3047 ~~attestation provided by the residency program director. The residency~~  
3048 ~~training program must be approved by the Residency Review Committee of~~  
3049 ~~the Accreditation Council for Graduate Medical Education or the Royal~~  
3050 ~~College of Physicians and Surgeons of Canada or the Council on~~  
3051 ~~Postdoctoral Training of the American Osteopathic Association and must~~  
3052 ~~include training and experience specified in 7F2.1.~~

3054 <sup>2</sup> Experience with at least three cases in Category 7F2.1(2)(f)(ii) also satisfies the requirement in  
3055 Category 7F2.1(2)(f)(i).

3056 and

3057 ~~7F3~~ Meets the following recentness of training requirements:

3058 7F3.1 ~~The training and experience required by Appendix 7F shall have been obtained: within~~  
3059 ~~the 7 years preceding the date of license application or amendment request;~~

3060 or

**Commented [JSJ163]:** This provision is revised, based on the 2018 amendments to [10 CFR 35.390\(b\)\(2\)\(i\)](#).

The previously referenced requirements of 7F4 are now addressed in Appendix 7P.

The revised provision clarifies that the preceptor must have experience administering materials in the same categories as the individual requesting authorization.

**Commented [JSJ164]:** This is a new provision based on the 2018 amendments to [10 CFR 35.390\(b\)\(2\)\(ii\)](#).

**Commented [JSJ165]:** This provision has been replaced by 7.65, which parallels the requirements of 10 CFR 35.59.

3061 ~~7F3.2—The individual must have had related, documented, continuing education and experience~~  
3062 ~~since the required training and experience was obtained.~~

3063 or

3064 ~~7F4—Meets the following requirements for an experienced authorized user for 7.36.2 uses:~~

3065 ~~7F4.1—An individual identified as an authorized user for the medical use of radioactive material~~  
3066 ~~on a license issued by the NRC or Agreement State, a permit issued under an NRC or~~  
3067 ~~Agreement State broad scope license that authorizes medical use before October 25,~~  
3068 ~~2005, who perform only those medical uses for which they were authorized on that date~~  
3069 ~~are not required to comply with the training requirements of 7F1 through 7F3.~~

3070 ~~7F4.2—Individuals not required to comply with the training requirements of 7F1 through 7F3 may~~  
3071 ~~serve as preceptors for, and supervisors of, applicants seeking authorization on licenses~~  
3072 ~~for the same uses for which these individuals are authorized.~~  
3073

Commented [JSJ166]: This provision has been replaced by Appendix 7P, consistent with the format of 10 CFR 35.390.

**PART 7, APPENDIX 7G: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES LESS THAN OR EQUAL TO 1.22 GBq (33 mCi) (7-36.3 USES)**

Commented [JJ167]: For final publication, insert a page break such that each appendix begins on a new page.

Appendix 7G is updated for consistency with [10 CFR 35.392](#).

~~The licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi), to be a physician who has a current active State of Colorado license and: Except as provided in Appendix 7P, the licensee shall require an authorized user for the oral administration of sodium iodide requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who:~~

**7G1** Is certified by a medical specialty board whose certification process includes all of the requirements in 7G3.1 and ~~7G3.1(2)~~ **7G3.2** of this Appendix and whose certification process has been recognized by the NRC or an Agreement State. ~~and who meets the requirements in paragraph 7G3.1(3) of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;~~

Commented [JSJ168]: Consistent with federal rule, this provision is amended to eliminate the requirement for a preceptor statement for individuals who have a board certification identified on NRC's medical toolkit web page for the applicable use. The board certification combined with the recency of training requirements (found in 7.65) are deemed acceptable to demonstrate adequate training and experience for regulatory purposes.

or

**7G2** Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii), Appendix 7H, or equivalent NRC or Agreement State requirements;

or

**7G3** ~~Has satisfied the following criteria:~~

7G3.1 Has ~~satisfactorily~~ **successfully** completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.: **The training must include:**

~~(1) — The 80 hours of classroom and laboratory training must include:~~

~~(a1)~~ Radiation physics and instrumentation;

~~(b2)~~ Radiation protection;

~~(c3)~~ Mathematics pertaining to the use and measurement of radioactivity;

~~(d4)~~ Chemistry of radioactive material for medical use; and

~~(e5)~~ Radiation biology;

and

**7G3.2(2)** Has work experience, under the supervision of an authorized user who meets the requirements of ~~7G5~~ **in Appendix 7P**, or Appendix 7F, Appendix 7G, Appendix 7H or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2.4, must also have experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii). ~~as the individual requesting authorized user status.~~ The work experience must involve:

- 3112 (a1) Ordering, receiving, and unpacking radioactive materials safely and performing  
3113 the related radiation surveys;
- 3114 (b2) Performing quality control procedures on instruments used to determine the  
3115 activity of dosages and performing checks for proper operation of survey meters;
- 3116 (e3) Calculating, measuring, and safely preparing patient or human research subject  
3117 dosages;
- 3118 (d4) Using administrative controls to prevent a ~~misadministration~~ **medical event**  
3119 involving the use of ~~unsealed~~ radioactive material;
- 3120 (e5) Using procedures to contain spilled radioactive material safely and using proper  
3121 decontamination procedures;
- 3122 and
- 3123 (f6) Administering dosages to patients or human research subjects that includes at  
3124 least 3 cases involving the oral administration of less than or equal to 1.22  
3125 gigabecquerels (33 millicuries) of sodium iodide I-131;
- 3126 and

3127 **7G3.3(3)** ~~Has provided written attestation(s), that the individual has completed the~~  
3128 ~~requirements of 7G3.1(1) and 7G3.1(2), and has achieved a level of competency~~  
3129 ~~sufficient to function independently as an authorized user for the medical uses of~~  
3130 ~~unsealed radioactive materials using Na I-131 authorized under 7.36. The written~~  
3131 ~~attestation must be signed by a preceptor authorized user who:~~ **Has obtained written**  
3132 **attestation that the individual has satisfactorily completed the requirements in**  
3133 **7G3.1 and 7G3.2, and is able to independently fulfill the radiation safety-related**  
3134 **duties as an authorized user for oral administration of less than or equal to 1.22**  
3135 **gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized**  
3136 **under 7.36. The attestation must be obtained from either:**

- 3137 (a1) **A preceptor authorized user who** ~~meets the requirements in 7G5~~ **Appendix**  
3138 **7P, Appendix 7F, Appendix 7G, or Appendix 7H, or equivalent NRC or**  
3139 **Agreement State requirements and has experience administering dosages as**  
3140 **specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii);**

3141 and/or

- 3142 (b) ~~The preceptor authorized user, who meets the requirements in 7F2.1 must have~~  
3143 ~~experience in administering dosages as specified in 7F2.1(2)(f)(i) or~~  
3144 ~~7F2.1(2)(f)(ii).~~

- 3145 **(2) A residency program director who affirms in writing that the attestation**  
3146 **represents the consensus of the residency program faculty where at least**  
3147 **one faculty member is an authorized user who meets the requirements in**  
3148 **Appendix 7P, Appendix 7F, Appendix 7G, Appendix 7H, or equivalent NRC**  
3149 **or Agreement State requirements, has experience in administering dosages**  
3150 **as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii), and concurs with the**  
3151 **attestation provided by the residency program director. The residency**  
3152 **training program must be approved by the Residency Review Committee of**  
3153 **the Accreditation Council for Graduate Medical Education or the Royal**  
3154 **College of Physicians and Surgeons of Canada or the Council on**

Commented [JSJ169]: This provision is new, based on the 2018 amendments to [10 CFR 35.392\(c\)\(3\)\(ii\)](#).

3155                                    **Postdoctoral Training of the American Osteopathic Association and must**  
3156                                    **include training and experience specified in 7G3.1 and 7G3.2.**

3157    **and**

3158    **7G4** — Meets the following recentness of training requirements:

3159                    ~~7G4.1~~ — The training and experience required by Appendix 7G shall have been obtained within  
3160                    the 7 years preceding the date of license application or amendment request;

3161                    **or**

3162                    ~~7G4.2~~ — The individual must have had related, documented, continuing education and experience  
3163                    since the required training and experience was obtained.

3164    **or**

3165    **7G5** — Meets the following requirements for an experienced authorized user for 7.36.3 uses:

3166                    ~~7G5.1~~ — An individual identified as an authorized user for the medical use of radioactive material  
3167                    on a license issued by the NRC or Agreement State, a permit issued under an NRC or  
3168                    Agreement State broad scope license that authorizes medical use before October 25,  
3169                    2005, who perform only those medical uses for which they were authorized on that date  
3170                    are not required to comply with the training requirements of 7G1 through 7G4.

3171                    ~~7G5.2~~ — Individuals not required to comply with the training requirements of 7G1 through 7G4 may  
3172                    serve as preceptors for, and supervisors of, applicants seeking authorization on licenses  
3173                    for the same uses for which these individuals are authorized.  
3174

~~PART 7, APPENDIX 7H: AUTHORIZED USER TRAINING FOR THE ORAL ADMINISTRATION OF SODIUM IODIDE I-131 REQUIRING A WRITTEN DIRECTIVE IN QUANTITIES GREATER THAN 1.22 GBq (33 mCi) (7.36.4 USES)~~

Commented [JJ170]: For final publication, insert a page break such that each appendix begins on a new page.

