

1 **DRAFT 1 07/21/2022**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS**

5 **6 CCR 1007-1 Part 07**

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

7 _____
 8 **Adopted by the Board of Health ~~June 17, 2020~~ **October 19, 2022**, effective date ~~August 14,~~
 9 ~~2020~~ **December 15, 2022**.**

10 **PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS**

11 **USE OF RADIONUCLIDES IN THE HEALING ARTS**

12 **Section A – General Information**

13 **7.1 Purpose and scope.**

14 7.1.1 Authority

15 Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-
 16 108, 25-1.5-101(1)(l), and 25-11-104, CRS.

17 7.1.2 Basis and Purpose.

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

20 7.1.3 Scope.

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

27 7.1.4 Applicability.

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

30 7.1.5 Published material incorporated by reference.

31 7.1.5.1 Throughout this Part 7, federal regulations, state regulations, and standards or guidelines
 32 of outside organizations have been adopted and incorporated by reference. Unless a
 33 prior version of the incorporated material is otherwise specifically indicated, the materials
 34 incorporated by reference cited herein include only those versions that were in effect as
 35 of the most recent effective date of this Part 7 (~~August 2020~~ **December 15, 2022**), and not
 36 later amendments or editions of the incorporated material.

Commented [JSJ1]:

Editorial note 1: All comments (such as this one) shown in the right side margin of this draft document are for information purposes only to assist the reader in understanding the proposed rule change during the review and comment process.

These side margin notes are **not** part of the rule and all comments will be deleted prior to publication of the final rule by the Colorado Secretary of State.

Editorial note 2: Alignment and formatting corrections and minor typographical adjustments may be made in the rule and may not be specifically identified with a side margin comment.

Editorial note 3: The acronym "RATS 2021-1" referenced in the side margin comments of this draft refers to the U.S. Nuclear Regulatory Commission (NRC) regulation amendment tracking system (RATS). This system and documents are used to identify and summarize changes to federal regulations that may be required for adoption by an NRC agreement state. To maintain agreement state status, and be consistent with statute, Colorado's radiation regulations must be compatible with federal regulations of the NRC.

Colorado statute also prescribes that the radiation control regulations must be consistent with the model regulations of the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD model regulation equivalent to part 7 was last updated in 2003, and does not yet reflect federal rule changes since that time.

Editorial note 4: This is not a complete rule. Some unaffected sections or provisions have been removed from the rule and are not shown in this draft. Unaffected sections/provisions are denoted with a " * * * *".

Commented [JSJ2]:

The stated adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule by the Board, and the Colorado Register publication dates.

The anticipated dates are based on the annual rulemaking schedule (regulatory agenda) for the Department which may be found [online](#).

37 [* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

38 * * *

39 **7.2 Definitions.**

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

41 * * *

42 “Authorized medical physicist” (AMP) means an individual who meets the requirements of
43 Appendix 7B; or

44 (1) Is identified as an authorized medical physicist or teletherapy physicist on:

- 45 a. A specific medical ~~use~~ license issued by the Department, NRC, or
46 Agreement State;
- 47 b. A medical use permit issued by an NRC master material
48 ~~license~~licensee;
- 49 c. A permit issued by an NRC or Agreement State broad scope medical
50 use licensee; or
- 51 d. A permit issued by an NRC master material license broad scope medical
52 use ~~license~~permittee.

53 “Authorized nuclear pharmacist” (ANP) means a pharmacist who meets the requirements of
54 Appendix 7C; or

55 (1) Is identified as an authorized nuclear pharmacist on:

- 56 a. A specific license issued by the Department, NRC, or Agreement State
57 that authorizes medical use or the practice of nuclear pharmacy;
- 58 b. A permit issued by an NRC master material ~~license~~licensee that
59 authorizes medical use or the practice of nuclear pharmacy;
- 60 c. A permit issued by an NRC or Agreement State broad scope medical
61 use licensee that authorizes medical use or the practice of nuclear
62 pharmacy; or
- 63 d. A permit issued by an NRC master material license broad scope medical
64 use ~~permitee~~permittee that authorizes medical use or the practice of
65 nuclear pharmacy; or

66 (2) Is identified as an authorized nuclear pharmacist by a commercial nuclear
67 pharmacy that has been authorized to identify authorized nuclear pharmacists; or

68 (3) Is designated as an authorized nuclear pharmacist in accordance with Part 3.

69 “Authorized user” (AU) means a physician, dentist, or podiatrist who meets the applicable
70 requirements of Appendix 7D through Appendix 7M; or

71 (1) Is identified as an authorized user on:

Commented [JSJ3]: Select definitions in 7.2 are updated for consistency with federal rule language and for consistency with formatting of Colorado rule.

Commented [JSJ4]: Minor wording corrections are made, consistent with the current language in [10 CFR Part 35.2](#).

Commented [JSJ5]: Minor wording corrections are made, consistent with the current language in [10 CFR Part 35.2](#).

Commented [JSJ6]: Minor wording corrections are made, consistent with the current language in [10 CFR Part 35.2](#).

- 72 a. A Department, NRC, or Agreement State license that authorizes the
- 73 medical use of radioactive material;
- 74 b. A permit issued by an NRC master material ~~license~~**licensee** that is
- 75 authorized to permit the medical use of radioactive material;
- 76 c. A permit issued by an NRC or Agreement State specific licensee of
- 77 broad scope that is authorized to permit the medical use of radioactive
- 78 material; or
- 79 d. A permit issued by an NRC master material license broad scope
- 80 ~~permitee~~**permittee** that is authorized to permit the medical use of
- 81 radioactive material.

