COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: James H. Grice, Radiation Program Manager, Hazardous Materials and Waste Management Division
James S. Jarvis, Regulatory Lead, Hazardous Materials and Waste Management Division

Through: Jennifer T. Opila, Division Director JTO

Date: June 17, 2020

Subject: Rulemaking Hearing concerning 6 CCR 1007-1 Part 3, Licensing of radioactive materials, and 6 CCR 1007-1 Part 7, Use of radionuclides in the healing arts

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The radiation program is proposing changes to Part 7 and Part 3 of the radiation regulations primarily for conformance to final regulations of the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 35, Part 32, and Part 30. Changes to these federal rules were published July 16, 2018 and became effective January 14, 2019 for NRC licensees. Consistent with its agreement with the NRC, Colorado must maintain its radiation regulations compatible with those of NRC and therefore is proposing rule changes to Colorado rules.

Part 7 of the regulations pertains to the use of radioactive materials in medicine on humans. Part 7 does not apply to veterinary uses of radioactive materials nor does it apply to x-ray machines used in the healing arts. While Part 3 contains the licensing requirements for all types of facilities using radioactive materials (industrial, research, and medical), the proposed changes are limited to those needed for conformance and consistency with the Part 7 changes for medical use and to address minor technical corrections, phrasing and formatting for consistency with federal and Colorado rules. Amendment of these regulations will help ensure consistency with the national framework for regulation of radioactive materials in the healing arts.

The more significant changes to the proposed rules include amending the notification requirements for medical events and written directives specific to permanent implant brachytherapy, removing the requirement for submitting written attestations for most board certified physicians to become an authorized user on a license, and allow for grandfathering of experienced board certified individuals in practice prior to 2005. The proposed rule also amends the requirements for reporting of radionuclide generator contamination, moving from an immediate notification to a 7 day notification allowing time for data verification by licensees. The rule also allows licensees to name one or more associate radiation safety officers which will replace Colorado's currently termed "alternate" radiation safety officers. The radiation program is also proposing a non-federally driven change to better align supervision provisions with the requirements for those in training or have a special need to administer radiopharmaceuticals while under the supervision of an authorized user.

The proposed Part 3 changes are for conformance and consistency with the Part 7 changes and to address minor formatting changes and corrections.

Throughout the rule, new text appears as red bold text while deleted current text of this regulation is shown in strikethrough. Consistent with Board practice, changes highlighted in yellow have been added or amended since the request for rulemaking.

At the June 17, 2020 rulemaking hearing, the Radiation Program requests that the Board of Health adopt the rules as proposed.

DRAFT STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1 Part 3, Licensing of radioactive materials
6 CCR 1007-1 Part 7, Use of radionuclides in the healing arts

Basis and Purpose.

The proposed amendments make technical and formatting changes to multiple sections in the Part 7 and Part 3 rules based on 2018 changes in federal regulation applicable to use of radioactive materials in medicine and in consideration of stakeholder feedback. The proposed changes are outlined below for each section.

Changes throughout the Part 3 and Part 7 rules

- Rephrases provisions and adds section headers to follow the flow and format of federal regulation, and corrects typographical errors and omissions.
- Specific sections of the Part 3 rule not previously identified for amendment have been reincorporated into the draft rule body in order to remove (delete) dates associated with documents incorporated by reference. In lieu of these specific dates, the general incorporation by reference language (of 3.1) at the front of the rules will be used.

Changes to Sections 3.1 and 7.1 (Purpose and scope)

- Adds and expands the standardized language pertaining to documents incorporated by reference, for consistency with the Colorado Administrative Procedure Act.

Changes to Section 7.2 (Definitions)

- Adds several new definitions, consistent with federal rule, including "Associate Radiation Safety Officer", and "Ophthalmic physicist".
- Deletes the term "misadministration" and replaces with the term "medical event" for consistency with federal rule and which is reflected throughout the body of the rule.
- Revises "Preceptor" definition to incorporate the newly added associate radiation safety officer and ophthalmic physicist definitions.
- Definitions related to radiation therapy technology are deleted due to these terms not being used in the body of the rule.

Changes to Section 7.3 (License required)

- Adds clarifying language and updates for consistency with the format and flow of federal regulation.

Changes to Section 7.4 (License amendments)

- Adds an exception which provides regulatory relief by allowing most board certified individuals or those already named on another license to work under the license prior to receiving a license amendment and provided that documentation is provided to the Department within 30 days (consistent with 7.5).
- Incorporates new ophthalmic physicist and associate radiation safety office definitions in body of rule.
- Clarifies and adds requirements that a licensee must receive a license amendment prior making certain changes to the radiation safety program, procedures, locations of use, and use of sealed sources different than those authorized on the license.

Changes to Section 7.5 (Notifications and maintenance of records)

- Clarifies that licensees must provide specific documentation for authorized "individuals" within 30 days. Per 7.4, licensees may need to receive a license amendment prior to allowing certain individual(s) to work under the license.
- The rule clarifies that licensees must (also) notify the Department within 30 days upon discontinuation of work by the newly defined associate radiation safety officer or ophthalmic physicist, or when a person when a different brachytherapy source is obtained.
- Clarifies that manual brachytherapy sources different than those listed on the license

Changes to Section 7.6 (License issuance)

- No substantive changes.

Changes to Section 7.7 (Authority for radiation protection program)

- Specify requirements for appointing associate radiation safety officers, and update current requirements for temporary radiation safety officers and recordkeeping.

Changes to Sections 7.8 – 7.9 (Rad safety committee / Rad protection program changes)

- No substantive changes

Changes to Section 7.10 (Supervision)

- Add requirement to strengthen tie to requirements for nuclear medicine technologists (App 7N) and other individuals administering radioactive materials to patients. This change is Colorado specific and is not driven by federal rule.
- Adds language to permit, the administration of radioactive materials by certain individuals in training while under the supervision of an authorized user physician.
- Adds language to permit, with written authorization, the administration of radioactive materials by certain individuals who may not qualify under the other provisions in 7.10 due to their specific medical qualification and while under the supervision of an authorized user physician.

Changes to Sections 7.11 – 7.12 (Written directives / Procedures for written directives)

- Adds written directive and procedural requirements specific to permanent implant brachytherapy.
- Adds requirements to incorporate evaluation for medical events as part of the written directive procedures.

Changes to Sections 7.13 – 7.16

- No substantive changes.

Changes to Section 7.17 (Calibration)

- Updates/reduces specificity of requirements for calibration of survey instruments.

Changes to Section 7.18 (Determination of dosages)

- No substantive changes.

Changes to Section 7.19 (Authorization for calib., transmission and reference sources)

- Clarifies that requirements also apply to transmission sources.
- Clarifies requirements related to redistribution of sources.

- Adds requirements to clarify that sources may not be bundled or aggregated beyond specified limits and that use of such sources on patients must be in accordance with 7.40.

Changes to Section 7.20 (Requirements for sealed sources and brachytherapy sources)
- Clarifies requirements for leak testing of sealed sources and related recordkeeping.

Changes to Section 7.21 (Report and notification of medical event)
- Modifies the term "misadministration" to "medical event" consistent with federal rule.
- Adds medical event criteria specific to permanent implant brachytherapy, consistent with federal rule.
- Revises the language to limit the use of social security numbers when possible in required reports, consistent with a current (2020) parallel federal rulemaking.

Changes to Sections 7.22 -7.29
- No substantive changes, with the exception of 7.23, which includes an update and reformatting of the section to parallel the approach used in 7.21. Language limiting use of social security numbers for required records is updated, consistent with a current (2020) parallel federal rulemaking.

Changes to Sections 7.30 – 7.32 (Use of unsealed radioactive material…)
- Rephrasing of section to follow flow and content of federal rule.

Changes to Section 7.33 (Permissible concentrations)
- Rephrasing of section to follow flow and content of federal rule.
- Changes notification period from immediate to 7 days per federal rule.
- Specifies additional detail on what must be included in the telephone and written reports.

Changes to Section 7.34 (Aerosols and gases)
- No substantive changes.

Changes to Section 7.35 (Radiation detection capability)
- Deletes section as it is not driven by federal rule and the current general requirements of Part 4 are deemed adequate.

Changes to Section 7.36 (Use of unsealed radioactive material…written directive required)
- Adds specificity by referring to provision 7F2.1(2)(f) of Appendix F for the types of material addressed by this section.

Changes to Section 7.37 (Safety instruction)
- Clarifies visitation requirements.

Changes to Sections 7.38 – 7.39 (Safety precautions / Reserved)
- Rephrases sections to follow flow and content of federal rule - no substantive changes.