~~The licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 GBq (33 mCi), to be a physician who has a current active State of Colorado license and: Except as provided in Appendix 7P, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who:~~

~~7H1 Is certified by a medical specialty board whose certification process includes all of the requirements in 7H3.1, and ~~7H3.1(2)~~ 7H3.2 and whose certification has been recognized by the NRC or an Agreement State, and who meets the requirements in paragraph 7H3.2 of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;~~

~~or~~

~~7H2 Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(ii), or equivalent NRC or Agreement State requirements;~~

~~or~~

~~7H3 Has satisfied the following criteria:~~

~~7H3.1 Has satisfactorily successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:~~

~~(1) The 80 hours of classroom and laboratory training must include:~~

~~(a1) Radiation physics and instrumentation;~~

~~(b2) Radiation protection;~~

~~(c3) Mathematics pertaining to the use and measurement of radioactivity;~~

~~(d4) Chemistry of radioactive material for medical use; and~~

~~(e5) Radiation biology;~~

~~and~~

~~7H3.2(2) Has work experience, under the supervision of an authorized user who meets the requirements of ~~7H5~~ Appendix 7P, Appendix 7F, Appendix 7H or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in ~~7F2-4~~ 7F2, must also have experience in administering dosages as specified in 7F2.1(2)(f)(ii). The work experience must involve:~~

~~(a1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

- 3213 (b2) Performing quality control procedures on instruments used to determine the  
3214 activity of dosages and performing checks for proper operation of survey meters;
- 3215 (e3) Calculating, measuring, and safely preparing patient or human research subject  
3216 dosages;
- 3217 (d4) Using administrative controls to prevent a ~~misadministration~~**medical event**  
3218 involving the use of ~~unsealed~~-radioactive material;
- 3219 (e5) Using procedures to contain spilled radioactive material safely and using proper  
3220 decontamination procedures;
- 3221 and
- 3222 (f6) Administering dosages to patients or human research subjects, that includes at  
3223 least 3 cases involving the oral administration of greater than 1.22  
3224 gigabecquerels (33 millicuries) of sodium iodide I-131;
- 3225 **andand**
- 3226 **7H3.3(3)** ~~Has provided written attestation(s), that the individual has completed the~~  
3227 ~~requirements of 7H3.1(1) and 7H3.1(2), and has achieved a level of competency~~  
3228 ~~sufficient to function independently as an authorized user for the medical uses of~~  
3229 ~~unsealed radioactive materials using Na I-131 in activities greater than 1.22 GBq (33~~  
3230 ~~mCi) authorized under 7.36. The written attestation must be signed by a preceptor~~  
3231 ~~authorized user who:~~**Has obtained written attestation that the individual has**  
3232 **satisfactorily completed the requirements in 7H3.1 and 7H3.2, and is able to**  
3233 **independently fulfill the radiation safety-related duties as an authorized user for**  
3234 **oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium**  
3235 **iodide I-131 for medical uses authorized under 7.36. The attestation must be**  
3236 **obtained from either:**
- 3237 (1) **A preceptor authorized user who** ~~Meetsmeets~~ the requirements in  
3238 ~~7H5~~**Appendix 7P**, Appendix 7F, or Appendix 7H, or equivalent NRC or Agreement State  
3239 requirements; **and has experience in administering dosages as specified in**  
3240 **7F2.1(2)(f)(ii); or**
- 3241 **andand**
- 3242 (2) ~~The preceptor authorized user, who meets the requirements in 7F2.1 must have~~  
3243 ~~experience in administering dosages as specified in 7F2.1(2)(f)(ii).~~
- 3244 **(2) A residency program director who affirms in writing that the attestation**  
3245 **represents the consensus of the residency program faculty where at least**  
3246 **one faculty member is an authorized user who meets the requirements in**  
3247 **Appendix 7P, Appendix 7F, Appendix 7H, or equivalent NRC or Agreement**  
3248 **State requirements, has experience in administering dosages as specified**  
3249 **in F2.1(2)(f)(ii), and concurs with the attestation provided by the residency**  
3250 **program director. The residency training program must be approved by the**  
3251 **Residency Review Committee of the Accreditation Council for Graduate**  
3252 **Medical Education or the Royal College of Physicians and Surgeons of**  
3253 **Canada or the Council on Postdoctoral Training of the American**  
3254 **Osteopathic Association and must include training and experience**  
3255 **specified in 7H3.1 and 7H3.2.**

Commented [JSJ171]: This provision is new, based on the 2018 amendments to [10 CFR 35.392\(c\)\(3\)\(ii\)](#).

3256 and

3257 ~~7H4~~ — Meets the following recentness of training requirements:

3258 ~~7H4.1~~ — The training and experience required by Appendix 7H shall have been obtained within the

3259 ~~7 years preceding the date of license application or amendment request;~~

3260 or

3261 ~~7H4.2~~ — The individual must have had related, documented, continuing education and experience

3262 ~~since the required training and experience was obtained.~~

3263 or

3264 ~~7H5~~ — Meets the following requirements for an experienced authorized user for 7.36.4 uses:

3265 ~~7H5.1~~ — An individual identified as an authorized user for the medical use of radioactive material

3266 ~~on a license issued by the NRC or Agreement State, a permit issued under an NRC or~~

3267 ~~Agreement State broad scope license that authorizes medical use before October 25,~~

3268 ~~2005, who perform only those medical uses for which they were authorized on that date~~

3269 ~~are not required to comply with the training requirements of 7H1 through 7H4.~~

3270 ~~7H5.2~~ — Individuals not required to comply with the training requirements of 7H1 through 7H4 may

3271 ~~serve as preceptors for, and supervisors of, applicants seeking authorization on licenses~~

3272 ~~for the same uses for which these individuals are authorized.~~

3273

3274 PART 7, ~~APPENDIX 7I: AUTHORIZED USER TRAINING FOR THE PARENTERAL ADMINISTRATION~~  
3275 ~~OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE (7.36.5~~  
3276 ~~USES)~~

3277 ~~The licensee shall require an authorized user for parenteral administration of unsealed radioactive~~  
3278 ~~material for which a written directive is required to be a physician who has a current active State~~  
3279 ~~of Colorado license and:~~

3280 **711** Except as provided in Appendix 7P, the licensee shall require an authorized user for the  
3281 parenteral administration requiring a written directive to be a physician who:

3282 **711.1** Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(iii) ~~or~~  
3283 ~~7F2.1(2)(f)(iv),~~ or equivalent NRC or Agreement State requirements;

3284 or

3285 **711.2** Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or  
3286 Agreement State requirements and who meets the requirements in 712;

3287 or

3288 **711.3** Is certified by a medical specialty board whose certification process has been  
3289 recognized by the NRC or an Agreement State under Appendix 7K or Appendix 7M,  
3290 and who meets the requirements in paragraph 712 of this section.

3291 or

3292 ~~712~~ Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State  
3293 requirements and who meets the requirements in 714;

3294 or

3295 ~~713~~ Is certified by a medical specialty board whose certification process has been recognized by the  
3296 NRC or an Agreement State under Appendix 7K or Appendix 7M, and who meets the  
3297 requirements in paragraph 714 of this section.

3298 or

3299 ~~714~~ Has satisfied the following criteria:

3300 **712** The physician:

3301 ~~714.12.1~~ Has ~~satisfactorily~~ **successfully** completed 80 hours of classroom and laboratory  
3302 training, applicable to parenteral administrations ~~listed in 7F2.1(2)(f)(iii), for which a~~  
3303 ~~written directive is required, of any beta emitter, or any photon-emitting radionuclide with~~  
3304 ~~a photon energy less than 150 keV, and/or parenteral administration of any other~~  
3305 ~~radionuclide for which a written directive is required. The training must include:~~

3306 (1) ~~The training must include:~~

3307 (a)(1) Radiation physics and instrumentation;

3308 (b)(2) Radiation protection;

Commented [JJ172]: For final publication, insert a page break such that each appendix begins on a new page.

This appendix is updated for consistency with the 2018 amendments to [10 CFR 35.396](#).

NRC RATS 2018-1  
NRC Compatibility B

Commented [JSJ173]: Provision replaced by 711.2 above.

Commented [JSJ174]: Provision replaced by 711.3 above.



3347 competency sufficient to function **is able to** independently **fulfill the radiation safety-**  
3348 **related duties** as an authorized user for the parenteral administration of unsealed  
3349 radioactive materials requiring a written directive. ~~The written attestation must be signed~~  
3350 ~~by a preceptor authorized user who:~~ **The attestation must be obtained from either:**

3351 (a) ~~Meets the requirements in 716, Appendix F, or Appendix I, or equivalent~~  
3352 ~~NRC or Agreement State requirements;~~

3353 and

3354 (b) ~~Meets the requirements in Appendix 7F must have experience in~~  
3355 ~~administering dosages as specified in 7F2.1(2)(f)(iii) and/or~~  
3356 ~~7F2.1(2)(f)(iv).~~

3357 (1) **A preceptor authorized user who meets the requirements in Appendix 7P,**  
3358 **Appendix 7F, 7I, or equivalent Agreement State or NRC requirements. A**  
3359 **preceptor authorized user who meets the requirements in Appendix 7F, 7I,**  
3360 **or equivalent Agreement State or NRC requirements, must have experience**  
3361 **in administering dosages in the same category or categories as the**  
3362 **individuals requesting authorized user status;**

3363 or

3364 (2) **A residency program director who affirms in writing that the attestation**  
3365 **represents the consensus of the residency program faculty where at least**  
3366 **one faculty member is an authorized user who meets the requirements in**  
3367 **Appendix 7P, Appendix 7F, Appendix 7I, or equivalent Agreement State or**  
3368 **NRC requirements, has experience in administering dosages in the same**  
3369 **dose category or categories as the individual requesting authorized user**  
3370 **status, and concurs with the attestation provided by the residency program**  
3371 **director. The residency training program must be approved by the**  
3372 **Residency Review Committee of the Accreditation Council for Graduate**  
3373 **Medical Education or the Royal College of Physicians and Surgeons of**  
3374 **Canada or the Council on Postdoctoral Training of the American**  
3375 **Osteopathic Association and must include training and experience**  
3376 **specified in 712.1 and 712.2.**

3377 and

3378 ~~715~~ ~~Meets the following recentness of training requirements:~~

3379 ~~715.1~~ ~~The training and experience required by Appendix 7I shall have been obtained within the~~  
3380 ~~7 years preceding the date of license application or amendment request;~~

3381 or

3382 ~~715.2~~ ~~The individual must have had related, documented, continuing education and experience~~  
3383 ~~since the required training and experience was obtained.~~

3384 or

3385 ~~716~~ ~~Meets the following requirements for an experienced authorized user for 7.36.5 uses:~~

3386 ~~716.1~~ ~~An individual identified as an authorized user for the medical use of radioactive material~~  
3387 ~~on a license issued by the NRC or Agreement State, a permit issued under an NRC or~~

Commented [JSJ175]: The recentness of training requirements have been relocated to a single location in 7.65.