* * *

82 "Ophthalmic physicist" means an individual who:

- 83 (1) Meets the requirements in 7.41.6.1(2) and 7.65; and
- 84 (2) Is identified as an ophthalmic physicist on a:
 - 85 a. Specific medical use license issued by the Department, NRC or an
 - 86 Agreement State;
 - 87 b. Permit issued by the Department, NRC or Agreement State broad scope
 - 88 medical use licensee;
 - 89 c. Medical use permit issued by a NRC master material licensee; or
 - 90 d. Permit issued by a NRC master material ~~licensee~~**license** broad scope
 - 91 medical use permittee.
 - 92

* * *

93
94 "Sealed Source and Device Registry" means the national registry that contains **all** the registration

95 certificates, ~~maintained~~**generated** by **both** the Nuclear Regulatory Commission **and the**

96 **Agreement States**, that summarize the radiation safety information for the sealed sources and

97 devices and describe the licensing and use conditions approved for the product.

* * *

98
99 7.3.1.1 A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer

100 radioactive material for medical use only in accordance with a specific license issued by

101 the Department, an Agreement State or NRC, or as allowed in ~~7.3.1.1 or~~ 7.3.1.2.

* * *

102
103 7.3.2.3 A licensee not authorized pursuant to **Part 3, Section 3.11** shall apply for and receive

104 approval of a specific amendment to its Department license before conducting research

105 involving human subjects;

* * *

106
107 7.3.4.5 An applicant that satisfies the requirements specified in **Part 3, Section 3.11** may apply

108 for a Type A specific license of broad scope.

Commented [JSJ7]:
Updated for consistency with similar phrasing in other proposed changes in this rule due to recent changes in federal rule.

Note - we believe that current wording in federal rule (10 CFR 35.2) for this provision is incorrect and inconsistent with other recent federal rule changes. This proposed change has been verified with NRC.

[NRC Compatibility B](#)

Commented [JSJ8]:
Definition is updated for clarity and consistency with language in [10 CFR Part 35.2](#).

Commented [JSJ9]:
Circular reference to 7.3.1.1 is not needed and is therefore deleted.

Commented [JSJ10]:
Language updated for consistency with formatting of other radiation regulations.

- 109 * * *
- 110 7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's
111 facility as a restricted area while radioactive material is present. For each location where
112 radioactive materials will be routinely used, the licensee shall provide to the Department:
- 113 (1) A diagram of the location of use, including information about the placement of
114 required postings; and
- 115 (2) Calculation(s) or survey(s) results that demonstrate compliance with applicable
116 dose limits in **Part 4, Sections 4.14** and 4.15 at the location of use.
- 117 7.3.5.8 The mobile medical service shall ensure that:
- 118 (1) Supervision by an authorized user is in accordance with 7.10.1;
- 119 (2) Radiation exposures to the client's personnel working in the client facility are:
- 120 (a) Below the dose limits to members of the public listed in **Part 4, Section**
121 4.14; or
- 122 (b) The client's personnel are instructed as described in **Part 10, Section**
123 10.3 and monitored for exposure in accordance with **Part 4, Section**
124 4.18 unless the licensee can demonstrate that **Section 4.18** does not
125 apply.

126 * * *

127 **7.3.6** A licensee possessing a Type A specific license of broad scope for medical use, issued under
128 Part 3 of these regulations, is exempt from:

129 * * *

130 7.4 License amendments.

131 A licensee shall apply for and must receive a license amendment:

- 132 7.4.1 Before it receives, prepares, or uses radioactive material for a type of use that is permitted under
133 this part but is not authorized on the licensee's current license issued under this part;
- 134 7.4.2 Before it permits anyone to work as an authorized user, authorized medical physicist, ophthalmic
135 physicist, or an authorized nuclear pharmacist under the license, except:
- 136 7.4.2.1 For an authorized user, an individual who meets the requirements in Appendix 7P and
137 one or more of the following: Section 7D1 of Appendix D, Section 7E1 of Appendix E,
138 Section 7F1 of Appendix F, Section 7G1 of Appendix 7G, Section 7H1 of Appendix 7H,
139 Section 7K1 of Appendix K, Section 7J1 of Appendix J, or Section 7M1 of Appendix M;
- 140 7.4.2.2 For an authorized nuclear pharmacist, an individual who meets the requirements in
141 Section 7C1 of Appendix 7C and 7.65;
- 142 7.4.2.3 For an authorized medical physicist, an individual who meets the requirements in Section
143 7B1 of Appendix 7B and 7.65;
- 144 **7.4.2.4** An individual who is identified as an authorized user, an authorized nuclear pharmacist,
145 authorized medical physicist, or an ophthalmic physicist ~~or~~:

Commented [JSJ11]:
Comma added.

Commented [JSJ12]:
Minor wording corrections are made, consistent with the
language in [10 CFR Part 35.13](#)**.

[**NOTE: Colorado made NRC aware of a likely error in 10
CFR Part 35 during the drafting of the rule. The provisions of
35.13(b)(4)(i) through (iv) in the [official CFR](#) (which parallel
7.4.2.4(1)-(4)) appear to have been inadvertently deleted from
the final federal rule in 2018. The NRC is aware of this issue
and has indicated a rulemaking will be initiated to correct this
error in late 2022 or 2023.]