Changes to Section 7.40 (Use of sealed sources and medical devices for diagnosis)
- Clarifies language to distinguish between sources that are used in conjunction as part of a medical device and those that may be used separately from a device.

- Adds clarification that sources used with or separate from a device must be used in accordance with the radiation safety conditions and limitations provisions found in the Sealed Source and Device Registry (SSDR), but may be used for purposes not explicitly listed in the SSDR.

Changes to Section 7.41 (Calibration measurements of brachytherapy sources)

- Adds specificity to the recordkeeping requirements.
- Clarifies which activities involving sources for ophthalmic treatments must be performed and who may perform them - an authorized medical physicist or the newly added ophthalmic physicist.

Changes to Section 7.42 (Use of sealed sources for manual brachytherapy)

- Similar to the amended phrasing in 7.40, adds clarification that sources must be used in accordance with the radiation safety conditions and limitations provisions found in the Sealed Source and Device Registry (SSDR), but may be used for purposes not explicitly listed in the SSDR.

Changes to Sections 7.43 – 7.47

- Rephrases section to follow flow and content of federal rule - no substantial changes.

Changes to Section 7.48 (Use of a sealed source in a remote afterloader…)

- Similar to the proposed language in 7.42, adds clarification that sources in therapeutic devices must be used in accordance with the radiation safety conditions and limitations provisions found in the Sealed Source and Device Registry (SSDR), but may be used for purposes not explicitly listed in the SSDR and for approved research purposes.

Changes to Section 7.49 – 7.50

- Rephrases section to follow flow and content of federal rule - no substantial changes.

Changes to Section 7.51 (Safety procedures…)

- Adds requirement that specifies only the manufacturer of the therapy unit (or someone certified by the manufacturer) must provide operational and safety training for a new unit or for upgrades affecting operation and safety, prior to initial use for patient treatment.
- Clarifies retention requirements for required procedures and records.

Changes to Section 7.52 – 7.62

- Clarifies recordkeeping duration in 7.62.

Changes to Section 7.63 (Full-inspection servicing…)

- Reduces regulatory burden by extending the full-inspection servicing of gamma stereotactic radiosurgery units from the current 5 years to 7 years, based on the expense of source exchanges and feedback from stakeholders (nationally).

Changes to Section 7.64 (Therapy-related computer systems)

- Adds (duplicates) language of the current 7.47 in this section to clarify the acceptance testing requirements for computer based therapy systems, and require that the accuracy of electronic transfer of treatment delivery parameters must also be verified.

Changes to Section 7.65 (Recentness of training)

- Relocates the recentness of training found in multiple appendices of Part 7 to a single section in the rule, consistent with the format and approach in 10 CFR Part 35.

Changes to Appendices 7A through 7M

- Provisions are rephrased to follow flow and content of federal rule.
- Replaces the current specific NRC website (URL) with a more generic reference to NRC's medical use toolbox website.
- Relocates the recentness of training requirements found in each appendix and consolidates them in new provision 7.65.
- Reduces the regulatory burden by removing preceptor statement requirements for most board certified individuals.
- Rewords attestation requirement and allows for residency program directors to provide attestations when needed.
- Clarifies and consolidates the parenteral administration requirements of Appendix 7F to more clearly address new and emerging radionuclides.

Changes to Appendix 7N

- Removes "alternate pathway" for nuclear medicine technologists and instead defers to national registration/certification, while allowing for grandfathering of those currently working in the field.
- Continues to allow for case-by-case evaluation of alternative certifications.

Changes to Appendix 7O

- Removes appendix pertaining to radiation therapy technologists as it is not used or referenced anywhere in the body of the rule nor are there equivalent federal regulations.

Addition of Appendix 7P

- Adds appendix 7P to effectively replace the limited requirements for an experienced "individual" found in each appendix (7A through 7M), consistent with the structure and approach in federal rule.
- Adds (reinstates) grandfathering requirements for experienced authorized individuals who were in practice prior to the specified 2005 date.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:

25-1.5-101(1)(k), 25-1.5-101(1)(l), 25-11-103, 25-11-104, and 25-1-108, C.R.S.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.
___X__ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

___X__ Yes ___ URL
_____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes
___X__ No

Does the proposed rule language create (or increase) a state mandate on local government?

_X_ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

___ Yes.

This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service. The state mandate is categorized as:

___ Necessitated by federal law, state law, or a court order
___ Caused by the State's participation in an optional federal program
___ Imposed by the sole discretion of a Department

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes _X_No. If "yes," please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

While most licensee facilities in Colorado are privately owned, some medical facilities may be wholly or partially owned or operated by a local government, town, county or special district. However, for consistency with the national framework for regulation of radioactive materials and consistent with Colorado's agreement with the U.S. Nuclear Regulatory Commission, all facilities regardless or ownership, must adhere to the same public health and safety requirements and regulations for use of radioactive materials in Colorado. The proposed rule changes provide both regulatory relief and an increase in some requirements and will therefore equally impact all types of medical facilities using radioactive materials whether privately or governmentally owned or operated.

DRAFT REGULATORY ANALYSIS
6 CCR 1007-1 Part 3, Licensing of radioactive materials
6 CCR 1007-1 Part 7, Use of radionuclides in the healing arts

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Healing arts (medical) facilities holding a Department license to use or prepare radioactive materials for diagnostic or therapeutic purposes on humans. This includes hospitals, clinics, and private medical practices.	89	C / CLG
Licensed nuclear pharmacy facilities that prepare radioactive materials for end use at medical facilities.	6	C*
Private companies providing services to medical licensees.	3	C
Other stakeholders who requested notification of proposed medical related radiation rule changes including private organizations and companies that may collectively represent medical facilities and/or specific practitioners that use radioactive materials in the practice of medicine. This includes individuals associated with professional associations, societies and organizations that may represent hospitals, physicians, medical physicists, radiologic technologists, and allied health professions.	400+	S
Human patients undergoing medical procedures involving use of radioactive materials and their families (per yr) in Colorado.	350k+	B

* With a few limited exceptions, nuclear pharmacy licensees fall within the requirements of Part 3 but are not required to implement most requirements of Part 7 since they prepare but do not administer radioactive materials to patients. Certain provisions of Part 3 defer to Part 7 for specific requirements applicable to nuclear pharmacies.

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, the following relationship categorization key is used:

C = individuals/entities that implement or apply the rule.
CLG = local governments that must implement the rule in order to remain in compliance with the law.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.

B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Economic outcomes
Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

Financial/economic costs:
C and CLG: Licensees - including those that are governmental owned, operated, or otherwise affiliated - who use radioactive materials at medical facilities will be required to modify some aspects of their radiation safety program to meet the proposed requirements. Licensees will need to expend some resources to:

- Update the written approval and authorizations for associate radiation safety officers (ARSO's), with the primary radiation safety officer assigning tasks and duties to those ARSO's in writing;
- Amend written procedures and forms for written directives to address changes in permanent implant brachytherapy procedures;
- Minor updates to written procedures to address notification requirements for generator breakthrough.

Financial/economic benefits:
Licensees are expected to benefit through cost savings due to the elimination or easing of certain requirements that should require less resources. Cost savings are expected as a result of:

- Removal of the requirement to obtain and submit a written attestation statement for most board certified physicians when requesting an amendment to add them to a license;
- Allowing the grandfathering of certain experienced authorized user physicians when adding them to a license;
- Easing the requirement for reporting of breakthrough of generator contaminants, allowing licensees additional time to determine if an actual breakthrough has occurred;
- Providing allowances for Ophthalmic physicists who are not necessarily fully qualified as Authorized Medical Physicists (AMP) to perform certain activities with these sources. This may benefit some rural facilities as certain activities typically reserved to the AMP could be performed by another individual specifically training and qualified on these sources;
- Requiring the use of activity based (versus the current dose-based) reporting criteria for medical events for permanent implant brachytherapy. Activity based reporting is expected to be easier for licensees to implement due to the technical limitations of dose-based determinations and reporting.

Expense/cost type	Description	Cost per licensee
Initial (one time)	Cost to implement the proposed requirements per licensee	<$1,100**
Annual	Cost to maintain ongoing compliance with the proposed requirements	$100

**The estimated initial cost per licensee is based on estimates of similar rule changes evaluated by NRC as part of the 2018 amendment to 10 CFR Part 35. The initial cost per licensee is likely to be less for Colorado licensees due to:

- The higher labor rates assumed by NRC for some calculations. For example, NRC assumed that revisions to procedures for written directives would be developed by individuals in the physician category. In reality, this activity is likely to be performed by the medical physicist/RSO at a lower labor rate than a physician.
- Up until the 2018 federal rule change, only the primary RSO could be named on an NRC license. However, Colorado and other agreement states have for many years, allowed both a primary RSO and Alternate RSO to be named on the license, holding both to the same training and experience requirements. Since that documentation has been previously submitted to the division, Colorado licensees will not have to expend efforts to make this transition. Colorado will administratively amend licenses to convert from the current Alternate RSO terminology to Associate RSO terminology without effort or expenditure from Colorado licensees.