Commented [JSJ176]: The requirements for an experienced authorized individual have been consolidated in Appendix 7P.

3388 ~~Agreement State broad scope license that authorizes medical use before October 25,~~  
3389 ~~2005, who perform only those medical uses for which they were authorized on that date~~  
3390 ~~are not required to comply with the training requirements of 711 through 715.~~

3391 ~~716.2—Individuals not required to comply with the training requirements of 711 through 715 may~~  
3392 ~~serve as preceptors for, and supervisors of, applicants seeking authorization on licenses~~  
3393 ~~for the same uses for which these individuals are authorized.~~  
3394

**PART 7, APPENDIX 7J: AUTHORIZED USER TRAINING FOR USE OF SEALED SOURCES AND MEDICAL DEVICES FOR DIAGNOSIS (7.40 USES)**

The licensee shall require an authorized user of a diagnostic sealed source for use in a device authorized under 7.40 to be a physician, dentist or podiatrist who has a current active State of Colorado license and: Except as provided in Appendix 7P, the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under 7.36 to be a physician, dentist, or podiatrist who:

**7J1** Is certified by a specialty board whose certification process includes all of the requirements in 7J2 and 7J3, and whose certification process has been recognized by the NRC or an Agreement State.; NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. Is certified by a specialty board whose certification process includes all of the requirements in 7J3 and 7J4 and whose certification process has been recognized by the NRC or an Agreement State. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;

or

**7J2** Has satisfied the following criteria: Is an authorized user for uses listed in 7.32 or equivalent NRC or Agreement State requirements; or

~~7J2.1~~ **7J3** Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. **The training must include**

(1) ~~The training must include:~~

(a1) Radiation physics and instrumentation;

(b2) Radiation protection;

(c3) Mathematics pertaining to the use and measurement of radioactivity;

(d4) Radiation biology;

and

~~7J3~~ **7J4** Has completed training in the use of the device for the uses requested.

and

~~7J4~~ Meets the following recentness of training requirements:

~~7J4.1~~ The training and experience required by Appendix 7J shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

~~7J4.2~~ The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

Commented [JJ177]: For final publication, insert a page break such that each appendix begins on a new page.

This appendix is updated for consistency with the 2018 amendments to [10 CFR 35.590](#).

3430 ~~7J5~~ — Meets the following requirements for an experienced authorized user for 7.40 uses:

3431 ~~7J5.1~~ — An individual identified as an authorized user for the medical use of radioactive material  
3432 on a license issued by the NRC or Agreement State, a permit issued under an NRC or  
3433 Agreement State broad scope license that authorizes medical use before October 25,  
3434 2005, who perform only those medical uses for which they were authorized on that date  
3435 are not required to comply with the training requirements of 7J1 through 7J4.;

3436 ~~7J5.2~~ — Individuals not required to comply with the training requirements of 7J1 through 7J4 may  
3437 serve as preceptors for, and supervisors of, applicants seeking authorization on licenses  
3438 for the same uses for which these individuals are authorized.  
3439

3440 PART 7, ~~APPENDIX 7K:~~ **AUTHORIZED USER TRAINING FOR THE USE OF MANUAL**  
3441 **BRACHYTHERAPY SOURCES (7.42 USES)**

Commented [JJ178]: For final publication, insert a page break such that each appendix begins on a new page.

This appendix is updated for consistency with the 2018 amendments to [10 CFR 35.490](#).

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3442 ~~The licensee shall require an authorized user of a manual brachytherapy source for the uses~~  
3443 ~~authorized under 7.42 to be a physician who has a current active State of Colorado license~~  
3444 ~~and: Except as provided in Appendix 7P, the licensee shall require an authorized of a manual~~  
3445 ~~brachytherapy source for the uses authorized under 7.42 to be a physician who:~~

3446 **7K1** Is certified by a medical specialty board whose certification process has been recognized by the  
3447 NRC or an Agreement State, ~~and who meets the requirements in paragraph 7K2.3 of this~~  
3448 ~~Appendix. NRC recognized specialty boards are posted on the NRC website at~~  
3449 ~~<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. The names of board~~  
3450 ~~certifications that have been recognized by the NRC or an Agreement State are posted on~~  
3451 ~~the NRC's Medical Uses Licensee Toolkit web page. To have its certification process~~  
3452 ~~recognized, a specialty board shall require all candidates for certification to:~~

3453 ~~7K1.1 To have its certification process recognized, a specialty board shall require all candidates~~  
3454 ~~for certification to:~~

3455 ~~(1)7K1.1~~ Successfully complete a minimum of 3 years of residency training in a radiation  
3456 oncology program approved by the Residency Review Committee of the Accreditation  
3457 Council for Graduate Medical Education or the Royal College of Physicians and  
3458 Surgeons of Canada or the ~~Committed on Post-Graduate~~ **Council on Postdoctoral**  
3459 ~~Training of the American Osteopathic Association; and~~

Commented [JSJ179]: "Committee" and "Post-Graduate" appear to be incorrect here and in NRC rule. "Council" appears to be consistent with other uses in part 35.

Clarification from NRC is pending

3460 **and**

3461 ~~(2)7K1.2~~ Pass an examination, administered by diplomates of the specialty board, that  
3462 tests knowledge and competence in radiation safety, radionuclide handling, treatment  
3463 planning, quality assurance, and clinical use of manual brachytherapy;

3464 or

3465 **7K2** ~~Has satisfied the following criteria:~~

3466 7K2.1 Has ~~satisfactorily~~ completed a structured educational program in basic radionuclide  
3467 handling techniques applicable to the ~~medical~~ use of manual brachytherapy sources, that  
3468 includes:

3469 (1) 200 hours of classroom and laboratory training in the following areas:

3470 (a) Radiation physics and instrumentation;

3471 (b) Radiation protection;

3472 (c) Mathematics pertaining to the use and measurement of radioactivity;

3473 (d) Radiation biology;

3474 **and**

3475 (2) 500 hours of work experience, under the supervision of an authorized user who  
3476 meets the requirements in ~~7K4~~ **Appendix 7P**, Appendix 7K, or equivalent NRC or

- 3477 Agreement State requirements at a medical ~~institution~~**facility authorized to use**  
3478 **radioactive materials under 7.42**, involving:
- 3479 (a) Ordering, receiving, and unpacking radioactive materials safely and  
3480 performing the related radiation surveys;
- 3481 (b) Checking survey meters for proper operation;
- 3482 (c) Preparing, implanting, and removing brachytherapy sources;
- 3483 (d) Maintaining running inventories of material on hand;
- 3484 (e) Using administrative controls to prevent a ~~misadministration~~**medical**  
3485 **event** involving the use of radioactive material;
- 3486 (f) Using emergency procedures to control radioactive material;
- 3487 and
- 3488 7K2.2 Has completed 3 years of supervised clinical experience in radiation oncology, under an  
3489 authorized user who meets the requirements in ~~7K4~~**Appendix 7P**, Appendix 7K, or  
3490 equivalent Agreement State or NRC requirements, ~~provided that the experience:~~
- 3491 (a) ~~Is~~**as** part of a formal training program approved by the Residency Review Committee **for**  
3492 **Radiation Oncology** of the Accreditation Council for Graduate Medical Education or **the**  
3493 Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral  
3494 Training of the American Osteopathic Association.; **This experience may be obtained**  
3495 **concurrently with the supervised work experience required by 7K2.1**
- 3496 and
- 3497 (b) ~~May be obtained concurrently with the supervised work experience required by~~  
3498 ~~7K2.1(2).~~
- 3499 and
- 3500 7K2.3 ~~Has provided written attestation(s), signed by a preceptor authorized user who meets the~~  
3501 ~~requirements in 7K4, Appendix 7K, or equivalent Agreement State or NRC requirements,~~  
3502 ~~that the individual has satisfactorily completed the requirements in 7K1.1(1), or~~  
3503 ~~paragraphs 7K2.1 and 7K2.2, and has achieved a level of competency sufficient to~~  
3504 ~~function independently as an authorized user of manual brachytherapy sources for the~~  
3505 ~~medical uses authorized under 7.42.~~**Has obtained written attestation that the**  
3506 **individual has satisfactorily completed the requirements in 7K2.1 and 7K2.2 and is**  
3507 **able to independently fulfill the radiation safety-related duties as an authorized**  
3508 **user of manual brachytherapy sources for the medical uses authorized under 7.42.**  
3509 **The attestation must be obtained from either:**
- 3510 (1) **A preceptor authorized user who meets the requirements in Appendix 7P,**  
3511 **Appendix 7K, or equivalent Agreement State or NRC requirements.**
- 3512 or
- 3513 (2) **A residency program director who affirms in writing that the attestation**  
3514 **represents the consensus of the residency program faculty where at least**  
3515 **one faculty member is an authorized user who meets the requirements in**

3516 Appendix 7P, Appendix 7K, or equivalent Agreement State or NRC  
3517 requirements, has experience in administering dosages in the same dose  
3518 category or categories as the individual requesting authorized user status,  
3519 and concurs with the attestation provided by the residency program  
3520 director. The residency training program must be approved by the  
3521 Residency Review Committee of the Accreditation Council for Graduate  
3522 Medical Education or the Royal College of Physicians and Surgeons of  
3523 Canada or the Council on Postdoctoral Training of the American  
3524 Osteopathic Association and must include training and experience  
3525 specified in 7K2.1 and 7K2.2.

3526 and

3527 ~~7K3~~ — Meets the following recentness of training requirements:

3528 ~~7K3.1~~ — The training and experience required by Appendix 7K shall have been obtained within  
3529 the 7 years preceding the date of license application or amendment request;

3530 or

3531 ~~7K3.2~~ — The individual must have had related, documented, continuing education and experience  
3532 since the required training and experience was obtained.

3533 or

3534 ~~7K4~~ — Meets the following requirements for an experienced authorized user for 7.42 uses:

3535 ~~7K4.1~~ — An individual identified as an authorized user for the medical use of radioactive material  
3536 on a license issued by the NRC or Agreement State, a permit issued under an NRC or  
3537 Agreement State broad scope license that authorizes medical use before October 25,  
3538 2005, who perform only those medical uses for which they were authorized on that date  
3539 are not required to comply with the training requirements of 7K1 through 7K3.