- 146 (1) **On a** NRC or Agreement State license or other equivalent permit or license
147 recognized by the Department that authorizes the use of radioactive material in
148 medical use or in the practice of nuclear pharmacy;
- 149 (2) **On a** permit issued by a NRC or Agreement State specific license of broad
150 scope that is authorized to permit the use of radioactive material in medical use
151 or in the practice of nuclear pharmacy;
- 152 (3) On a permit issued by a NRC master material licensee that is authorized to
153 permit the use of radioactive material in medical use or in the practice of nuclear
154 pharmacy; or
- 155 (4) By a commercial nuclear pharmacy that has been authorized to identify
156 authorized nuclear pharmacists.

* * *

158 **7.5 Notifications and maintenance of records.**

* * *

160 7.5.2 A licensee shall notify the Department in writing no later than 30 days after:

* * *

162 7.5.2.4 The licensee's name changes, but the name change does not constitute a transfer of
163 control of the license as described in **Part 3, Section 3.15.2** of these regulations; or

* * *

165 **7.7 Authority and responsibilities for the radiation protection program**

166 7.7.1 In addition to the radiation protection program requirements of **Part 4, Section 4.5** of these
167 regulations, a licensee's management shall approve in writing:

* * *

169 **7.10 Supervision.**

170 7.10.1 A licensee that permits the receipt, possession, use, or transfer of radioactive material by an
171 individual under the supervision of an authorized user as allowed by 7.3.1.2(1) shall:

172 7.10.1.1 In addition to the requirements of **Part 10, Section 10.3** of these regulations,
173 instruct the supervised individual in the licensee's written radiation protection
174 procedures, written directive procedures, regulations of Part 7, and license
175 conditions with respect to the use of radioactive material; and

176 7.10.1.2 Require the supervised individual to follow the instructions of the supervising
177 authorized user for medical uses of radioactive material, written radiation
178 protection procedures, written directive procedures, regulations of Part 7, and
179 license conditions with respect to the medical use of radioactive material.

180 7.10.2 A licensee that permits the preparation of radioactive material for medical use by an individual
181 under the supervision of an authorized nuclear pharmacist or physician who is an authorized
182 user, as allowed by 7.3.1.2(2), shall:

Commented [JSJ13]:
Text is formatted in Section 7.10 for alignment purposes.
There are no changes to rule text or requirements.

183 7.10.2.1 In addition to the requirements of **Part 10, Section** 10.3, instruct the supervised
 184 individual in the preparation of radioactive material for medical use, as
 185 appropriate to that individual's use of radioactive material; and

186 7.10.2.2 Require the supervised individual to follow the instructions of the supervising
 187 authorized user or authorized nuclear pharmacist regarding the preparation of
 188 radioactive material for medical use, the written radiation protection procedures,
 189 the regulations of Part 7, and license conditions.

190 * * *

191 **7.23 Report and notification of a dose to an embryo/fetus or a nursing child**

192 7.23.1 A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) dose
 193 equivalent that is a result of an administration of radioactive material or radiation from radioactive
 194 material to a pregnant individual unless the dose to the embryo/fetus was specifically approved,
 195 in advance, by the authorized user.

196 7.23.2 A licensee shall report any dose to a nursing child, that was not specifically approved, in advance,
 197 by the authorized user, that is a result of an administration of radioactive material to a breast
 198 feeding individual that:

199 7.23.2.1 Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or

200 7.23.2.2 Has resulted in unintended permanent functional damage to an organ or a
 201 physiological system of the child, as determined by a physician.

202 7.23.3 The licensee shall notify by telephone the Department no later than the next calendar day after
 203 discovery of a dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

204 7.23.4 The licensee shall submit a written report to the Department within 15 days after discovery of a
 205 dose to the embryo/fetus or nursing child that requires a report in 7.23.1 or 7.23.2.

206 7.23.4.1 The written report must include:

207 (1) The licensee's name;

208 (2) The name of the prescribing physician;

209 (3) A brief description of the event;

210 (4) Why the event occurred;

211 (5) The effect on the embryo/fetus or the nursing child;

212 (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and

213 (7) Certification that the licensee notified the pregnant individual or mother (or the
 214 mother's or child's responsible relative or guardian), and if not, why not.

215 7.23.4.2 The report must not contain the individual's or child's name or any other
 216 information that could lead to identification of the individual or child.

217
 218
 219
 220
 221

Commented [JSJ14]: In Section 7.23, text is formatted for alignment purposes along with removal of unneeded/excess space. There are no changes to rule text or requirements.

Commented [JSJ15]: Remove unneeded space between 7.23.4.2 and 7.23.4.3; and align/format text. There are no changes to rule text or requirements.

222

223 7.23.5 The licensee shall provide notification of the event to the referring physician and also notify the
 224 pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours
 225 after discovery of an event that would require reporting under 7.23.1 or 7.23.2, unless the
 226 referring physician personally informs the licensee either that he or she will inform the mother or
 227 that, based on medical judgment, telling the mother would be harmful. The licensee is not
 228 required to notify the mother without first consulting with the referring physician. If the referring
 229 physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate
 230 notifications as soon as possible thereafter. The licensee may not delay any appropriate medical
 231 care for the embryo/fetus or for the nursing child, including any necessary remedial care as a
 232 result of the event, because of any delay in notification. To meet the requirements of 7.23.5, the
 233 notification may be made to the mother's or child's responsible relative or guardian instead of the
 234 mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or
 235 the mother's or child's responsible relative or guardian, that a written description of the event can
 236 be obtained from the licensee upon request. The licensee shall provide such a written description
 237 if requested.