Please describe any anticipated financial costs or benefits to these individuals/entities.

S: There are no anticipated financial costs or benefits to these entities as a result of the proposed changes.

B: There are no anticipated financial costs or benefits to these entities as a result of the proposed changes. The rule changes are not expected to increase or change the cost of imaging or treatment services.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

C/CLG: The favorable outcomes for licensees (regulated entities) and the personnel that work for them, is that licenses and the radiation safety programs they conduct will be consistent and align with the national framework for regulating radioactive materials. Individuals named as Associate RSOs on licenses will be able to work in other states where similar requirements have been implemented.

B: Overall, the proposed requirements are expected to benefit patient safety. The enhanced requirements for reporting of actual or potential medical events resulting from permanent implant brachytherapy helps ensure that problems are identified promptly in order to detect failures in process, procedure, and training and limit unneeded exposure to future patients. Similarly, requiring manufacturer training prior to the first patient use of a therapy system will help ensure staff are appropriately trained on any new updates or therapy treatment systems prior to first patient use. The proposed rule updates,

clarifies and strengthens the existing regulatory requirements, and, thereby, promotes public health and safety.

S: Organizations such as medical societies or associations (formally or informally) will not be directly impacted by the proposed changes and will not have favorable or non-favorable outcomes. Only the facilities/entities they represent will be impacted.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   A. Anticipated CDPHE personal services, operating costs or other expenditures:

   The initial 1st year costs (outline below) primarily involve the administrative amendments to licenses to convert to the new associate radiation safety officer terminology. The ongoing regulatory program costs beyond the first year are expected to be "net neutral" as these will be absorbed into the routine licensing and inspection activities costs.

Type of Expenditure	Year 1	Year 2
Cost to administratively amend ~83 licenses to convert to the Associate RSO term.	$4,565	N/A*
Licensing and compliance activities associated other amended requirements in the rules are expected to be absorbed into routine activities with no additional expenditures by the division.	N/A	N/A
Total	$4,565	N/A

*Beyond the initial conversion to the Associate RSO terminology, no additional expenses are anticipated, as routine license changes and updates are part of and absorbed into the normal licensing business processes.

   Anticipated CDPHE Revenues: NA

   B. Anticipated personal services, operating costs or other expenditures by another state agency: NA

   Anticipated Revenues for another state agency: NA

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   Along with the costs and benefits discussed above, the proposed revisions:

   _X_ Comply with a statutory mandate to promulgate rules.
   _X_ Comply with federal or state statutory mandates, federal or state regulations, and Department funding obligations.
   _X_ Maintain alignment with other states or national standards.
   _X_ Implement a Regulatory Efficiency Review (rule review) result
   _X_ Improve public and environmental health practice.
   _X_ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Performs targeted programming to increase immunization rates. ___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.

___ Implements the CDPHE Digital Transformation Plan.
___ Optimizes processes prior to digitizing them.
___ Improves data dissemination and interoperability methods and timeliness.

10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.

___ Reduces emissions from employee commuting
___ Reduces emissions from CDPHE operations

11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.

___ Used a budget equity assessment

___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

The cost of inaction will result in Colorado regulations being inconsistent with the national framework and federal regulations pertaining to use of radioactive materials at medical facilities. Failing to have final regulations that are compatible with those of the NRC could result in enhanced regulatory oversight of the radiation program and potential revocation of authorization as an agreement state.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute or state agreement. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholders on a national level. Local stakeholders also provided feedback regarding certain proposed provisions. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute and federal regulations.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

Other than the modifications described for 7.10.5 based on stakeholder feedback, no alternative rules or alternative rulemaking was considered. To varying degrees, Colorado's rules pertaining to radiation control must be maintained consistent with the regulations of the U.S. NRC in order to maintain its status as an Agreement State. Also see response #4 and 5.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

With the exception of the proposed change pertaining to individuals specifically authorized for administration of radioactive materials to patients, the proposed changes to the requirements in Part 7 and Part 3 are based upon changes to the overarching federal regulations which establish a national and consistent framework for regulation of radioactive materials in medicine. The last major revision to the federal regulation took place in 2002. Since that time, the medical community and other stakeholders have identified issues and concerns on a national level regarding the implementation of certain requirements. A number of medical events occurring on a national level have also affected change in federal regulations. These were taken into consideration in the development of final federal regulations on a national basis. The discussion, considerations, and evaluation of the federal rule changes may be found in the following federal register document:

Federal Register Volume 83, Issue 136 (July 16, 2018)

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1007-1 Part 3, Licensing of radioactive materials
6 CCR 1007-1 Part 7, Use of radionuclides in the healing arts

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Organization	Representative Name and Title (if known)
Medical licensees in Colorado.	Radiation Safety Officer(s)
Nuclear pharmacy licensees in Colorado.	Radiation Safety Officer(s)
Medical related service provider licensees in Colorado.	Radiation Safety Officer(s)
Medical related associations, societies and organizations.	NA
Other stakeholders with interest in changes to rules and regulations pertaining to radiation control.	NA

Approximately 500+ stakeholders (identified above) were notified by email of the opportunity to provide comment on the proposed draft rules which were posted on the department website. Two stakeholder meetings were held in January and February to provide stakeholders the opportunity to hear a presentation on the proposed regulations and to provide feedback and ask questions. A total of three individuals attended the two meetings - two by phone and one in person. The department received comment letters from two of the attendees.

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

____ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

__X_ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The primary feedback received in two comment letters from stakeholders was in regard to the potential limitations of 7.10.5 as originally proposed and the removal of an alternate pathway for nuclear medicine technologists (NMTs) in Appendix 7N. These proposed changes

are not associated with the other federal rule changes but are based on the division's desire to remove ambiguity from the current rule, to enhance the tie between the definition for a nuclear medicine technologist (7.2), the supervision requirements of 7.10, and Appendix 7N, and to allow flexibility in applying training requirements for non-technologists. While some states require licensure of NMTs in a manner similar to that for physicians, nurses and other allied health professionals, Colorado does not have such a requirement and therefore the division defers to national certification requirements.

Stakeholders commented that the rule as proposed in 7.10.5 did not address students in nuclear medicine technology or others who may handle, assay and inject radioactive material under supervision as part of their initial or ongoing training. Similarly, stakeholders also noted that some specific procedures involving radioactive materials may involve administration of radionuclides by non-nuclear medicine personnel due to the unique qualifications of those individuals in order to optimize patient imaging or treatment.

As a result of these comments the division has revised the language in 7.10.5 to include an allowance for individuals in-training for nuclear medicine or medical physics. Also included in the revised proposed rule is the option for a case-by-case evaluation and authorization process (by the division) that would allow individual(s) to use materials under the supervision of an AU named on the license and who do not fit any of the other user categories in 7.10.5. We believe the revised proposed language provides flexibility and would allow for a variety of situations where radioactive materials may be handled or administered by persons not falling within the other more common categories addressed in 7.10.5.

A stakeholder commented that the proposal to remove the alternate pathway for training of nuclear medicine technologists in Appendix 7N is inconsistent with the other radiation professional positions defined in the rule, such as the Radiation Safety Officer, Authorized Users, etc. all of which have alternate pathways that would allow them to be named on a license. The commenter stated that the alternate pathway is needed to provide flexibility to facilities to ensure qualified persons are available for facilities to provide essential care in nuclear medicine.

While the division recognizes the need to have qualified personnel to perform nuclear medicine procedures we disagree that the alternate pathway is the best approach for achieving this for NMTs. It should be noted that the alternate pathway training requirements for all other authorized individuals (non-NMTs) named on the license are driven by federal regulation. The current federal structure does not mention or recognize NMTs in regulation or in the licensing process. Other than national certification requirements for NMTs, we are unaware of a nationally recognized or consistent approach for training of individuals to serve as NMTs or carry out certain functions normally performed by NMTs. While the elimination of the alternate pathway might present challenges for a very limited number of facilities, the division feels that the alternate pathway criteria for nuclear medicine technologists is generally inadequate to qualify an individual as an NMT. The criteria in current rule gives the wrong impression that it requires only a limited number hours for an individual to achieve status as an NMT to perform all types of nuclear medicine related activities. Conversely, the criteria found in the alternate pathway may be an excessive amount of training for some limited administration of radioactive material by non-NMTs.