3540 ~~7K4.2~~ — Individuals not required to comply with the training requirements of 7K1 through 7K3 may  
3541 serve as preceptors for, and supervisors of, applicants seeking authorization on licenses  
3542 for the same uses for which these individuals are authorized.  
3543

3544 PART 7, ~~APPENDIX 7L: AUTHORIZED USER TRAINING FOR OPHTHALMIC USE OF STRONTIUM-~~  
3545 ~~90 (7.42 USES)~~

3546 ~~The licensee shall require an authorized user of a Strontium-90 source for ophthalmic radiotherapy~~  
3547 ~~authorized under 7.42 to be a physician who has a current active State of Colorado license and: Except~~  
3548 ~~as provided in Appendix 7P, the licensee shall require the authorized of strontium-90 for~~  
3549 ~~ophthalmic radiotherapy to be a physician who:~~

3550

3551 7L1 Is an authorized user under Appendix 7K or equivalent NRC or Agreement State requirements;

3552 or

3553 7L2 ~~Has satisfied the following criteria:~~

3554 7L2.1 Has ~~satisfactorily~~ completed 24 hours of classroom and laboratory training applicable to  
3555 the medical use of strontium-90 for ophthalmic radiotherapy. ~~The training must include:~~

3556 ~~(1) The training must include:~~

3557 ~~(a1) Radiation physics and instrumentation;~~

3558 ~~(b2) Radiation protection;~~

3559 ~~(c3) Mathematics pertaining to the use and measurement of radioactivity; and~~

3560 ~~(d4) Radiation biology;~~

3561 and

3562 ~~(2) 7L2.2~~ Supervised clinical training in ophthalmic radiotherapy under the supervision of  
3563 an authorized user at a medical institution, clinic, or private practice that includes the use  
3564 of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical  
3565 training must involve:

3566 ~~(a1) Examination of each individual to be treated;~~

3567 ~~(b2) Calculation of the dose to be administered;~~

3568 ~~(c3) Administration of the dose; and~~

3569 ~~(d4) Follow-up and review of each individual's case history;~~

3570 and

3571 ~~(3) 7L3.3~~ Has ~~provided~~ **obtained** written attestation(s), signed by a preceptor authorized  
3572 user who meets the requirements in ~~7L4~~ **Appendix 7P**, Appendix 7K, Appendix 7L, or  
3573 equivalent NRC or Agreement State requirements, that the individual has satisfactorily  
3574 completed the requirements of ~~7L2~~ **7L2.1 and 7L2.2** and ~~has achieved a level of~~  
3575 ~~competency sufficient to function independently as an authorized user of strontium-90 for~~  
3576 ~~ophthalmic radiotherapy uses authorized under 7.42.~~ **is able to independently fulfill the**  
3577 **radiation safety-related duties as an authorized user of strontium-90 for ophthalmic**  
3578 **use.**

Commented [JJ180]: For final publication, insert a page break such that each appendix begins on a new page.

[10 CFR 35.491](#)

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3579 and

3580 ~~7L3 — Meets the following recentness of training requirements:~~

3581 ~~7L3.1 — The training and experience required by Appendix 7L shall have been obtained within the~~  
3582 ~~7 years preceding the date of license application or amendment request;~~

3583 or

3584 ~~7L3.2 — The individual must have had related, documented, continuing education and experience~~  
3585 ~~since the required training and experience was obtained.~~

3586 or

3587 ~~7L4 — Meets the following requirements for an experienced authorized user for 7.42 ophthalmic~~  
3588 ~~radiotherapy uses:~~

3589 ~~7L4.1 — An individual identified as an authorized user for the medical use of radioactive material~~  
3590 ~~on a license issued by the NRC or Agreement State, a permit issued under an NRC or~~  
3591 ~~Agreement State broad scope license that authorizes medical use before October 25,~~  
3592 ~~2005, who perform only those medical uses for which they were authorized on that date~~  
3593 ~~are not required to comply with the training requirements of 7L1 through 7L3.~~

3594 ~~7L4.2 — Individuals not required to comply with the training requirements of 7L1 through 7L3 may~~  
3595 ~~serve as preceptors for, and supervisors of, applicants seeking authorization on licenses~~  
3596 ~~for the same uses for which these individuals are authorized.~~  
3597

**PART 7, APPENDIX 7M: AUTHORIZED USER TRAINING FOR USE OF SEALED SOURCES IN REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS (7.48 USES)**

~~The licensee shall require an authorized user of a sealed source for use in a device authorized under 7.48 to be a physician who has a current active State of Colorado license and:~~**Except as provided in Appendix 7P, the licensee shall require an authorized user of a sealed source for a use authorized under 7.48 to be a physician who:**

**7M1** Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in ~~paragraph 7M2.3 and 7M3.~~**of this Appendix. NRC recognized specialty boards are posted on the NRC website at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:**

~~7M1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:~~

~~(+)7M1.1~~ Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate~~**Council on Postdoctoral** Training of the American Osteopathic Association;

and

~~(+)7M1.2~~ Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy;

or

**7M2** ~~Has satisfied the following criteria:~~

7M2.1 Has ~~satisfactorily~~ completed a structured educational program in basic radionuclide ~~handling~~ techniques applicable to the use of ~~a sealed sources~~ in a therapeutic medical unit that includes:

(1) 200 hours of classroom and laboratory training in the following areas:

- (a) Radiation physics and instrumentation;
- (b) Radiation protection;
- (c) Mathematics pertaining to the use and measurement of radioactivity; **and**
- (d) Radiation biology;

and

**Commented [JJ181]:** For final publication, insert a page break such that each appendix begins on a new page.

This appendix is updated for consistency with the 2018 changes to [10 CFR 35.690](#).

NRC RATS 2018-1  
NRC Compatibility B

**Commented [JSJ182]:** "Committee" and "Post-Graduate" appear to be incorrect here and in NRC rule. "Council" appears to be consistent with other uses in part 35.

Clarification from NRC is pending.

- 3636 (2) 500 hours of ~~supervised~~ work experience, under the supervision of an authorized  
3637 user who meets the requirements in ~~7M5~~**Appendix 7P**, Appendix 7M, or  
3638 equivalent Agreement State or NRC requirements at a medical ~~institution~~**facility**  
3639 **that is authorized to use radioactive materials in 7.48**, involving:
- 3640 (a) Reviewing full calibration measurements and periodic spot checks;
- 3641 (b) Preparing treatment plans and calculating treatment doses and times;
- 3642 (c) Using administrative controls to prevent a ~~misadministration~~**medical**  
3643 **event** involving the use of radioactive material;
- 3644 (d) Implementing emergency procedures to be followed in the event of the  
3645 abnormal operation of the medical unit or console;
- 3646 (e) Checking and using survey meters; and
- 3647 (f) Selecting the proper dose and how it is to be administered;
- 3648 and
- 3649 7M2.2 Has completed 3 years of supervised clinical experience in radiation therapy, under an  
3650 authorized user who meets the requirements in ~~7M5~~**Appendix 7P**, Appendix 7M, or  
3651 equivalent Agreement State or NRC requirements, as part of a formal training program  
3652 approved by the Residency Review Committee for Radiation Oncology of the  
3653 Accreditation Council for Graduate Medical Education or the Royal College of Physicians  
3654 and Surgeons of Canada or the ~~Committee~~**Council** on Postdoctoral Training of the  
3655 American Osteopathic Association. This experience may be obtained concurrently with  
3656 the supervised work experience required by ~~paragraph 7M2.1(2) of this section; and;~~
- 3657 **and**
- 3658 7M2.3 ~~Has provided written attestation(s) that the individual has satisfactorily completed the~~  
3659 ~~requirements of 7M1 or 7M2.1 and 7M2.2, and 7M3, and has achieved a level of~~  
3660 ~~competency sufficient to function independently as an authorized user of each type of~~  
3661 ~~therapeutic medical unit for which the individual is requesting authorized user status. The~~  
3662 ~~written attestation must be signed by a preceptor authorized user who meets the~~  
3663 ~~requirements in 7M5, Appendix 7M, or equivalent Agreement State or NRC requirements~~  
3664 ~~for an authorized user for each type of therapeutic medical unit for which the individual is~~  
3665 ~~requesting authorized user status; Has obtained written attestation that the individual~~  
3666 ~~has satisfactorily completed the requirements in 7M2.1 and 7M2.2 and 7M3; and is~~  
3667 ~~able to independently fulfill the radiation safety-related duties as an authorized~~  
3668 ~~user of each type of therapeutic medical unit for which the individual is requesting~~  
3669 ~~authorized user status. The attestation must be obtained from either:~~
- 3670 (1) **A preceptor authorized user who meets the requirements in Appendix 7P,**  
3671 **Appendix 7M, or equivalent Agreement State or NRC requirements for the**  
3672 **type(s) of therapeutic medical unit for which the individual is requesting**  
3673 **authorized user status;**
- 3674 **or**
- 3675 (2) **A residency program director who affirms in writing that the attestation**  
3676 **represents the consensus of the residency program faculty where at least**  
3677 **one faculty member is an authorized user who meets the requirements in**

**Commented [JSJ183]:**

"Committee" appear to be incorrect here and in NRC rule.  
"Council" appears to be consistent with other uses in part 35.

Clarification from NRC is pending

3678 Appendix 7P, Appendix 7M, or equivalent Agreement State or NRC  
3679 requirements, for the type(s) of therapeutic medical unit for which the  
3680 individual is requesting authorized user status, and concurs with the  
3681 attestation provided by the residency program director. The residency  
3682 training program must be approved by the Residency Review Committee of  
3683 the Accreditation Council for Graduate Medical Education or the Royal  
3684 College of Physicians and Surgeons of Canada or the Council on  
3685 Postdoctoral Training of the American Osteopathic Association and must  
3686 include training and experience specified in 7M2.1 and 7M2.2.