238 7.23.6 A licensee shall:

239 7.23.6.1 Annotate a copy of the report provided to the Department with the:

240 (1) Name of the pregnant individual or the nursing child who is the subject of the
 241 event; and

242 (2) Identification number or if no other identification number is available, the social
 243 security number of the individual who is the subject of the event.

244 7.23.7 A copy of the record required under 7.23.6 shall be provided to the referring physician, if other
 245 than the licensee, within 15 days after discovery of the event.

246

* * *

247 Section F – Sealed Sources for Diagnosis

248 7.40 Use of sealed sources and medical devices for diagnosis.

249 7.40.1 A licensee must use only sealed sources that are not in medical devices for diagnostic medical
 250 uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic
 251 medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly
 252 listed in the Sealed Source and Device Registry but must be used in accordance with the
 253 radiation safety conditions and limitations described in the Sealed Source and Device Registry.

254 7.40.2 A licensee must only use medical devices containing sealed sources for diagnostic medical uses
 255 if both the sealed sources and medical devices are approved in the Sealed Source and Device
 256 Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic
 257 medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be
 258 used in accordance with the radiation safety conditions and limitations described in the Sealed
 259 Source and Device Registry.

260 7.40.3 Sealed sources and devices for diagnostic medical uses may be used in research in accordance
 261 with ~~an~~ active Investigational Device Exemption (IDE) application accepted by the U.S. Food
 262 and Drug Administration provided the requirements of 7.14.1 are met.

263 7.40.4 Training for use of sealed sources and medical devices for diagnosis.

Commented [JSJ16]:
Correction of typographical error.

264 The licensee shall require an authorized user under 7.40 to meet the requirements of Appendix
265 7J.

266 **Section G – Manual Brachytherapy**

267 **7.41 Calibration measurements of brachytherapy sources.**

268 7.41.1 Before the first medical use of a brachytherapy source, a licensee shall have:

269 7.41.1.1 Determined the source output or activity using a dosimetry system that meets the
270 requirements of 7.53;

271 7.41.1.2 Determined source positioning accuracy within applicators; and

272 7.41.1.3 Used published protocols currently accepted by nationally recognized bodies to
273 meet the requirements of 7.41.1.1 and 7.41.1.2.

274 7.41.2 Instead of a licensee making its own measurements as required in 7.41.1, the licensee may use
275 measurements provided by the source manufacturer or by a calibration laboratory accredited by
276 the American Association of Physicists in Medicine that are made in accordance with 7.41.1.

277 7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical
278 decay at intervals consistent with 1 percent physical decay.

279 7.41.4 An authorized medical physicist shall perform or review the measurements and calculations made
280 pursuant to 7.41.1, 7.41.2, or 7.41.3.

281 7.41.5 A licensee shall retain a record of each calibration as follows:

282 7.41.5.1 A licensee shall maintain a record of the calibrations of brachytherapy sources
283 required by 7.41.1 for 3 years after the last use of the source.

284 7.41.5.2 The record must include:

285 (1) The date of the calibration;

286 (2) The manufacturer's name, model number, and serial number for the source and
287 the instruments used to calibrate the source;

288 (3) The source output or activity;

289 (4) The source positioning accuracy within the applicators; and

290 (5) The name of the individual, the source manufacturer, or the calibration laboratory
291 that performed the calibration.

292 7.41.6 Strontium-90 sources for ophthalmic treatments.

293 7.41.6.1 Licensees who use strontium-90 for ophthalmic treatments must ensure that
294 certain activities as specified in 7.41.6.2 are performed by either:

295 (1) An authorized medical physicist; or

296 (2) An individual who:

297 (a) Is identified as an ophthalmic physicist on a specific medical use license
298 issued by NRC or an Agreement State; permit issued by a NRC or

Commented [JSJ17]: Section 7.41 is formatted for alignment of text. There are no changes to rule text or requirements.

Commented [JSJ18]: Formatted for alignment of text. There are no changes to rule text or requirements.

Commented [JSJ19]: Updated for consistency with similar phrasing in other proposed changes in this rule due to recent amendments to federal rule.

[Note - the current wording in federal rule ([10 CFR Part 35.433\(a\)\(2\)\(i\)](#)) equivalent to this provision is inconsistent with other recent federal rule changes. NRC has been made aware of this error in the federal rule and will be initiated a rulemaking to address this in the future.]

[NRC Compatibility B](#)

- 299 Agreement State broad scope medical use licensee; medical use permit
 300 issued by a NRC master material licensee; or permit issued by a NRC
 301 master material **licensee** licensee broad scope medical use permittee; and
- 302 (b) Holds a master's or doctor's degree in physics, medical physics, other
 303 physical sciences, engineering, or applied mathematics from an
 304 accredited college or university; and
- 305 (c) Has successfully completed 1 year full-time training in medical physics
 306 and an additional year of full-time work experience under the supervision
 307 of a medical physicist; and
- 308 (d) Has documented training in:
- 309 (i) The creation, modification, and completion of written directives;
- 310 (ii) Procedures for administrations requiring a written directive; and
- 311 (iii) Performing the calibration measurements of brachytherapy
 312 sources as detailed in 7.41.1 through 7.41.5.
- 313 7.41.6.2 The individuals who are identified in 7.41.6.1 must:
- 314 (1) Calculate the activity of each strontium-90 source that is used to determine the
 315 treatment times for ophthalmic treatments. The decay must be based on the
 316 activity determined under 7.41.1 through 7.41.5; and
 317
- 318 (2) Assist the licensee in developing, implementing, and maintaining written
 319 procedures to provide high confidence that the administration is in accordance
 320 with the written directive. These procedures must include the frequencies that the
 321 individual meeting the requirements in 7.41.6.1 will observe treatments, review
 322 the treatment methodology, calculate treatment time for the prescribed dose, and
 323 review records to verify that the administrations were in accordance with the
 324 written directives.
- 325 **7.41.6.3** Licensees must retain a record of the activity of each strontium-90 source as
 326 follows:
- 327 (1) A licensee shall maintain a record of the activity of a strontium-90 source
 328 required by 7.41.6 for the life of the source.
- 329 (2) The record must include:
- 330 (a) The date and initial activity of the source as determined under 7.41.1
 331 through 7.41.5; and
- 332 (b) For each decay calculation, the date and the source activity as determined under
 333 7.41.6.