Unlike other authorized individuals named on the license whose qualifications are reviewed up front during licensing activities, the training and experience of NMTs present a challenge to the division as this information is normally only evaluated during routine inspections. We

believe the updated proposed language of 7.10.5 affords facilities the opportunity to provide additional information on how individuals might be trained for their specific application and needs. At least two licensees in Colorado have license conditions in place to address specific and limited handling, use, or administration of radioactive materials by non-NMTs.

Stakeholders had a few questions regarding implementation of the proposed changes driven by federal rule but did not suggest specific changes to those proposed requirements and changes.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking: None.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	X	Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

DRAFT 2 (05/27/2020)

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - LICENSING OF RADIOACTIVE MATERIAL

6 CCR 1007-1 PART 03

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

Adopted by the Board of Health on ~~May 17, 2017~~June 17, 2020; effective ~~June 30, 2017~~August 14, 2020.

[* * * = Unaffected sections or text]

* * *

~~3.1.4.3 In accordance with Section 24-4-103(12.5)(c), CRS, https://www.colorado.gov/cdphe/radregs identifies where incorporated material is available to the public on the internet at no cost. If the incorporated material is not available on the internet at no cost to the public, copies of the incorporated material has been provided to the State Publications Depository and Distribution Center, also known as the State Publications Library. The State Librarian at the State Publication Library retains a copy of the material and will make the copy available to the public.~~

3.1.4.3 Throughout this Part 3, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in effect as of the most recent effective date of this Part 3 (August 2020), and not later amendments or editions of the incorporated material.

3.1.4.4 Materials incorporated by reference are available for public inspection, and copies (including certified copies) can be obtained at reasonable cost, during normal business hours from the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Additionally, https://www.colorado.gove/cdphe/radregs identifies where the incorporated federal and state regulations are available to the public on the internet at no cost. A copy of the materials incorporated in this Part is available for public inspection at the state publications depository and distribution center.

3.1.4.5 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Printing Office, online at www.govinfo.gov.

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/

EDITORIAL NOTE 3: This draft rule includes additional changes beyond those proposed in the rule presented to the Board of Health in March 2020. These additions/changes are highlighted in yellow and were added to address changes and updates associated with the documents incorporated by reference as proposed in Section 3.1.4.3.

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]: Provisions in section 3.1.4.3, are revised and enhanced for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS) regarding documents incorporated by reference.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/RegisterHome.do.

* * *

3.3.2.4 No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule 3B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 3.3.2 or equivalent regulations of NRC or any Agreement State except in accordance with a specific license issued by NRC pursuant to Section 32.18 of 10 CFR Part 32 ~~(January 1, 2015)~~, which license states that the radioactive material may be transferred by the licensee to persons exempt under 3.3.2 or the equivalent regulations of NRC or an Agreement State.[1]

* * *

3.5.8.3 * * *

(1) * * *

(2) * * *

(3) * * *

(4) * * *

(5) Shall not export such depleted uranium except in accordance with a license issued by NRC pursuant to 10 CFR Part 110 ~~(January 1, 2015)~~.

* * *

3.6.4.2 The general license in 3.6.4.1 applies only to radioactive material contained in devices which have been:

(1) Manufactured or initially transferred and labeled for distribution to persons generally licensed in accordance with the specifications contained in a specific license issued by:

(a) The Department pursuant to 3.12.4 or

(b) By NRC or an Agreement State[4]

[4] Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21 ~~(April 1, 2012)~~.

(2) Received from one of the specific licensees described in 3.6.4.2(1) or through a transfer made under 3.6.4.3(8).

3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers radioactive material in a device pursuant to the general license in 3.6.4.1:

(1) * * *

(2) * * *

(3) * * *

Commented [JSJ4]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

Commented [JSJ5]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

Commented [JSJ6]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

Commented [JSJ7]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

(4) * * *

(5) * * *

(6) * * *

(7) Shall not export the device except in accordance with 10 CFR Part 110 ~~(January 1, 2015)~~ and shall obtain written approval from NRC before transferring the device to any other specific licensee not specifically identified in 3.6.4.3(8);

(8) * * *

(9) Shall transfer the device to another general licensee only:

(a) Where the device remains in use at a particular location.

In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Department the manufacturer's (or initial transferor's) name and model number and serial number of device transferred, the identity of the radionuclide(s) present and assayed or calculated activity present, the transferee's name and mailing address for the location of use, and the name, title, and phone number of the responsible individual identified by the transferee in accordance with 3.6.4.3(12) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

Commented [JSJ8]: Correction of typographical error by adding a comma between "name" and "title".

* * *

3.6.5.1 * * *

Commented [JSJ9]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

(1) * * *

(2) Each device has been manufactured, assembled or imported in accordance with a specific license issued by NRC or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 ~~(January 1, 2015)~~.

* * *

3.6.7.4 The general licenses in 3.6.7.1, 3.6.7.2, and 3.6.7.3 apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by NRC pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 (January 1, 2015) or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department or any Agreement State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 ~~(January 1, 2015)~~.

Commented [JSJ10]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

* * *

3.6.10.1 A general license is hereby issued to receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains

Commented [JSJ11]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

not more than 1.85 MBq (50 µCi) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by NRC or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Department or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 ~~(January 1, 2015)~~.

* * *

DECOMMISSIONING WARRANTY

3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a dollar amount determined by the ~~agency~~**Department** as necessary to protect public health and safety, to ensure corrective action during operation, to ensure decontamination and decommissioning of a facility and disposal of radioactive materials in the event of abandonment, default or inability of the licensee to meet the requirements of the Act, these regulations, or the license.

3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

(1) Each licensee authorized to possess and use greater than 370 MBq (10 mCi) of source material in a readily dispersible form; and

(2) Each licensee authorized to possess and use radioactive material with a half-life greater than 120 days, in quantities:

(a) Greater than 10^3 times the applicable quantity of Schedule 3B in unsealed form. For a combination of isotopes if R divided by 10^3 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Schedule 3B.

(b) Greater than 10^{10} times the applicable quantity of Schedule 3B in sealed sources or plated foils. For a combination of isotopes if R divided by 10^{10} is greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).

(c) 370 Bq (0.01 µCi) shall be used as the Schedule 3B value for any alpha emitting radionuclide not listed in Schedule 3B, or mixtures of alpha emitters of unknown composition, for the purpose of determining if the quantity of licensed radioactive material requires a decommissioning warranty or a decommissioning funding plan as defined in 3.9.6.

(3) Former U.S. Atomic Energy Commission or NRC licensed facilities;

(4) Radioactive waste collection and/or processing licensees;

(5) Radioactive waste disposal licensees;

(6) Source material milling licensees;

(7) Ore refineries; and

(8) Other persons with, or applicants for, a specific license as determined by the ~~agency~~**Department**.

* * *

Commented [JSJ12]: 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.

3.9.6.3 Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish an ~~agency~~**Department**-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility.

* * *

3.11.5 Specific licenses of broad scope are subject to the following conditions:

3.11.5.1 Unless specifically authorized, persons licensed pursuant to 3.11 shall not:

(1) Conduct tracer studies in the environment involving direct release of radioactive material;

(2) Receive, acquire, own, possess, use; or transfer devices containing 3.7 PBq (100 kCi) or more of radioactive material in sealed sources used for irradiation of materials;

(3) Conduct activities for which a specific license issued by the Department under ~~3.10, 3.12, or Parts 7, 14, and 18~~**Part 3, 5, or 7** is required; or

Commented [JSJ13]: Provision is modified to correct a past error in cross references, consistent with similar requirements in 10 CFR 33.17.

* * *

3.12.4.5 * * *

Commented [JSJ14]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

(1) * * *

(2) * * *

(3) * * *

(a) Report the information specified in 3.12.4.5(2) to NRC for all transfers of such devices to persons for use under NRC general license in Section 31.5 of 10 CFR Part 31 ~~(January 1, 2015)~~.

* * *

3.12.5.1 * * *

Commented [JSJ15]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

(1) * * *

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56 of 10 CFR Part 32 ~~(January 1, 2015)~~, or their equivalent.

* * *

3.12.6.1 * * *

Commented [JSJ16]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

(1) * * *

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 ~~(January 1, 2015)~~ or their equivalent.

* * *

3.12.9.1 * * *

(1) * * *

(2) The criteria of Sections 32.61, and 32.62 of 10 CFR Part 32 ~~(January 1, 2015)~~ are met.