3687 and

3688 **7M3** Has received training in device operation, safety procedures, and clinical use for the type(s) of  
3689 use for which authorization is sought. This training requirement may be satisfied by: **satisfactory**  
3690 **completion of a training program provided by the vendor for new users or by receiving**  
3691 **training supervised by an authorized user or authorized medical physicist, as appropriate,**  
3692 **who is authorized for the type(s) of use for which the individual is seeking authorization.**

3693 ~~7M3.1—Satisfactorily completing a vendor training program;~~

3694 or

3695 ~~7M3.2—By receiving training supervised by an authorized user or authorized medical physicist, as~~  
3696 ~~appropriate, who is authorized for the type(s) of use for which the individual is seeking~~  
3697 ~~authorization;~~

3698 and

3699 **7M4** — Meets the following recentness of training requirements:

3700 ~~7M4.1—The training and experience required by Appendix 7M shall have been obtained within~~  
3701 ~~the 7 years preceding the date of license application or amendment request;~~

3702 or

3703 ~~7M4.2—The individual must have had related, documented, continuing education and experience~~  
3704 ~~since the required training and experience was obtained.~~

3705 or

3706 **7M5** — Meets the following requirements for an experienced authorized user for 7.48 uses.

3707 ~~7M5.1—An individual identified as an authorized user for the medical use of radioactive material~~  
3708 ~~on a license issued by the NRC or Agreement State, a permit issued under an NRC or~~  
3709 ~~Agreement State broad scope license that authorizes medical use before October 25,~~  
3710 ~~2005, who perform only those medical uses for which they were authorized on that date~~  
3711 ~~are not required to comply with the training requirements of 7M1 through 7M4.~~

3712 ~~7M5.2—Individuals not required to comply with the training requirements of 7M1 through 7M4~~  
3713 ~~may serve as preceptors for, and supervisors of, applicants seeking authorization on~~  
3714 ~~licenses for the same uses for which these individuals are authorized.~~

3715  
3716

3717 **PART 7, APPENDIX 7N: NUCLEAR MEDICINE TECHNOLOGIST (NMT) ADEQUATE RADIATION**  
3718 **SAFETY TRAINING AND EXPERIENCE**

3719 **The licensee shall require the nuclear medicine technologist using radioactive materials under the**  
3720 **supervision of an authorized user to be an individual who:**

3721 **7N1** Has provided:

3722 7N1.1 Evidence of:

3723 (1) Current registration with The American Registry of Radiologic Technologists with  
3724 competency in Nuclear Medicine (ARRT(N));

3725 or

3726 (2) Current certification by The Nuclear Medicine Technology Certification Board in  
3727 Nuclear Medicine (CNMT);

3728 or

3729 (3) Being board-eligible to take the CNMT or ARRT(N) examination;

3730 or

3731 (4) Current certification by a ~~recognized~~-specialty board **recognized in writing by**  
3732 **the department(see 7N5);**

3733 and

3734 ~~7N1.2 Has provided written attestation(s), signed by a preceptor authorized user, that the~~  
3735 ~~individual has achieved a level of competency sufficient to function independently as a~~  
3736 ~~nuclear medicine technologist;~~

3737 (1) ~~Each preceptor authorized user supervising the experiential training required by~~  
3738 ~~Appendix 7N shall meet the requirements of Appendix 7N, or equivalent~~  
3739 ~~Agreement State or NRC requirements.~~

3740 or

3741 ~~7N2~~ Has satisfied the following criteria:

3742 ~~7N2.1 Has provided written attestation(s), signed by a preceptor authorized user, that the~~  
3743 ~~individual has satisfactorily completed 80 hours in a structured educational program in~~  
3744 ~~basic radionuclide handling techniques applicable to the medical use of unsealed~~  
3745 ~~radioactive materials, including:~~

3746 (1) ~~Classroom and laboratory training in the following areas:~~

3747 (a) ~~Radiation physics and instrumentation;~~

3748 (b) ~~Radiation protection;~~

3749 (c) ~~Mathematics pertaining to the use and measurement of radioactivity;~~

**Commented [JJ184]:** There are no equivalent requirements in NRC regulations. NRC does not recognize nuclear medicine technologists.

See also provision in 7.10 of the proposed rule.

**Commented [JJ185]:** For final publication, insert a page break such that each appendix begins on a new page.

**Commented [JSJ186]:** This proposed change eliminates the option of an alternate pathway for Nuclear Medicine Technologists, effectively requiring certification.

- 3750 (d) — Chemistry of radioactive material for medical use; and
- 3751 (e) — Radiation biology; and
- 3752 (2) — Work experience, involving:
- 3753 (a) — Ordering, receiving, and unpacking radioactive materials safely and  
3754 performing the related radiation surveys;
- 3755 (b) — Quality Control checking of instruments used to determine the activity of  
3756 dosages and performing checks for proper operation of survey meters;
- 3757 (c) — Calculating, measuring, and safely preparing patient or human research  
3758 subject dosages;
- 3759 (d) — Using administrative controls to prevent a misadministration involving the  
3760 use of unsealed radioactive material;
- 3761 (e) — Using procedures to contain spilled radioactive material safely and using  
3762 proper decontamination procedures; and
- 3763 (f) — Administering dosages to patients or human research subjects;
- 3764 ~~7N2.2~~ Has provided written attestation(s), signed by a preceptor authorized user, that the  
3765 individual has achieved a level of competency sufficient to function independently as a  
3766 nuclear medicine technologist;
- 3767 or
- 3768 **7N32** Has demonstrated adequate prior experience as:
- 3769 ~~7N32.1~~ A full-time nuclear medicine technologist for a minimum of two years performing during  
3770 the past five-year period under the supervision of an authorized user and has provided  
3771 written attestation(s), signed by a preceptor authorized user, that the individual has  
3772 achieved a level of competency sufficient to function independently as a nuclear medicine  
3773 technologist;
- 3774 or
- 3775 ~~7N32.2~~ An experienced nuclear medicine technologist working at a facility holding a Department  
3776 license before October 25, 2005. ~~(and thus need not comply with the requirements of~~  
3777 ~~7N2);~~
- 3778 ~~7N4~~ — Meets the following recentness of training requirements:
- 3779 ~~7N4.1~~ — The training and experience required by Appendix 7N shall have been obtained within the  
3780 7 years preceding the date of license application or amendment request;
- 3781 or
- 3782 ~~7N4.2~~ — The individual must have had related, documented, continuing education and experience  
3783 since the required training and experience was obtained.

3784 ~~7N5 — To be recognized by the Department, a specialty board shall require that each candidate for~~  
3785 ~~certification as a nuclear medicine technologist satisfactorily complete a certification process that~~  
3786 ~~includes all of the training requirements in 7N2.1.~~  
3787

~~PART 7, APPENDIX 70: RADIATION THERAPY TECHNOLOGIST (RTT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE RESERVED~~

~~The licensee shall require the radiation therapy technologist using radioactive materials under the supervision of an authorized user to be an individual who:~~

~~701 — Has provided:~~

~~701.1 — Evidence of:~~

~~(1) — Current registration with The American Registry of Radiologic Technologists with competency in Radiation Therapy;~~

~~or~~

~~(2) — Current certification by a recognized specialty board (see 705);~~

~~or~~

~~(3) — Being board-eligible to take the ARRT(T) examination;~~

~~or~~

~~(4) — Having successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology (consult the Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist, Joint Review Committee on Education in Radiologic Technology, 1988);~~

~~and~~

~~701.2 — Written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a radiation therapy technologist;~~

~~(1) — Each preceptor authorized user supervising the experiential training required by Appendix 70 shall meet the requirements of Appendix 70, or equivalent Agreement State or NRC requirements.~~

~~or~~

~~702 — Has satisfied the following criteria:~~

~~702.1 — Has provided written attestation(s), signed by a preceptor authorized user, that the individual has satisfactorily completed 80 hours in a structured educational program in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials, including:~~

~~(1) — Classroom and laboratory training in the following areas:~~

~~(a) — Radiation physics and instrumentation;~~

**Commented [JSJ187]:**

The requirements of this appendix is proposed for deletion as it is generally not used by the radiation program during licensing or compliance activities. The radiation program is generally unaware of radiation therapy technologists who are performing activities involving radioactive material. Requirements for radiation therapy technologists are generally dictated by the specific facilities occupational and/or accreditation requirements.

There is no equivalent to these requirements in 10 CFR Part 35.

- 3823 (b) — Radiation protection;
- 3824 (c) — Mathematics pertaining to the use and measurement of radioactivity;
- 3825 (d) — Radiation biology;
- 3826 and
- 3827 (2) — Work experience, involving:
- 3828 (a) — Ordering, receiving, and unpacking radioactive materials safely and  
3829 performing the related radiation surveys;
- 3830 (b) — Assisting the authorized user in simulating the patient for treatment;
- 3831 (c) — Preparing the patient for treatment;
- 3832 (d) — Implementing treatment plans as prescribed by the authorized user;
- 3833 (e) — Providing written documentation of treatment setup and patient  
3834 treatments;
- 3835 (f) — Quality control checks to determine that devices used to deliver the  
3836 radiation doses are in compliance with institutional standards and  
3837 performing checks for proper operation of survey meters;
- 3838 (g) — Preparing or assisting in the preparation of sources, and implantation  
3839 and removal of sealed sources;
- 3840 (h) — Delivering doses to patients or human research subjects under the  
3841 supervision of the authorized user;
- 3842 (i) — Maintaining running inventories of radioactive material on hand;
- 3843 (j) — Using administrative controls to prevent a misadministration involving the  
3844 use of radioactive material; and,
- 3845 (k) — Properly implementing emergency procedures;
- 3846 ~~7O2.2~~ Has provided written attestation(s), signed by a preceptor authorized user, that the  
3847 individual has achieved a level of competency sufficient to function independently as a  
3848 radiation therapy technologist;
- 3849 or
- 3850 ~~7O3~~ — Has demonstrated adequate prior experience as:
- 3851 ~~7O3.1~~ A full-time radiation therapy technologist for a minimum of two years performing during  
3852 the past five-year period under the supervision of an authorized user and has provided  
3853 written attestation(s), signed by a preceptor authorized user, that the individual has  
3854 achieved a level of competency sufficient to function independently as a radiation therapy  
3855 technologist;
- 3856 or

3857 ~~703.2—An experienced radiation therapy technologist working at a facility holding a Department~~  
3858 ~~license before October 25, 2005 (and thus need not comply with the requirements of~~  
3859 ~~702);~~