* * *

335 7.43 Safety instruction.

336 In addition to the requirements of Part 10 of these regulations:

Commented [JSJ20]:
 Section 7.41.6.3 is formatted for alignment of text.
 There are no changes to rule text or requirements.

- 337 7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel
 338 caring for patients or human research subjects that are undergoing implant therapy and cannot
 339 be released in accordance with 7.26.
- 340 7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and
 341 include:
- 342 7.43.2.1 Size and appearance of the brachytherapy sources;
- 343 7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;
- 344 7.43.2.3 Patient or human research subject control;
- 345 7.43.2.4 Visitor control, including both;
- 346 (1) Routine visitation to hospitalized individuals in accordance with **Part 4, Section**
 347 4.14.1.1; and
- 348 (2) Visitation authorized in accordance with **Part 4, Section** 4.14.3; and
- 349 **7.43.2.5** Notification of the RSO, or his or her designee, and the authorized user if the
 350 patient or the human research subject dies or has a medical emergency.
- 351 7.43.3 A licensee shall retain a record of individuals receiving safety instructions required by 7.43.1 and
 352 maintain such records for 3 years. The record must include a list of the topics covered, the date of
 353 the instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who provided
 354 the instruction.
- 355 **7.44 Safety precautions.**
- 356 7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be
 357 released in accordance with 7.26, a licensee shall:
- 358 7.44.1.1 Not place the patient or the human research subject in the same room with a
 359 patient who is not receiving radiation therapy;
- 360 7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution:
 361 Radioactive Material" sign and note on the door or on the patient's or human
 362 research subject's chart where and how long visitors may stay in the patient's or
 363 human research subject's room.
- 364 7.44.2 A licensee shall have emergency response equipment available near each treatment room to
 365 respond to a source that inadvertently becomes:
- 366 7.44.2.1 Dislodged from the patient; or
- 367 7.44.2.2 Lodged within the patient following removal of the source applicators.
- 368 7.44.3 A licensee shall notify the RSO, or his or her designee, and an authorized user as soon as
 369 possible if the patient or human research subject has a medical emergency or dies.
- 370 * * *
- 371 **7.47 Therapy-related computer systems.**

Commented [JSJ21]:
 Section 7.43.2.5 is formatted for alignment of text.
 There are no changes to rule text or requirements.

Commented [JSJ22]:
 Section 7.44 is formatted for alignment of text.
 There are no changes to rule text or requirements.

372 7.47.1 The licensee shall perform acceptance testing on the treatment planning system **of therapy-**
 373 **related computer systems** in accordance with published protocols accepted by nationally
 374 recognized bodies.

Commented [JSJ23]:
 Language added for clarity and consistency with the current
[10 CFR Part 35.457](#).

Section 7.47.2 has also been formatted for alignment of text.

375 7.47.2 At a minimum, the acceptance testing required by 7.47.1 shall include, as applicable, verification
 376 of:

377 7.47.2.1 The source-specific input parameters required by the dose calculation algorithm;

378 7.47.2.2 The accuracy of dose, dwell time, and treatment time calculations at
 379 representative points;

380 7.47.2.3 The accuracy of isodose plots and graphic displays; and

381 7.47.2.4 The accuracy of the software used to determine radioactive source positions
 382 from radiographic images.

383 **Section H - Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma**
 384 **Stereotactic Radiosurgery Units**

385 **7.48 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma**
 386 **stereotactic radiosurgery unit.**

Commented [JSJ24]:
 Section 7.48 is formatted for alignment of text. There are no
 changes to rule text or requirements.

387 7.48.1 A licensee must only use sealed sources:

388 7.48.1.1 Approved and as provided for in the Sealed Source and Device Registry in
 389 photon emitting remote afterloader units, teletherapy units, or gamma
 390 stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

391 7.48.1.2 In research involving photon-emitting remote afterloader units, teletherapy units,
 392 or gamma stereotactic radiosurgery units in accordance with an active
 393 Investigational Device Exemption (IDE) application accepted by the U.S. Food
 394 and Drug Administration provided the requirements of 7.14.1 are met.

395 7.48.2 A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma
 396 stereotactic radiosurgery units:

397 7.48.2.1 Approved in the Sealed Source and Device Registry to deliver a therapeutic dose
 398 for medical use. These devices may be used for therapeutic medical treatments
 399 that are not explicitly provided for in the Sealed Source and Device Registry, but
 400 must be used in accordance with radiation safety conditions and limitations
 401 described in the Sealed Source and Device Registry; or

402 7.48.2.2 In research in accordance with an active Investigational Device Exemption (IDE)
 403 application accepted by the FDA provided the requirements of 7.14.1 are met.