* * *

3.12.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for Medical Use.

3.12.10.1 An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs **containing radioactive material for use by persons authorized under**~~for medical use pursuant to~~ Part 7 will be approved if:

(1) The applicant satisfies the general requirements specified in 3.9;

(2) The applicant submits evidence that the applicant is at least one of the following:

(a) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR **Part** 207.20(a);

(b) Registered or licensed with the State Board of Pharmacy as a drug manufacturer;

(c) Licensed as a pharmacy by the State Board of Pharmacy;

(d) Operating as a nuclear pharmacy within a Federal medical institution; or

(e) A Positron Emission Tomography (PET) drug production facility registered with the State Board of Pharmacy.

(3) The applicant submits information on the radionuclide~~,~~**;** **the** chemical and physical form~~,~~**;** the maximum activity per vial, syringe, generator, or other container of the radioactive drug~~,~~**;** and the shielding provided by the packaging ~~of the radioactive material~~ to show it is appropriate for safe handling and storage of **the** radioactive drugs by medical use licensees; and

(4) The applicant has procedures ~~to assure~~ **which commit to** the following labeling requirements:

(a) A label ~~shall be~~**is** affixed to each transport radiation shield**,** ~~(~~whether it is constructed of lead, glass, plastic, or other material~~)~~ of a radioactive drug to be transferred for commercial distribution.

(i) The label ~~shall~~**must** include the radiation symbol prescribed in 4.27 and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the

Commented [JSJ17]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

Commented [JSJ18]: A sentence is added to this provision, consistent with 2018 amendments to 10 CFR 32.72.

NRC RATS 2018-1
NRC Compatibility B

Commented [JSJ19]: This provision parallels the requirements in 10 CFR 32.72(a)(4)) to clarify that the applicant has procedures to address the specified labeling requirements. The radiation program wants to retain the ability to review procedures applicable to labeling.

NRC RATS 2018-1
NRC Compatibility B

radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time.

(ii) For radioactive drugs with a half-life greater than 100 days, the time may be omitted.

(b) A label ~~shall be~~**is** affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution~~. and shall include:~~**The label must include:**

(i) The radiation symbol prescribed in 4.27 and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; and

(ii) An identifier that ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.

3.12.10.2 ~~A radioactive materials licensee who is also licensed by the State Board of Pharmacy:~~**A licensee described by 3.12.10.1(2)(c) or 3.12.10.1(2)(d):**

(1) May prepare radioactive drugs for medical use, as defined in **Part 1, Section** 1.2 and Part 7, provided that the radioactive drug is prepared by either:

(a) An authorized nuclear pharmacist, as specified in 3.12.10.2(2) or 3.12.10.2(4), or

(b) An individual under the direct supervision of an authorized nuclear pharmacist as specified in **Part 7, Section** 7.10;

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) This individual qualifies as an Authorized Nuclear Pharmacist as defined in **Part 7, Section** 7.2;

(b) This individual meets the requirements specified in Part 7~~,~~ Appendix 7C**2 and Section 7.65**, and the licensee has received ~~a Department~~ **an approved** license amendment identifying this individual as an authorized nuclear pharmacist; or

(c) This individual is designated as an authorized nuclear pharmacist in accordance with 3.12.10.2(4).

(3) The actions authorized in 3.12.10.2(1) and 3.12.10.2(2) are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in **Part 7, Section** 7.2) as an authorized nuclear pharmacist if:

(a) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(b) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Department~~: a copy of each individual's:~~

(a) **A copy of each individual's** ~~C~~certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State as specified in Part 7, Appendix 7C**1** ~~with the written attestation signed by a preceptor as required by Part 7, Appendix 7C, Section 7C2.2~~; or

(b) **The** Department, NRC or Agreement State license ~~that allows such work~~, or

(c) NRC master materials licensee permit, or

(d) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(e) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(f) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 3.12.10.2(2)(a) and 3.12.10.2(2)(c), the individual to work as an authorized nuclear pharmacist.

3.12.10.3 A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs.

(1) The licensee shall have procedures for use of the instrumentation.

(2) The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta- or photon-emitting radioactive drugs prior to transfer for commercial distribution.

(3) In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

3.12.10.4 A licensee shall satisfy the labeling requirements in 3.12.10.1(4).

3.12.10.~~4~~**5** Nothing in this section relieves the licensee from complying with applicable FDA, Federal, and state requirements governing radioactive drugs.

3.12.11 Reserved.

3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

Commented [JSJ20]: 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

Commented [JSJ21]: This provision formatted for alignment.

Commented [JSJ22]: 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.

NRC RATS 2018-1
NRC Compatibility B

3.12.12.1 An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part 7 for use as a calibration, transmission, or reference source or for the uses listed in **Part 7, Sections** 7.19, 7.40, 7.42, 7.48 and 7.62 will be approved if:

(1) The applicant satisfies the general requirements in 3.9 of this part;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(a) The radioactive material contained, its chemical and physical form, and amount,

(b) Details of design and construction of the source or device,

(c) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(d) For devices containing radioactive material, the radiation profile of a prototype device,

(e) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(f) Procedures and standards for calibrating sources and devices,

(g) Legend and methods for labeling sources and devices as to their radioactive content, and

(h) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Department for distribution to persons licensed pursuant to **Part 7, Sections** 7.40 and 7.42 or under equivalent licenses of NRC or an Agreement State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(4) The source or device has been registered in the Sealed Source and Device Registry.

* * *

3.12.13.4 Each person licensed pursuant to 3.12.13.1 shall:

(1) * * *

(2) * * *

(3) * * *

(4) * * *

(5) * * *

(6) Report to NRC all transfers of industrial products or devices to persons for use under NRC general license in Section 40.25 of 10 CFR Part 40 ~~(January 1, 2010)~~.

* * *

3.15.6 Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Part 7. The licensee shall record the results of each test and retain each record for 3 years after the record is made. **The licensee shall report the results of any test that exceeds the permissible concentration listed in Part 7, Section 7.33.1 at the time of generator elution, in accordance with Part 7, Section 7.33.5.**

Commented [JSJ23]: 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.

NRC RATS 2018-1
NRC Compatibility B

* * *

3.16.2.7 Each licensee or person responsible for a facility or site which includes a non-exempt source of radiation or which may be contaminated by residual radioactivity shall, no less than 30 days before vacating or relinquishing possession or control of the facility or site, notify the ~~agency~~**Department**, in writing, of the intent to vacate.

Commented [JSJ24]: Language updated in this provision for consistency with other wording in Section 3.16.2.

* * *

3.19 ~~Agency~~**Department** Action on Applications to Renew and Amend.

* * *

3.24.4 Each general licensee operating within the state under reciprocity in areas of exclusive federal jurisdiction shall comply with the applicable provisions of 10 CFR 150.20 ~~(January 1, 2013)~~.

Commented [JSJ25]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

* * *

PART 3, SCHEDULE 3B: EXEMPT QUANTITIES (3.3.2)

* * *

[EDITORIAL NOTE - NO CHANGES TO MAIN BODY/TABLE OF SCHEDULE 3B]

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 of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and **divide by** 1,000 times the amount in Schedule 3B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

Amount of Radionuclide A possessed	+Amount of Radionuclide B possessed	≤ 1
1000 x Schedule 3B quantity for Radionuclide A.	1000 x Schedule 3B quantity for Radionuclide B	

Note 2: To convert microcuries (µCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 µCi multiplied by 37 is equivalent to 370 kBq).

* * *

3C.12.1 Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by NRC pursuant to section 32.22 of 10 CFR Part 32 ~~(January 1, 2015)~~, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

* * *

3C.13.1 Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in the Act and from the regulations in 3, 4, 5, 7, 10, 16, and 19 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by NRC[18] pursuant to section 32.26 of 10 CFR Part 32~~(January 1, 2015)~~, which license authorizes the initial transfer of the detectors to persons who are exempt from regulatory requirements. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by NRC or an Agreement State under comparable provisions to 10 CFR Part 32.26 authorizing distribution to persons exempt from regulatory requirements.

* * *

[EDITORIAL NOTE - NO CHANGES TO REMAINDER OF RULE FOLLOWING FOOTNOTES OF SCHEDULE 3B]

Commented [JSJ26]: Correction of cross-reference errors in footnotes of Schedule 3B as item "(5)" does not exist.

Commented [JSJ27]: The reference to a specific CFR date is removed in order to defer to the revised standard incorporation by reference language in section 3.1.4.