3860 **704** — Meets the following recentness of training requirements:

3861 ~~704.1—The training and experience required by Appendix 70 shall have been obtained within~~  
3862 ~~the 7 years preceding the date of license application or amendment request;~~

3863 ~~or~~

3864 ~~704.2—The individual must have had related, documented, continuing education and experience~~  
3865 ~~since the required training and experience was obtained.~~

3866 **705** — To be recognized by the Department, a specialty board shall require that each candidate for  
3867 certification as a radiation therapy technologist satisfactorily complete a certification process that  
3868 includes all of the training requirements in 702.1.  
3869

3870 **PART 7, APPENDIX 7P: TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER,**  
3871 **TELE THERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST,**  
3872 **AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR**  
3873 **PHARMACIST.**

3874 **7P1**

3875 **7P1.1 An individual identified on a department, NRC or an Agreement State license or a**  
3876 **permit issued by a department, NRC or an Agreement State broad scope licensee**  
3877 **or master material license permit or by a master material license permittee of**  
3878 **broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an**  
3879 **authorized medical physicist, a nuclear pharmacist or an authorized nuclear**  
3880 **pharmacist on or before July 15, 2020 need not comply with the training**  
3881 **requirements of Appendix 7A, 7B, or 7C, respectively, except the Radiation Safety**  
3882 **Officers and authorized medical physicists identified in 7P1.1 must meet the**  
3883 **training requirements in 7A4 of Appendix 7A or 7B3 of Appendix 7B, as**  
3884 **appropriate, for any material or uses for which they were not authorized prior to**  
3885 **this date.**

3886 **7P1.2 Any individual certified by the American Board of Health Physics in**  
3887 **Comprehensive Health Physics; American Board of Radiology; American Board of**  
3888 **Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of**  
3889 **Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical**  
3890 **Physics in radiation oncology physics; Royal College of Physicians and Surgeons**  
3891 **of Canada in nuclear medicine; American Osteopathic Board of Radiology; or**  
3892 **American Osteopathic Board of Nuclear Medicine on or before October 24, 2005,**  
3893 **need not comply with the training requirements of Appendix 7A to be identified as**  
3894 **a Radiation Safety Officer or as an Associate Radiation Safety Officer on an NRC or**  
3895 **an Agreement State license or NRC master material license permit for those**  
3896 **materials and uses that these individuals performed on or before October 24, 2005.**

3897 **7P1.3 Any individual certified by the American Board of Radiology in therapeutic**  
3898 **radiological physics, Roentgen ray and gamma ray physics, xray and radium**  
3899 **physics, or radiological physics, or certified by the American Board of Medical**  
3900 **Physics in radiation oncology physics, on or before October 24, 2005, need not**  
3901 **comply with the training requirements for an authorized medical physicist**  
3902 **described in Appendix 7B, for those materials and uses that these individuals**  
3903 **performed on or before October 24, 2005.**

3904 **7P1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used**  
3905 **only accelerator-produced radioactive materials, discrete sources of radium-226,**  
3906 **or both, for medical uses or in the practice of nuclear pharmacy at a Government**  
3907 **agency or Federally recognized Indian Tribe before November 30, 2007, or at all**  
3908 **other locations of use before August 8, 2009, or an earlier date as noticed by the**  
3909 **NRC, need not comply with the training requirements of Appendix 7A, 7B, or 7C**  
3910 **respectively, when performing the same uses. A nuclear pharmacist, who prepared**  
3911 **only radioactive drugs containing accelerator-produced radioactive materials, or a**  
3912 **medical physicist, who used only accelerator-produced radioactive materials, at**  
3913 **the locations and during the time period identified in 7P1.4, qualifies as an**  
3914 **authorized nuclear pharmacist or an authorized medical physicist, respectively, for**  
3915 **those materials and uses performed before these dates, for the purposes of the**  
3916 **regulations.**

3917 **7P2**

**Commented [JJ188]:**

This is a new appendix that parallels the requirements found in [10 CFR 35.57](#), which was amended in 2018.

Some requirements of this appendix are already contained in and are repeated multiple times in the existing Appendices of Part 7. Within this proposed rule, the requirements for an experienced authorized "individual" (such as RSO, medical physicist, authorized user, etc.) would be captured in one location rather than being repeated in multiple locations in the rule, parallel with the approach used in 10 CFR 35. This appendix will consolidate the requirements in one location and replace multiple (repeated) provisions found in other appendices.

As a result of the 2018 changes to the CFR, the following provisions are new: 7P1.2, 7P1.3, and 7P2.2(1) through (4). These provisions were added to federal rule in 2018 based on a stakeholder petition to NRC to address (correct) a grandfathering related issue that existed in the (federal) rule prior to 2018.

**NRC [RATS 2018-1](#)**

All provisions are NRC Compatibility B, with the exception of 7P1.4, which is compatibility D.

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- 7P2.1** Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before July 15, 2020, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Sections D through H.
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- 7P2.2** Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the NRC or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued by a NRC master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of Sections D through H for those materials and uses that these individuals performed on or before October 24, 2005, as follows:
- 3933  
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- (1) For uses authorized under 7.30 or 7.32, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;
- 3941  
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- (2) For uses authorized under 7.36, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;
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- (3) For uses authorized under 7.42 or 7.48, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and
- 3954  
3955  
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3959
- (4) For uses authorized under 7.40, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.
- 3960  
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3967
- 7P2.3** Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-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, need not comply with the training requirements of Sections D through H when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time

3968                    period identified in 7P2, qualifies as an authorized user for those materials and  
3969                    uses performed before these dates, for the purposes of the regulations.

3970    **7P3**    Individuals who need not comply with training requirements as described in Appendix 7P  
3971    may serve as preceptors for, and supervisors of, applicants seeking authorization on  
3972    department licenses for the same uses for which these individuals are authorized.

1 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT  
2 Hazardous Materials and Waste Management Division  
3 RADIATION CONTROL - LICENSING OF RADIOACTIVE MATERIAL

4 6 CCR 1007-1 PART 03

5 [Editor's Notes follow the text of the rules at the end of this CCR Document.]

6 \_\_\_\_\_  
7 **Adopted by the Board of Health on May 17, 2017May 20, 2020; effective June 30, 2017July 15,**  
8 **2020.**

9  
10 [ \* \* \* = Unaffected sections ]

11  
12 \* \* \*  
13 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers  
14 radioactive material in a device pursuant to the general license in 3.6.4.1:

- 15 \* \* \*  
16  
17  
18 (9) Shall transfer the device to another general licensee only:  
19 (a) Where the device remains in use at a particular location.

20 In such case the transferor shall give the transferee a copy of this  
21 regulation and any safety documents identified in the label on the device  
22 and within 30 days of the transfer, report to the Department the  
23 manufacturer's (or initial transferor's) name and model number and serial  
24 number of device transferred, the identity of the radionuclide(s) present  
25 and assayed or calculated activity present, the transferee's name and  
26 mailing address for the location of use, and the name, title, and phone  
27 number of the responsible individual identified by the transferee in  
28 accordance with 3.6.4.3(12) to have knowledge of and authority to take  
29 actions to ensure compliance with the appropriate regulations and  
30 requirements; or

31  
32 \* \* \*  
33  
34

**Commented [JJ1]:**  
EDITORIAL NOTE 1:  
These side margin comments as shown here are not part of the rule and are for information only with the intent to aid the reader in understanding the proposed changes in the draft regulations. All side margin comments will be removed prior to publication as a final rule.

EDITORIAL NOTE 2:  
Except where otherwise indicated, proposed changes herein are derived from NRC Regulatory Action Tracking System (RATS) 2018-1 to address changes made to 10 CFR Part 30, 32 and 35 which were amended in 2018.

NRC regulations may be found at:  
<https://www.nrc.gov/reading-rm/doc-collections/cfr/>

**Commented [JSJ2]:** Adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule, and the Colorado Register publication dates.

**Commented [JSJ3]:** Correction of typographical error by adding a comma between "name" and "title".

35 **3.6.11 General license for certain items and self-luminous products containing radium-226**

- 36  
37 **3.6.11.1 A general license is hereby issued to any person to acquire, receive,**  
38 **possess, use, or transfer, in accordance with the provisions of 3.6.11.2,**  
39 **3.6.11.3, and 3.6.11.4, radium-226 contained in the following products**  
40 **manufactured prior to November 30, 2007.**
- 41  
42 (1) **Antiquities originally intended for use by the general public. For the**  
43 **purposes of 3.6.11, antiquities mean products originally intended for use**  
44 **by the general public and distributed in the late 19th and early 20th**  
45 **centuries, such as radium emanator jars, revigators, radium water jars,**  
46 **radon generators, refrigerator cards, radium bath salts, and healing pads.**
- 47  
48 (2) **Intact timepieces containing greater than 0.037 megabecquerel (1**  
49 **microcurie), nonintact timepieces, and timepiece hands and dials no longer**  
50 **installed in timepieces.**
- 51  
52 (3) **Luminous items installed in air, marine, or land vehicles.**
- 53  
54 (4) **All other luminous products, provided that no more than 100 items are**  
55 **used or stored at the same location at any one time.**
- 56  
57 (5) **Small radium sources containing no more than 0.037 megabecquerel (1**  
58 **microcurie) of radium-226. For the purposes of this paragraph, "small**  
59 **radium sources" means discrete survey instrument check sources,**  
60 **sources contained in radiation measuring instruments, sources used in**  
61 **educational demonstrations (such as cloud chambers and**  
62 **spinhartiscopes), electron tubes, lightning rods, ionization sources, static**  
63 **eliminators, or as designated by the department[NRC\*\*].**
- 64  
65 **3.6.11.2 Persons who acquire, receive, possess, use, or transfer radioactive**  
66 **material under the general license issued in 3.6.11 are exempt from the**  
67 **provisions of 3.15.4, Part 4, and Part 10, to the extent that the receipt,**  
68 **possession, use, or transfer of radioactive material is within the terms of**  
69 **the general license; provided, however, that this exemption shall not be**  
70 **deemed to apply to any such person specifically licensed under Part 3.**
- 71  
72 **3.6.11.3 Any person who acquires, receives, possesses, uses, or transfers**  
73 **radioactive material in accordance with the general license in 3.6.11:**
- 74  
75 (1) **Shall notify the department should there be any indication of possible**  
76 **damage to the product so that it appears it could result in a loss of the**  
77 **radioactive material. A report containing a brief description of the event,**  
78 **and the remedial action taken, must be furnished to the department within**  
79 **30 days.**
- 80  
81 (2) **Shall not abandon products containing radium-226. The product, and any**  
82 **radioactive material from the product, may only be disposed of according**  
83 **to Part 4, Section 4.39.2 or by transfer to a person authorized by a specific**  
84 **license to receive the radium-226 in the product or as otherwise approved**  
85 **by the department.**
- 86  
87 (3) **Shall not export products containing radium-226 except in accordance with**  
88 **10 CFR 110.**
- 89

**Commented [JSJ4]:** This provision is added for consistency with [10 CFR 31.12](#), which was omitted during prior rule amendments.