404 7.48.3 Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic
 405 Radiosurgery Unit.

406 The licensee shall require an authorized user under 7.48 to meet the requirements of Appendix
 407 7M.

408 * * *

409 **7.58 Periodic spot checks for teletherapy units.**

- 410 7.58.1 A licensee authorized to use teletherapy units for medical use shall perform output spot checks
411 on each teletherapy unit once in each calendar month; that include determination of:
- 412 7.58.1.1 Timer accuracy, and timer linearity over the range of use;
- 413 7.58.1.2 "On off" error;
- 414 7.58.1.3 The coincidence of the radiation field and the field indicated by the light beam
415 localizing device;
- 416 7.58.1.4 The accuracy of all distance measuring and localization devices used for medical
417 use;
- 418 7.58.1.5 The output for one typical set of operating conditions measured with the
419 dosimetry system described in 7.53; and
- 420 7.58.1.6 The difference between the measurement made in 7.58.1.5 and the anticipated
421 output, expressed as a percentage of the anticipated output (i.e., the value
422 obtained at last full calibration corrected mathematically for physical decay).
- 423 7.58.2 A licensee shall perform spot checks required by 7.58.1 in accordance with procedures
424 established by the authorized medical physicist. That individual need not actually perform the
425 output spot-check measurements.
- 426 7.58.3 A licensee shall have the authorized medical physicist review the results of each spot check
427 within 15 days. The authorized medical physicist shall **promptly** notify the licensee **as soon as**
428 **possible** in writing of the results of each spot check.
- 429 7.58.4 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks
430 of each teletherapy facility once in each calendar month and after each source installation to
431 assure proper operation of:
- 432 7.58.4.1 Electrical interlocks at each teletherapy room entrance;
- 433 7.58.4.2 Electrical or mechanical stops installed for the purpose of limiting use of the
434 primary beam of radiation restriction of source housing angulation or elevation,
435 carriage or stand travel, and operation of the beam "on off" mechanism;
- 436 7.58.4.3 Source exposure indicator lights on the teletherapy unit, on the control console,
437 and in the facility;
- 438 7.58.4.4 Viewing and intercom systems;
- 439 7.58.4.5 Treatment room doors from inside and outside the treatment room; and
- 440 7.58.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical
441 power turned "off".
- 442 7.58.5 If the results of the checks required in 7.58.4 indicate the malfunction of any system, a licensee
443 shall lock the control console in the "off" position and not use the unit except as may be
444 necessary to repair, replace, or check the malfunctioning system.
- 445 7.58.6 A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.4, and a copy
446 of the procedures required by 7.58.2 for 3 years. The record shall include:
- 447 7.58.6.1 The date of the spot check;

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Remove unneeded comma in 7.58.1.

Where needed, 7.58.1 through 7.58.6.9 has been formatted for alignment of text.

Commented [JSJ26]:Language clarified for consistency with [10 CFR Part 35.642\(c\)](#).

- 448 7.58.6.2 The manufacturer's name, model number, and serial number for the teletherapy
449 unit, source, and instrument used to measure the output of the teletherapy unit;
- 450 7.58.6.3 An assessment of timer linearity and constancy;
- 451 7.58.6.4 The calculated "on off" error;
- 452 7.58.6.5 A determination of the coincidence of the radiation field and the field indicated by
453 the light beam localizing device
- 454 7.58.6.6 The determined accuracy of each distance measuring or localization device;
- 455 7.58.6.7 The difference between the anticipated output and the measured output;
- 456 7.58.6.8 Notations indicating the operability of each entrance door electrical interlock,
457 each electrical or mechanical stop, each source exposure indicator light, and the
458 viewing and intercom system and doors; and
- 459 7.58.6.9 The name of the individual who performed the periodic spot check and the
460 signature of the authorized medical physicist who reviewed the record of the spot
461 check.

462 * * *

463

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

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

469 **7A1** Is certified by a specialty board whose certification process has been recognized by the NRC or
470 an Agreement State and who meets the requirements in 7A4 of this Appendix. The names of
471 board certifications that have been recognized by the NRC or an Agreement State are posted on
472 the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized,
473 a specialty board shall require all candidates for certification to:

474 7A1.1

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

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

481 and

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

486 or

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Prior to final publication, ensure that this Appendix **and all subsequent appendices** begin at the top of the page.

- 487 7A1.2
- 488 (1) Hold a master's or doctor's degree in physics, medical physics, other physical
489 science, engineering, or applied mathematics from an accredited college or
490 university;
- 491 and
- 492 (2) Have 2 years of full-time practical training and/or supervised experience in
493 medical physics:
- 494 (a) Under the supervision of a medical physicist who is certified in medical
495 physics by a specialty board recognized by an Agreement State or NRC;
- 496 or
- 497 (b) In clinical nuclear medicine facilities providing diagnostic or therapeutic
498 services under the direction of physicians who meet the requirements for
499 Authorized Users in Appendix 7P, Appendix 7E or Appendix 7F;
- 500 and
- 501 (3) Pass an examination administered by diplomates of the specialty board, that
502 assesses knowledge and competence in clinical diagnostic radiological or
503 nuclear medicine physics and in radiation safety.
- 504 or
- 505 **7A2**
- 506 7A2.1 Has completed a structured educational program consisting of both:
- 507 (1) 200 hours of classroom and laboratory training in the following areas:
- 508 (a) Radiation physics and instrumentation;
- 509 (b) Radiation protection;
- 510 (c) Mathematics pertaining to the use and measurement of radioactivity;
- 511 (d) Radiation biology; and
- 512 (e) Radiation dosimetry;
- 513 and
- 514 (2) One year of full-time radiation safety experience, under the supervision of the
515 individual identified as the RSO, on a NRC or an Agreement State license or
516 permit issued by a NRC master material licensee that authorizes similar type(s)
517 of use(s) of radioactive material. An Associate Radiation Safety Officer may
518 provide supervision for those areas for which the Associate Radiation Safety
519 Officer is authorized on a NRC or an Agreement State license or permit issued
520 by a NRC master material licensee. The full-time radiation safety experience
521 must involve the following:
- 522 (a) Shipping, receiving, and performing related radiation surveys;