DRAFT 2 – 06/04/2020

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - USE OF RADIONUCLIDES IN THE HEALING ARTS

6 CCR 1007-1 Part 07

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

Adopted by the Board of Health June 17, 2020, effective date August 14, 2020

PART 7: USE OF RADIONUCLIDES IN THE HEALING ARTS

USE OF RADIONUCLIDES IN THE HEALING ARTS

Section A – General Information

7.1 ~~Purpose and Scope.~~**Purpose and scope.**

7.1.1 Authority

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

7.1.2 Basis and Purpose.

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

7.1.3 Scope.

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

7.1.4 Applicability.

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

7.1.5 Published ~~M~~material ~~i~~incorporated by ~~R~~reference.

~~Published material incorporated in Part 7 by reference is available in accord with 1.4.~~

7.1.5.1 Throughout this Part 7, federal regulations, state regulations, and standards or guidelines of outside organizations have been adopted and incorporated by reference. Unless a prior version of the incorporated material is otherwise specifically indicated, the materials incorporated by reference cited herein include only those versions that were in

Commented [JJ28]:
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/cfr/. Links to specific CFR 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/impeptoolbox/impepcompatibility.html.

EDITORIAL NOTE 4:
The NRC has issued implementation guidance on the federal regulations. These may be found at:
https://www.nrc.gov/docs/ML1817/ML18176A377.pdf

Commented [JSJ29]: 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 [JSJ30]: 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 [JJ31]:
Provisions in section 7.1.5, are revised and amended for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS) regarding documents incorporated by reference.

effect as of the most recent effective date of this Part 7 (August 2020), and not later amendments or editions of the incorporated material.

7.1.5.2 Materials incorporated by reference are available for public inspection, and copies (including certified copies) can be obtained at reasonable cost, during normal business hours from the Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246. Additionally, https://www.colorado.gove/cdphe/radregs identifies where the incorporated federal and state regulations are available to the public on the internet at no cost. A copy of the materials incorporated in this Part is available for public inspection at the state publications depository and distribution center.

7.1.5.3 Availability from Source Agencies or Organizations.

(1) All federal agency regulations incorporated by reference herein are available at no cost in the online edition of the Code of Federal Regulations (CFR) hosted by the U.S. Government Printing Office, online at www.govinfo.gov.

(2) All state regulations incorporated by reference herein are available at no cost in the online edition of the Code of Colorado Regulations (CCR) hosted by the Colorado Secretary of State's Office, online at https://www.sos.state.co.us/CCR/RegisterHome.do.

(3) Copies of the standards or guidelines of outside organizations are available either at no cost or for purchase from the source organizations listed below.

a. The Federal Policy for the Protection of Human Subjects: hhs.gov or https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html or
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C.20201
Phone: 1-877-696-6775.

b. NUREG-1556, Vol. 9: nrc.gov or https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/ or
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Phone: 1-800-368-5642.

7.2 Definitions.

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

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

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

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

(1) Meets the requirements in Appendix 7A and 7.65; and

Commented [JJ32]: 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

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

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

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

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

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

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

b. A medical use permit issued by an NRC master material license;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee; or

d. A permit issued by an NRC master material license broad scope medical use license

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

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

a. A specific license issued by the Department, NRC, or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

b. A permit issued by an NRC master material license that authorizes medical use or the practice of nuclear pharmacy;

c. A permit issued by an NRC or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

d. A permit issued by an NRC master material license broad scope medical use permitee that authorizes medical use or the practice of nuclear pharmacy; or

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

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

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

(1) Is identified as an authorized user on:

a. A Department, NRC, or Agreement State license that authorizes the medical use of radioactive material;

b. A permit issued by an NRC master material license that is authorized to permit the medical use of radioactive material;

c. A permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

d. A permit issued by an NRC master material license broad scope permitee that is authorized to permit the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

"Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

"Client" means, for mobile medical service, the person for whom, or in conjunction with whom, medical service is provided.

"Client's address" means the address of use for the purpose of providing mobile medical service in accordance with 7.27.

"Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to practice dentistry.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Ophthalmic physicist" means an individual who:

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

(2) Is identified as an ophthalmic physicist on a:

a. Specific medical use license issued by the Department, NRC or an Agreement State;

b. Permit issued by the Department, NRC or Agreement State broad scope medical use licensee;

c. Medical use permit issued by a NRC master material licensee; or

d. Permit issued by a NRC master material licensee broad scope medical use permittee.

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

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

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

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

Commented [JSJ33]: For consistency with NRC language in 10 CFR Part 35, medical event replaces the current "misadministration" term here and throughout the rule.

Commented [JJ34]: Updated for consistency with same definition in 10 CFR 35.2.

Compatibility D.

Commented [JSJ35]: This term is deleted here and is replaced by "medical event", consistent with the terminology of 10 CFR 35.

Commented [JJ36]: 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.

NRC Compatibility B
NRC RATS 2018-1

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

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

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

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

(1) A written directive as specified in 7.11; or

(2) Accordance with the directions of the authorized user for procedures performed pursuant to 7.30, 7.32, or 7.36.

"Prescribed dose" means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive;

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

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

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

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

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

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

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

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

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

Commented [JJ37]: 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.

The reference to preceptors for nuclear medicine technologists is removed as this term is proposed for removal from Appendix 7N. The reference to preceptors for radiation therapy technologists is excluded since that term is only used in Appendix 7O which is proposed for deletion (in its entirety).

NRC Compatibility D
NRC RATS 2018-1

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

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

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

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

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

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

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

"Teletherapy", as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Temporary job site", as used in Part 7, means a location where mobile medical services are confined to the mobile unit not at a licensed address of use.

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Trunnion" means a support bar sometimes used as a bearing instead of a socket.

"Type of use" means use of radioactive material as specified under 7.30, 7.32, 7.36, 7.40, 7.42, 7.48 or 7.62.

"Unit dosage" means a dosage that:

(1) Is obtained or prepared in accordance with the regulations for uses described in 7.30, 7.32, or 7.36; and

(2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 7.11.

Commented [JSJ38]:
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 [JSJ39]:
This definition is not used in the body of the rule nor is it used in 10 CFR 35.

GENERAL REGULATORY REQUIREMENTS

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

7.3.1

7.3.1.**1** A person ~~shall~~**may** manufacture, produce, ~~prepare,~~ acquire, receive, possess, **prepare,** use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Department, an Agreement State or NRC, or as allowed in 7.3.1.1 or 7.3.1.2.

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

~~7.3.1.~~**(**1**)** ~~Unless prohibited by license condition, an individual may r~~**R**eceive**s**, possess, use**s**, or transfer**s** radioactive material in accordance with the regulations ~~in this part~~ under the supervision of an authorized user as provided in 7.10**, unless prohibited by license condition.; or**

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

7.3.2 Provisions for the protection of Human Research Subjects.

A licensee may conduct research involving human subjects using radioactive material under the following conditions:

7.3.2.1 For research conducted, funded, supported, or regulated by a federal agency which has implemented The Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall:

(1) Obtain prior informed consent from the human research subjects; and

(2) Obtain prior review and approval of the research activities by an “Institutional Review Board” in accordance with the meaning of these terms as defined and described in the Federal Policy; or

7.3.2.2 For research not conducted, funded, supported, or regulated by a federal agency which has implemented the Federal Policy, then:

(1) The licensee shall apply for and receive a specific amendment to its Department license before conducting such research. The amendment request shall include a written commitment that the licensee will, before conducting research:

(a**)**~~.~~ Obtain prior informed consent from the human research subjects; and

(b**)**~~.~~ Obtain prior review and approval of the research activities by an “Institutional Review Board” in accordance with the meaning of these terms as defined and described in the Federal Policy;

7.3.2.3 A licensee not authorized pursuant to 3.11 shall apply for and receive approval of a specific amendment to its Department license before conducting research involving human subjects;

7.3.2.4 The research involving human subjects authorized in 7.3.2 shall be conducted using radioactive material authorized for medical use in the license; and

Commented [JSJ40]: 7.3.1 is updated/realigned for consistency with the format and content of 10 CFR 35.11.

[NON-RATS ITEM]

7.3.2.5 Nothing in 7.3.2 relieves licensees from complying with the other requirements in Part 7.

7.3.3 Nothing in this part relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs or devices.

7.3.4 Application for ~~L~~license, ~~A~~amendment, or ~~R~~renewal.

7.3.4.1 An application ~~shall~~**must** be signed by the applicant's or licensee's management.

7.3.4.2 An application for a new or renewal license for medical use of radioactive material as described in 7.30, 7.32, 7.36, 7.40, 7.42, 7.48 or 7.62 must be made by:

(1) Filing **an original** ~~a completed~~ Department Form R-12 (7C) **that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s);** and

(2) Submitting procedures required by Form R-12 (7C), and 7.12, 7.15, 7.51, 7.58, 7.59, and 7.61, as applicable, and other procedures as requested by the Department.