The provision provides for a general license for antiquities and similar items of low radiological hazard. The provision is expected to provide some regulatory relief for facilities and individuals owning the described devices.

NRC Compatibility C

CROSS REFERENCES:  
3.6.11 = 10 CFR 31.12(a)  
3.6.11.2 = 10 CFR 31.12(b)  
3.6.11.3 = 10 CFR 31.12(c)  
3.6.11.4 = 10 CFR 31.12(d)  
3.6.11 = 10 CFR 31.12(a)

- 90 (4) Shall dispose of products containing radium-226 at a disposal facility  
91 authorized to dispose of radioactive material in accordance with any  
92 Federal or State solid or hazardous waste law, including the Solid Waste  
93 Disposal Act, as authorized under the Energy Policy Act of 2005, by  
94 transfer to a person authorized to receive radium-226 by a specific license  
95 issued under Part 3, or equivalent regulations of an Agreement State, NRC  
96 or as otherwise approved by the department.  
97  
98 (5) Shall respond to written requests from the department to provide  
99 information relating to the general license within 30 calendar days of the  
100 date of the request, or other time specified in the request. If the general  
101 licensee cannot provide the requested information within the allotted time,  
102 it shall, within that same time period, request a longer period to supply the  
103 information by providing the department, a written justification for the  
104 request.  
105  
106 3.6.11.4 The general license in 3.6.11 does not authorize the manufacture,  
107 assembly, disassembly, repair, or import of products containing radium-  
108 226, except that timepieces may be disassembled and repaired.

109

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\* \* \*

111

112 **DECOMMISSIONING WARRANTY**

113 3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a  
114 dollar amount determined by the ~~agency~~department as necessary to protect public  
115 health and safety, to ensure corrective action during operation, to ensure  
116 decontamination and decommissioning of a facility and disposal of radioactive materials  
117 in the event of abandonment, default or inability of the licensee to meet the requirements  
118 of the Act, these regulations, or the license.

119 3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

- 120 (1) Each licensee authorized to possess and use greater than 370 MBq (10 mCi) of  
121 source material in a readily dispersible form; and  
122  
123 (2) Each licensee authorized to possess and use radioactive material with a half-life  
greater than 120 days, in quantities:  
124 (a) Greater than  $10^3$  times the applicable quantity of Schedule 3B in  
125 unsealed form. For a combination of isotopes if R divided by  $10^3$  is  
126 greater than 1 (unity rule), where R is defined here as the sum of the  
127 ratios of the quantity of each isotope to the applicable value in Schedule  
128 3B.  
129 (b) Greater than  $10^{10}$  times the applicable quantity of Schedule 3B in sealed  
130 sources or plated foils. For a combination of isotopes if R divided by  $10^{10}$   
131 is greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).  
132 (c) 370 Bq (0.01  $\mu$ Ci) shall be used as the Schedule 3B value for any alpha  
133 emitting radionuclide not listed in Schedule 3B, or mixtures of alpha

**Commented [JSJ5]:** Here, and in subsequent sections – where applicable – the more generic “agency” is replaced with “department” for clarity and specificity.

The model regulations of the Conference of Radiation Control Program Directors (CRCPD) Inc., on which this rule is partly based, typically use the term “agency” in its model rules since the actual regulatory agency regulating sources of radiation varies from state to state. The intent is that each regulatory agency will modify the language and specify its specific name or title.

134 emitters of unknown composition, for the purpose of determining if the  
135 quantity of licensed radioactive material requires a decommissioning  
136 warranty or a decommissioning funding plan as defined in 3.9.6.

- 137 (3) Former U.S. Atomic Energy Commission or NRC licensed facilities;
- 138 (4) Radioactive waste collection and/or processing licensees;
- 139 (5) Radioactive waste disposal licensees;
- 140 (6) Source material milling licensees;
- 141 (7) Ore refineries; and
- 142 (8) Other persons with, or applicants for, a specific license as determined by the  
143 ~~agency~~department.

144

145 \* \* \*

146

147 3.9.6.3 Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish  
148 an ~~agency~~department-approved decommissioning funding plan to assure the availability  
149 of funds for decommissioning activities conducted over the life of the licensed facility.

150

151 \* \* \*

152

153 3.11.5 Specific licenses of broad scope are subject to the following conditions:

154 3.11.5.1 Unless specifically authorized, persons licensed pursuant to 3.11 shall not:

- 155 (1) Conduct tracer studies in the environment involving direct release of radioactive  
156 material;
- 157 (2) Receive, acquire, own, possess, use; or transfer devices containing 3.7 PBq (100  
158 kCi) or more of radioactive material in sealed sources used for irradiation of  
159 materials;
- 160 (3) Conduct activities for which a specific license issued by the Department under  
161 ~~3-10, 3-12, or Parts 7, 14, and 18~~Parts 3, 5, or 7 is required; or

162

163 \* \* \*

164

165 ~~3.12.10~~ Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for  
166 Medical Use.

**Commented [JSJ6]:** Provision is modified to correct a past error in cross references, consistent with similar requirements in 10 CFR 33.17.

**Commented [JSJ7]:** A sentence is added to this provision, consistent with 2018 amendments to [10 CFR 32.72](#).

NRC [RATS 2018-1](#)  
NRC Compatibility B

- 167 3.12.10.1 An application for a specific license to manufacture, prepare, or transfer for  
168 commercial distribution radioactive drugs **containing radioactive material for**  
169 **use by persons authorized underfor medical use pursuant to** Part 7 will be  
170 approved if:
- 171 (1) The applicant satisfies the general requirements specified in 3.9;
- 172 (2) The applicant submits evidence that the applicant is at least one of the following:
- 173 (a) Registered or licensed with the U.S. Food and Drug Administration  
174 (FDA) as the owner or operator of a drug establishment that engages in  
175 the manufacture, preparation, propagation, compounding, or processing  
176 of a drug under 21 CFR 207.20(a);
- 177 (b) Registered or licensed with the State Board of Pharmacy as a drug  
178 manufacturer;
- 179 (c) Licensed as a pharmacy by the State Board of Pharmacy;
- 180 (d) Operating as a nuclear pharmacy within a Federal medical institution; or
- 181 (e) A Positron Emission Tomography (PET) drug production facility  
182 registered with the State Board of Pharmacy.
- 183 (3) The applicant submits information on the radionuclide; **the** chemical and  
184 physical form; the maximum activity per vial, syringe, generator, or other  
185 container of the radioactive drug; and the shielding provided by the packaging **of**  
186 **the radioactive material** to show it is appropriate for safe handling and storage of  
187 **the** radioactive drugs by medical use licensees; and
- 188 **(4)** The applicant ~~has procedures to assure~~ **commits to** the following labeling  
189 requirements:
- 190 (a) A label ~~shall be~~ **is** affixed to each transport radiation shield, (whether it is  
191 constructed of lead, glass, plastic, or other material) of a radioactive drug  
192 to be transferred for commercial distribution.
- 193 (i) The label ~~shall~~ **must** include the radiation symbol prescribed in  
194 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL" or  
195 "DANGER, RADIOACTIVE MATERIAL"; the name of the  
196 radioactive drug or its abbreviation; and the quantity of  
197 radioactivity at a specified date and time.
- 198 (ii) For radioactive drugs with a half-life greater than 100 days, the  
199 time may be omitted.
- 200 (b) A label ~~shall be~~ **is** affixed to each syringe, vial, or other container used to  
201 hold a radioactive drug to be transferred for commercial distribution. ~~and~~  
202 ~~shall include:~~ **The label must include:**
- 203 (i) The radiation symbol prescribed in 4.27 and the words  
204 "CAUTION, RADIOACTIVE MATERIAL" or "DANGER,  
205 RADIOACTIVE MATERIAL"; and

**Commented [JSJ8]:** This provision (equivalent to 10 CFR 32.72(a)(4)) is amended to clarify that the applicant "commits to" rather than "satisfies" the labeling requirements. This was done to remove ambiguity related to the label contents under the current wording – as the proposed wording is more explicit.