- 523 (b) Using and performing checks for proper operation of instruments used to
 524 determine the activity of dosages, survey meters, and instruments used
 525 to measure radionuclides;
- 526 (c) Securing and controlling radioactive material;
- 527 (d) Using administrative controls to avoid mistakes in the administration of
 528 radioactive material;
- 529 (e) Using procedures to prevent or minimize radioactive contamination and
 530 using proper decontamination procedures;
- 531 (f) Using emergency procedures to control radioactive material; and
- 532 (g) Disposing of radioactive material;

533 and

534

535 7A2.2 This individual must obtain a written attestation, signed by a preceptor RSO or ARSO
 536 who has experience with the radiation safety aspects of similar types of use of radioactive
 537 material for which the individual is seeking approval as a RSO or an ARSO. The written
 538 attestation must state that the individual has satisfactorily completed the requirements in
 539 7A2.1 and 7A4 of Appendix 7A and is able to independently fulfill the radiation safety
 540 related duties as a RSO or as an ARSO for a medical use license;

541 or

542 **7A3**

543 7A3.1 Is a medical physicist who has been certified by a specialty board whose certification
 544 process has been recognized by the NRC or an Agreement State under Appendix 7B,
 545 Section 7B1, has experience with the radiation safety aspects of similar types of use of
 546 radioactive material for which the licensee seeks the approval of the individual as RSO or
 547 an ARSO, and meets the requirements in 7A4.

548 or

549 7A3.2 Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist
 550 identified on a Department, NRC or an Agreement State license, a permit issued by a
 551 NRC master material ~~license~~**licensee**, a permit issued by a NRC or an Agreement State
 552 licensee of broad scope, or a permit issued by a NRC master material **license** broad
 553 scope ~~permitee~~**permittee**, has experience with the radiation safety aspects of similar
 554 types of use of radioactive material for which the licensee seeks the approval of the
 555 individual as the RSO or ARSO, and meets the requirements in 7A4;

556 or

557 ~~7A3.3~~ Has experience with the radiation safety aspects of the types of use of radioactive
 558 material for which the individual is seeking simultaneous approval both as the Radiation
 559 Safety Officer and the authorized user on the same new medical use permit issued by a
 560 NRC master material ~~license~~**licensee**. The individual must also meet the requirements in
 561 7A4.

562 and

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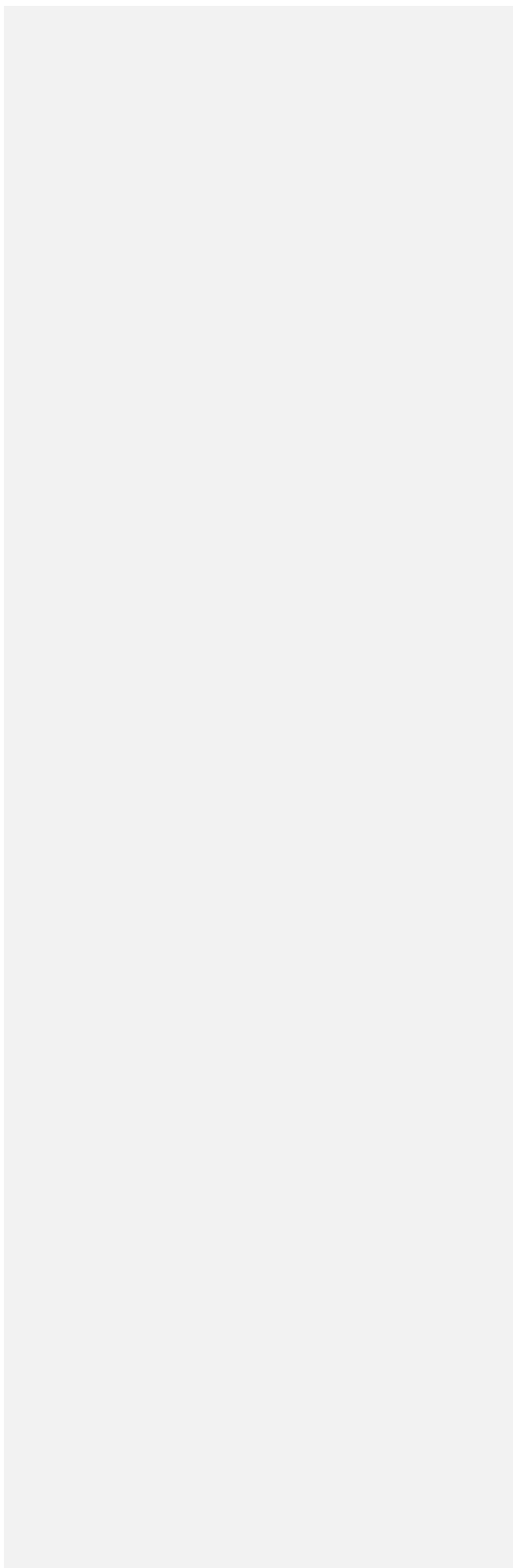
Minor technical correction/update for consistency with federal regulations in [10 CFR 35.50\(c\)\(3\)](#).