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

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

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

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, renewal license, or amendment for medical use of radioactive material as described in 7.62 must also include**:** ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in 7.1 through 7.29, as well as any specific information on:~~

~~(1)~~ ~~Radiation safety precautions and instructions;~~**Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from:**

(a) Section A through C (7.1 through 7.29);

(b) Sections D through H (recordkeeping requirements);

(c) Section I (7.65);

(d) Appendix 7A, 7B, 7C and 7P;

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

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

(3) Any additional specific information on:

(a) Radiation safety precautions and instructions;

Commented [JSJ41]: 7.3.4 is updated for consistency with the wording of 10 CFR 35.12.

The revised language clarifies what information must be included in the application process, including the newly added Associate RSO and Ophthalmic physicist definitions.

NRC Compatibility D (all provisions within 7.3.4)
NRC RATS 2018-1

Commented [JSJ42]: Note: due to structural differences, the "Subparts" of 10 CFR Part 35 do not exactly parallel the "Sections" of Part 7.

10 CFR 35.12(d)(1) specifies that the license or amendment application include additional aspects applicable to radiation safety that are not addressed in subpart A through C, L, and M.

For reference:
- Subparts A through C of the CFR parallel Part 7 Sections A through C.
- Subpart B of the CFR also includes the training requirements of 35.50, 35.51, 35.55, and 35.57. For Part 7, these training requirements are found in Appendices 7A, 7B, 7C, and 7P, and are called out separately.
- Subpart B of the CFR also includes the recentness of training requirements of 35.59 which is found in Section 7I (provision 7.65).
- Subpart L of the CFR contains the recordkeeping requirements which are found in Sections D through H of Part 7.
-Subpart M of the CFR contains the reporting requirements which are contained within Sections C through D of Part 7.

NRC Compatibility D

Commented [JSJ43]: Subparts D through H as referenced in the equivalent requirement of 10 CFR 35.12(d)(2) parallel the requirements of Section D through H of Part 7.

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

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

(4) Any other information requested by the Department in its review of the application.

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

Commented [JSJ44]: Provision replaced by revised 7.3.4.4(4).

7.3.4.~~6~~**5** An applicant that satisfies the requirements specified in 3.11 may apply for a Type A specific license of broad scope.

7.3.5 Mobile Medical Service Administrative Requirements.

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

7.3.5.2 Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

7.3.5.3 A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

7.3.5.4 A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

7.3.5.5 A licensee providing mobile medical services shall retain the letter required in 7.3.5.2 for 3 years after the last provision of service.

7.3.5.6 A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

(1) The current operating and emergency procedures;

(2) A copy of the license;

(3) Copies of the letter required by 7.3.5.2;

(4) Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

(5) Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

7.3.5.7 The mobile medical service shall designate and manage each area of use in the client's facility as a restricted area while radioactive material is present. For each location where radioactive materials will be routinely used, the licensee shall provide to the Department:

(1) A diagram of the location of use, including information about the placement of required postings; and

(2) Calculation(s) or survey(s) results that demonstrate compliance with applicable dose limits in 4.14 and 4.15 at the location of use.

7.3.5.8 The mobile medical service shall ensure that:

(1) Supervision by an authorized user is in accordance with 7.10.1;

(2) Radiation exposures to the client's personnel working in the client facility are:

(a) Below the dose limits to members of the public listed in 4.14; or

(b) The client's personnel are instructed as described in 10.3 and monitored for exposure in accordance with 4.18 unless the licensee can demonstrate that 4.18 does not apply.

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

(1) A single address of use:

(a) Identified as the records retention location; and

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

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

(a) Identified in the license; and

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

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

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

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

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

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

Commented [JJ45]: Section updated for consistency with 2018 amendments to 10 CFR 35.15.

NRC Compatibility D (all of 10 CFR 35.15)

Commented [JJ46]: Updated for consistency with 10 CFR 35.15(c).

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

7.3.6.6 The provisions of 7.5.2.5; and

7.3.6.~~5~~**7** The provisions of 7.14 regarding suppliers for sealed sources.

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

7.4 License ~~A~~amendments.

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

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

7.4.2 **Before it permits**~~Permits~~ anyone to work as an authorized user, authorized medical physicist, **ophthalmic physicist,** or an authorized nuclear pharmacist under the license**, except:** ~~in accordance with the training and experience requirements specified in:~~

7.4.2.1 ~~Appendix 7D through Appendix 7M for an authorized user for a specific type of use of radioactive material;~~**For an authorized user, an individual who meets the requirements in Appendix 7P and one or more of the following: Section 7D1 of Appendix D, Section 7E1 of Appendix E, Section 7F1 of Appendix F, Section 7G1 of Appendix 7G, Section 7H1 of Appendix 7H, Section 7K1 of Appendix K, Section 7J1 of Appendix J, or Section 7M1 of Appendix M;**

7.4.2.2 ~~Appendix 7B for an authorized medical physicist;~~**For an authorized nuclear pharmacist, an individual who meets the requirements in Section 7C1 of Appendix 7C and 7.65;**

7.4.2.3 ~~Appendix 7C for an authorized nuclear pharmacist; and~~**For an authorized medical physicist, an individual who meets the requirements in Section 7B1 of Appendix 7B and 7.65;**

7.4.2.4 An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist on:

(1) A NRC or Agreement State license or other equivalent permit or license recognized by the Department that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) A permit issued by a NRC or Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(3) On a permit issued by a NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

Commented [JJ47]: Added for consistency with 10 CFR 35.15(e).

Commented [JJ48]: Added for consistency with 10 CFR 35.15(f).

Commented [JSJ49]: Language updates in section 7.4 are made consistent with 2018 changes to 10 CFR Part 35.13.

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

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Commented [JSJ50]: For cross reference to 10 CFR 35:

- 7.65 = 10 CFR 35.59 (recentness of training)
- App 7D = 10 CFR 35.190 (uptake, dilution, excretion)
- App 7E = 10 CFR 35.290 (imaging and localization)
- App 7F = 10 CFR 35.390 (unsealed - written dir. req)
- App 7G = 10 CFR 35.392 (I-131 < 33 mCi)
- App 7H= 10 CFR 35.394 (I-131 > 33 mCi)
- App 7K = 10 CFR 35.490 (manual brachytherapy)
- App 7J = 10 CFR 35.590 (sources for diagnosis)
- App 7M = 10 CFR 35.690 (afterloaders, GSR)

Commented [JSJ51]:
App 7C = 10 CFR 35.55 (auth nuclear pharmacist)

Commented [JSJ52]:
App 7B = 10 CFR 35.51 (authorized medical phys)

7.4.2.5 A physician, podiatrist, or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates.

7.4.3 **Before it** ~~C~~changes a Radiation Safety Officer, except as provided in ~~7.7.6~~**7.7.3**;

7.4.4 Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

7.4.~~4~~**5 Before it** ~~R~~receives radioactive material in excess of the amount or in a different physical or chemical form**, or receives a different radionuclide** than is authorized on the license;

7.4.~~5~~**6** ~~Adds to or changes the area(s) of use or address(es) of use identified in the application or on the license, except as specified in 7.5.2.4; and~~**Before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either 7.30 or 7.32 if the change includes addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area. Other areas of use where radioactive material is used only in accordance with either 7.30 or 7.32 are exempt;**

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

7.4.~~6~~**8 Before it** ~~C~~changes statements, representations, and procedures which are incorporated into the license; or

7.4.~~7~~**9 Before it** ~~R~~releases licensed facilities for unrestricted use.

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

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

7.5 Notifications **and maintenance of records.**

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

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

(1) Training for the authorized medical physicist under 7B3 of Appendix 7B;

(2) Any additional case experience required in 7F2.1(2)(f) of Appendix 7F for an authorized user under 7.36; or

Commented [JSJ53]: Added for consistency with 10 CFR 35.13(d).

Commented [JSJ54]:
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 [JJ55]: Updated for consistency with 2018 amendments to 10 CFR 35.14(a).

The proposed language allows for a 30 day window in which documentation must be provided to the Department. Consistent with 7.4.2, certain individuals may work under the license prior to the licensee providing the necessary documentation.