- 206 (ii) An identifier that ensures that the syringe, vial or other container  
207 can be correlated with the information on the transport radiation  
208 shield label.
- 209 3.12.10.2 ~~A radioactive materials licensee who is also licensed by the State Board of~~  
210 ~~Pharmacy:~~ **A licensee described by 3.12.10.1(2)(c) or 3.12.10.1(2)(d):**
- 211 (1) May prepare radioactive drugs for medical use, as defined in **Part 1, Section** 1.2  
212 and Part 7, provided that the radioactive drug is prepared by either:
- 213 (a) An authorized nuclear pharmacist, as specified in 3.12.10.2(2) or  
214 3.12.10.2(4), or
- 215 (b) An individual under the direct supervision of an authorized nuclear  
216 pharmacist as specified in **Part 7, Section** 7.10;
- 217 (2) May allow a pharmacist to work as an authorized nuclear pharmacist if:
- 218 (a) This individual qualifies as an Authorized Nuclear Pharmacist as defined  
219 in **Part 7, Section** 7.2;
- 220 (b) This individual meets the requirements specified in Part 7, Appendix 7C2  
221 **and Section 7.65**, and the licensee has received ~~a Department an~~  
222 **approved** license amendment identifying this individual as an authorized  
223 nuclear pharmacist; or
- 224 (c) This individual is designated as an authorized nuclear pharmacist in  
225 accordance with 3.12.10.2(4).
- 226 (3) The actions authorized in 3.12.10.2(1) and 3.12.10.2(2) are permitted in spite of  
227 more restrictive language in license conditions.
- 228 (4) May designate a pharmacist (as defined in **Part 7, Section** 7.2) as an authorized  
229 nuclear pharmacist if:
- 230 (a) The individual was a nuclear pharmacist preparing only radioactive drugs  
231 containing accelerator-produced radioactive material, and
- 232 (b) The individual practiced at a pharmacy at a Government agency or  
233 Federally recognized Indian Tribe before November 30, 2007 or at all  
234 other pharmacies before August 8, 2009, or an earlier date as noticed by  
235 the NRC.
- 236 (5) Shall provide to the Department: ~~a copy of each individual's:~~
- 237 (a) **A copy of each individual's** ~~C~~certification by a specialty board whose  
238 certification process has been recognized by the NRC or an Agreement  
239 State as specified in Part 7, Appendix 7C ~~with the written attestation~~  
240 ~~signed by a preceptor as required by Part 7, Appendix 7C, Section~~  
241 ~~7C2.2;~~ or
- 242 (b) **The** Department, NRC or Agreement State license ~~that allows such~~  
243 ~~work,~~ or
- 244 (c) NRC master materials licensee permit, or

**Commented [JSJ9]:** The proposed changes are being made for consistency with the 2018 amendments to [10 CFR 32.72\(b\)\(5\)\(i\)](#).

Consistent with other changes related to training and experience requirements in Part 7, the proposed rule removes the written attestation requirement for individuals wanting to be listed as an Authorized Nuclear Pharmacist whose board certification has been recognized by NRC or an Agreement State.

The proposed rule provides some regulatory relief for licensees since the current rule requires both the written attestation and board certification.

NRC [RATS 2018-1](#)  
NRC Compatibility B

- 245 (d) The permit issued by a licensee or NRC master materials permittee of  
246 broad scope or the authorization from a commercial nuclear pharmacy  
247 authorized to list its own authorized nuclear pharmacist, or
- 248 (e) Documentation that only accelerator-produced radioactive materials  
249 were used in the practice of nuclear pharmacy at a Government agency  
250 or Federally recognized Indian Tribe before November 30, 2007 or at all  
251 other locations of use before August 8, 2009, or an earlier date as  
252 noticed by the NRC; and
- 253 (f) A copy of the State pharmacy licensure or registration, no later than 30  
254 days after the date that the licensee allows, under 3.12.10.2(2)(a) and  
255 3.12.10.2(2)(c), the individual to work as an authorized nuclear  
256 pharmacist.
- 257 **3.12.10.3** A licensee shall possess and use instrumentation to measure the radioactivity of  
258 radioactive drugs.
- 259 (1) The licensee shall have procedures for use of the instrumentation.
- 260 (2) The licensee shall measure, by direct measurement or by combination of  
261 measurements and calculations, the amount of radioactivity in dosages of alpha-,  
262 beta- or photon-emitting radioactive drugs prior to transfer for commercial  
263 distribution.
- 264 (3) In addition, the licensee shall:
- 265 (a) Perform tests before initial use, periodically, and following repair, on  
266 each instrument for accuracy, linearity and geometry dependence, as  
267 appropriate for the use of the instrument; and make adjustments when  
268 necessary; and
- 269 (b) Check each instrument for constancy and proper operation at the  
270 beginning of each day of use.
- 271 **3.12.10.4** A licensee shall satisfy the labeling requirements in 3.12.10.1(4).
- 272 3.12.10.45 Nothing in this section relieves the licensee from complying with applicable FDA,  
273 Federal, and state requirements governing radioactive drugs.
- 274 3.12.11 Reserved.
- 275 3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical  
276 Use.
- 277 3.12.12.1 An application for a specific license to manufacture and distribute sources and  
278 devices containing radioactive material to persons licensed pursuant to Part 7 for use as  
279 a calibration, transmission, or reference source or for the uses listed in **Part 7, Sections**  
280 7.19, 7.40, 7.42, 7.48 and 7.62 will be approved if:
- 281 (1) The applicant satisfies the general requirements in 3.9 of this part;
- 282 (2) The applicant submits sufficient information regarding each type of source or  
283 device pertinent to an evaluation of its radiation safety, including:

**Commented [JSJ10]:** This provision formatted for alignment.

**Commented [JSJ11]:** This is a new provision, added for consistency with the 2018 amendments to [10 CFR 32.72\(d\)](#).

The provision is added to clarify that the labeling requirements that applicants commit to are also applicable to current licensees. The language of the current rule lacks clarity in this regard.

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- 284 (a) The radioactive material contained, its chemical and physical form, and  
285 amount,
- 286 (b) Details of design and construction of the source or device,
- 287 (c) Procedures for, and results of, prototype tests to demonstrate that the  
288 source or device will maintain its integrity under stresses likely to be  
289 encountered in normal use and accidents,
- 290 (d) For devices containing radioactive material, the radiation profile of a  
291 prototype device,
- 292 (e) Details of quality control procedures to assure that production sources  
293 and devices meet the standards of the design and prototype tests,
- 294 (f) Procedures and standards for calibrating sources and devices,
- 295 (g) Legend and methods for labeling sources and devices as to their  
296 radioactive content, and
- 297 (h) Instructions for handling and storing the source or device from the  
298 radiation safety standpoint; these instructions are to be included on a  
299 durable label attached to the source or device or attached to a  
300 permanent storage container for the source or device; provided, that  
301 instructions which are too lengthy for such label may be summarized on  
302 the label and printed in detail on a brochure which is referenced on the  
303 label;
- 304 (3) The label affixed to the source or device, or to the permanent storage container  
305 for the source or device, contains information on the radionuclide, quantity, and  
306 date of assay, and a statement that the source or device is licensed by the  
307 Department for distribution to persons licensed pursuant to **Part 7, Sections 7.40**  
308 and 7.42 or under equivalent licenses of NRC or an Agreement State, provided  
309 that such labeling for sources which do not require long term storage may be on  
310 a leaflet or brochure which accompanies the source;
- 311 (4) The source or device has been registered in the Sealed Source and Device  
312 Registry.
- 313
- 314 \* \* \*
- 315 (6) Report to NRC all transfers of industrial products or devices to persons for use  
316 under NRC general license in Section 40.25 of 10 CFR Part 40 (January 1,  
317 2010).
- 318 (a) Such report shall identify each general licensee by name and address,  
319 an individual by name and/or position who may constitute a point of  
320 contact between the **agencyNRC** and the general licensee, the type and  
321 model number of device transferred, and the quantity of depleted  
322 uranium contained in the product or device.

324 \* \* \*

325 3.15.6 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-  
326 99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator  
327 eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination,  
328 respectively, in accordance with Part 7. The licensee shall record the results of each test and  
329 retain each record for 3 years after the record is made. **The licensee shall report the results of**  
330 **any test that exceeds the permissible concentration listed in Part 7, Section 7.33.1 at the**  
331 **time of generator elution, in accordance with Part 7, Section 7.33.5.**

**Commented [JSJ12]:** A sentence is added to this provision, consistent with 2018 amendments to [10 CFR 30.34](#).

The language adds a reporting requirement for when a generator eluate exceeds specified values.

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332 \* \* \*

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334

335 3.16.2.7 Each licensee or person responsible for a facility or site which includes a non-  
336 exempt source of radiation or which may be contaminated by residual  
337 radioactivity shall, no less than 30 days before vacating or relinquishing  
338 possession or control of the facility or site, notify the **agencydepartment**, in  
339 writing, of the intent to vacate.

**Commented [JSJ13]:** See prior similar comment relating to this change in language.

340 \* \* \*

341

342 3.19 **AgencyDepartment** Action on Applications to Renew and Amend.

343 \* \* \*

344

345

346 PART 3, SCHEDULE 3B: EXEMPT QUANTITIES (3.3.2)

347

348

\* \* \*

349

[NO CHANGES TO MAIN BODY OF SCHEDULE 3B]

350

351 **Note 1:** For purposes of 3.9.5.3(5)(a)(2)(a) and 3.9.5.3(5)(b)(2)(b) where there is involved a combination  
352 of radionuclides, the limit for the combination should be derived as follows:

353 Determine the amount of each radionuclide possessed and **divide by** 1,000 times the amount in  
354 Schedule 3B for each of those radionuclides when not in combination. The sum of the ratios of those  
355 quantities may not exceed 1.

356 Example:

$$\frac{\text{Amount of Radionuclide A possessed}}{1000 \times \text{Schedule 3B quantity for Radionuclide A.}} + \frac{\text{Amount of Radionuclide B possessed}}{1000 \times \text{Schedule 3B quantity for Radionuclide B}} \leq 1$$

357 **Note 2:** To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

358 Example: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

359

360

361

\* \* \*

362

363 [NO CHANGES TO REMAINDER OF RULE FOLLOWING FOOTNOTES OF SCHEDULE 3B]

364

365

**Commented [JSJ14]:** Correction of cross-reference errors in footnotes to Schedule 3B as item "(5)" does not exist.

GOOGLE FORM - RAC MEETING MINUTES APPROVAL

Timestamp	Email Address	Please enter your name:	For the RAC meeting minutes of October 17, 2019:
12/30/2019 12:43:35	[REDACTED]	Jennifer Stickel	I APPROVE the meeting minutes as written.
12/30/2019 16:48:51	[REDACTED]	Selina Muccio	I APPROVE the meeting minutes as written.
12/31/2019 11:38:02	[REDACTED]	Riad Safadi	I APPROVE the meeting minutes as written.
1/2/2020 10:57:44	[REDACTED]	Jennifer Kwak	I APPROVE the meeting minutes as written.
1/6/2020 11:38:42	[REDACTED]	Tom Johnson	I APPROVE the meeting minutes as written.
1/15/2020 9:22:34	[REDACTED]	Vicki LaRue	I APPROVE the meeting minutes as written.
1/15/2020 9:32:42	[REDACTED]	steve brown	I APPROVE the meeting minutes as written.