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563 **7A4** Has training in the radiation safety, regulatory issues, and emergency procedures for the types of
564 use for which a licensee seeks approval. This training requirement may be satisfied by
565 completing training that is supervised by an RSO, an Associate RSO, authorized medical
566 physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for
567 the type(s) of use for which the licensee is seeking approval.

568
569

* * *



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

571 Except as provided in Appendix 7P, the licensee shall require the authorized nuclear pharmacist to be a
572 pharmacist who:

573 **7C1** Is certified by a specialty board whose certification process has been recognized by the NRC or
574 an Agreement State. The names of board certifications that have been recognized by the NRC or
575 an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have
576 its certification process recognized, a specialty board shall require all candidates for certification
577 to:

578 **7C1.1** Have graduated from a pharmacy program accredited by the **Accreditation Council for**
579 **Pharmacy Education (ACPE) (previously named the** American Council on
580 **Pharmaceutical Education)** ~~(ACPE)~~ or have passed the Foreign Pharmacy Graduate
581 Examination Committee (FPGEC) examination;

582 * * *
583

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Minor technical correction/update for consistency with 2021 federal regulation changes to [10 CFR 35.55\(a\)\(1\)](#).
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584 **PART 7, APPENDIX 7P: TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER,**
585 **TELE THERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST,**
586 **AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR**
587 **PHARMACIST.**

588 **7P1**

589 7P1.1 An individual identified on a Department, NRC or an Agreement State license or a permit
590 issued by a Department, NRC or an Agreement State broad scope licensee or master
591 material license permit or by a master material license permittee of broad scope as a
592 Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical
593 physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before August
594 14, 2020 need not comply with the training requirements of Appendix 7A, 7B, or 7C,
595 respectively, except the Radiation Safety Officers and authorized medical physicists
596 identified in 7P1.1 must meet the training requirements in 7A4 of Appendix 7A or 7B3 of
597 Appendix 7B, as appropriate, for any material or uses for which they were not authorized
598 prior to this date.

599 7P1.2 Any individual certified by the American Board of Health Physics in Comprehensive
600 Health Physics; American Board of Radiology; American Board of Nuclear Medicine;
601 American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in
602 Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics;
603 Royal College of Physicians and Surgeons of Canada in nuclear medicine; American
604 Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on
605 or before October 24, 2005, need not comply with the training requirements of Appendix
606 7A to be identified as a Radiation Safety Officer or as an Associate Radiation Safety
607 Officer on an NRC or an Agreement State license or NRC master material license permit
608 for those materials and uses that these individuals performed on or before October 24,
609 2005.

610 7P1.3 Any individual certified by the American Board of Radiology in therapeutic radiological
611 physics, Roentgen ray and gamma ray physics, xray and radium physics, or radiological
612 physics, or certified by the American Board of Medical Physics in radiation oncology
613 physics, on or before October 24, 2005, need not comply with the training requirements
614 for an authorized medical physicist described in Appendix 7B, for those materials and
615 uses that these individuals performed on or before October 24, 2005.

616 7P1.4 A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only
617 accelerator-produced radioactive materials, discrete sources of radium-226, or both, for
618 medical uses or in the practice of nuclear pharmacy at a Government agency or
619 Federally recognized Indian Tribe before November 30, 2007, or at all other locations of
620 use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply
621 with the training requirements of Appendix 7A, 7B, or 7C respectively, when performing
622 the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing
623 accelerator-produced radioactive materials, or a medical physicist, who used only
624 accelerator-produced radioactive materials, at the locations and during the time period
625 identified in 7P1.4, qualifies as an authorized nuclear pharmacist or an authorized
626 medical physicist, respectively, for those materials and uses performed before these
627 dates, for the purposes of the regulations.

628 **7P2**

629 7P2.1 Physicians, dentists, or podiatrists identified as authorized users for the medical use of
630 radioactive material on a license issued by the NRC or an Agreement State, a permit
631 issued by a NRC master material licensee, a permit issued by a NRC or an Agreement
632 State broad scope licensee, or a permit issued by a NRC master material license broad
633 scope permittee on or before August 14, 2020, who perform only those medical uses for

634 which they were authorized on or before that date need not comply with the training
635 requirements of Sections D through H.

636 7P2.2 Physicians, dentists, or podiatrists not identified as authorized users for the medical use
637 of radioactive material on a license issued by the NRC or an Agreement State, a permit
638 issued by a NRC master material licensee, a permit issued by a NRC or an Agreement
639 State broad scope licensee, or a permit issued ~~by~~ **in accordance with** a NRC master
640 material ~~license of~~ broad scope **license** on or before October 24, 2005, need not comply
641 with the training requirements of Sections D through H for those materials and uses that
642 these individuals performed on or before October 24, 2005, as follows:

643

* * *

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Minor technical correction for wording consistency with 2021 federal regulation changes to [10 CFR 35.57\(b\)\(2\)](#).

[NRC RATS 2021-1](#)
[NRC Compatibility B](#)