NRC Compatibility D

Commented [JSJ56]: 7.4.2 = 10 CFR 35.13(b)

Commented [JJ57]: 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

(3) Device specific training in 7M3 of Appendix 7M for the authorized user under 7.48; or

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

Commented [JJ58]: Added for consistency with 10 CFR 35.14(a)(2)

NRC Compatibility D

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

Commented [JJ59]: Updated for consistency with 10 CFR 35.14(b).

NRC Compatibility D

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

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

Commented [JSJ60]:
CROSS REFERENCES:
7A = 35.50
7.65 = 35.59
7.7.6 = 35.24(c)

7.5.2.~~2~~**3** The licensee's mailing address changes;

7.5.2.~~3~~**4** The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 3.15.2 of these regulations; or

7.5.2.~~4~~**5** The licensee has added to or changed the areas **of use identified in the application or on the license** where radioactive material is used in accordance with **either** 7.30 ~~and~~**or** 7.32 **if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area**~~.~~**; or**

7.5.2.6 The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in 7.4.11. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

Commented [JSJ61]: CROSS REFERENCE:
7.4.11 = 10 CFR 35.13(i)

7.5.3 The licensee shall submit the documents required in 7.5.1 and 7.5.2 to the Department.

7.5.~~3~~**4** Maintenance of Records.

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

7.6 License ~~i~~issuance.

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

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

7.6.1.2 The applicant has paid any applicable fee;

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

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

7.6.2 The Department shall issue a license for mobile services if the applicant:

7.6.2.1 Meets the requirements in 7.6.1, and in particular 7.3.5; and

7.6.2.2 Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with 7.26.

~~**ADDITIONAL OVERALL REQUIREMENTS**~~

Section B – General Administrative Requirements

7.7 Authority and ~~R~~responsibilities for the ~~R~~radiation ~~P~~protection ~~P~~program

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

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

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

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

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

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

Commented [JSJ62]: Section 7.7 is updated, consistent with 2018 updates to 10 CFR 35.24

NRC RATS 2018-1

Commented [JJ63]: Provision updated, consistent with 2018 updates to 10 CFR 35.24(b)

The amended language introduces the new Associate Radiation Safety Officer terminology and associated requirements.

NRC RATS 2018-1
NRC Compatibility: H&S (7.7.2 / 35.24(b))

Commented [JSJ64]: Provision 7.7.3 revised, consistent with 10 CFR 35.24(c). This provision replaces current 7.7.6.

CROSS REFERENCES:
Appendix 7A = 10 CFR 35.50
7.65 = 10 CFR 35.59

7.7.2 = 10 CFR 35.24(b)
7.7.5 = 10 CFR 35.24(e)
7.7.6 = 10 CFR 35.24(g)
7.7.7 = 10 CFR 35.24(h)
7.5.2 = 10 CFR 35.35.14(b)

NRC RATS 2018-1
NRC Compatibility: D (7.7.3 / 35.24(c))

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

Commented [JSJ65]: Provision 7.7.4 added, consistent with 10 CFR 35.24(d). This provision was previously omitted from Colorado rule.

CROSS REFERENCE:
7.7.3 = 10 CFR 35.24(c)

7.7.3~~5~~ ~~A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer, and of the Alternate RSO, if required.~~**A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.**

Commented [JSJ66]: Language revised for consistency with the phrasing of 10 CFR 35.24(e). No change in requirements.

NRC Compatibility D

7.7.4~~6~~ A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

7.7.4~~6~~.1 Identify radiation safety problems;

7.7.4~~6~~.2 Initiate, recommend, or provide corrective actions;

7.7.4~~6~~.3 Stop unsafe operations; and

7.7.4~~6~~.4 Verify implementation of corrective actions.

~~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, including:~~

Commented [JSJ67]: This provision has been replaced by new 7.7.7.

NRC Compatibility D

~~7.7.5.1 A summary of the actions taken (and a signature of licensee management) in accordance with 7.7.1;~~

~~7.7.5.2 A signed copy of the RSO's agreement (including the signature of the RSO and licensee management) to be responsible for implementing the radiation safety program, as required by 7.7.2; and~~

~~7.7.5.3 A current copy of the authorities, duties and responsibilities of the RSO as required by 7.7.3.~~

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: Records of authority and responsibilities for radiation protection programs.

Commented [JSJ68]: 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 the 2018 CFR changes, and addresses the recordkeeping requirements pertaining to the (new) Associate Radiation Safety Officer position.

NRC RATS 2018-1
NRC Compatibility D

CROSS REFERENCES:
7.7.1 = 10 CFR 35.24(a)
7.7.2 = 10 CFR 35.24(b)
7.7.5 = 10 CFR 35.24(e)

7.7.7.1 A licensee shall retain a record of actions taken by the licensee's management in accordance with 7.7.1 for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

7.7.7.2 The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by 7.7.5, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 7.7.2, for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

7.7.7.3 For each Associate Radiation Safety Officer appointed under 7.7.2, the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

~~7.7.6 For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 7.7.4, provided the licensee takes the actions required in 7.7.2, 7.7.3, 7.7.4 and 7.7.5.~~

Commented [JJ69]: This provision is replaced by NEW 7.7.3 (above).

~~A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.~~

Commented [JSJ70]: This provision is replaced by NEW 7.7.4 (above).

7.8 Radiation ~~S~~safety ~~C~~committee.

7.8.1 Licensees that are authorized for one or more different types of radioactive material use under 7.36, 7.42, 7.48, or 7.62 shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license.

7.8.2 The Committee shall:

7.8.2.1 Include:

(1) An authorized user of each type of use permitted by the license;

(2) The Radiation Safety Officer

(3) A representative of the nursing service

(4) A representative of management who is neither an authorized user nor a Radiation Safety Officer; and

(5) Other members as the licensee deems appropriate.

7.8.2.2 Meet as necessary, but at a minimum shall meet at intervals not to exceed 6 months.

7.8.2.3 Maintain minutes of each meeting, including:

(1) The date of the meeting;

(2) Members present;

(3) Members absent; and

(4) Summary of deliberations and discussions.

7.9 Radiation ~~P~~protection ~~P~~program ~~C~~changes.

7.9.1 A licensee may revise its radiation protection program without Department approval if:

7.9.1.1 The revision does not require an amendment under 7.4;

7.9.1.2 The revision is in compliance with the regulations and the license;

7.9.1.3 The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and

7.9.1.4 The affected individuals are instructed on the revised program before the changes are implemented.

7.9.2 A licensee shall retain a record of each change for 5 years, including

7.9.2.1 A copy of the old and new procedures;

7.9.2.2 The effective date of the change; and

7.9.2.2 The signature of the licensee management that reviewed and approved the change.

7.10 Supervision.

7.10.1 A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by ~~7.3.2~~**7.3.1.2(1)** shall:

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

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

7.10.2 A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by ~~7.3.3~~**7.3.1.2(2)**, shall:

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

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

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

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

7.10.5 A licensee who permits supervised activities under 7.10.1 and 7.10.2 shall require that the administration of radioactive material or radiation from radioactive material under the supervision of an authorized user be performed only by:

7.10.5.1 A physician;

7.10.5.2 An individual who meets the requirements of Appendix 7B or 7N;

7.10.5.3 An individual in training in medical physics while under personal supervision of an individual meeting the requirements of Appendix 7B;

7.10.5.4 An individual in training in nuclear medicine technology while under personal supervision of an individual meeting the requirements of Appendix 7N; or

7.10.5.5 An individual otherwise authorized in writing by the Department, or through license condition(s).

7.11 Written ~~D~~directives.

Commented [JJ71]: Updated to correct prior cross-reference and typographical errors and align with the renumbering of section 7.3.1. Formatting and alignment corrections are also made to this section.

Commented [JJ72]: Updated to correct a prior cross-reference error and align with the renumbering of section 7.3.1.

Commented [JSJ73]:
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 named on the license. Such individuals may include physicians who may be training on a particular type of use and are not yet named as authorized users on a license for that material; authorized medical physicists; and nuclear medicine technologists.

As a result of stakeholder feedback, the originally proposed language is modified and expanded to include individuals in training for medical physics and nuclear medicine and to permit case-by-case authorizations for certain allied health and medical professionals who may be involved with administration of radioactive materials. The Department recognizes that certain medical procedures may involve administration of radioactive materials under the supervision of an AU by persons other than a physician in training, authorized medical physicist, or nuclear medicine technologist. These other individuals may include neurodiagnostic technicians trained to perform injections during seizures, or other individuals who may be involved in sentinel node procedures. The proposed provision provides a mechanism for licensees to request and be granted authorization for individuals who do not meet the requirements of 7.10.5.1 through 7.10.5.4.

In all instances, the administration of radioactive materials is performed under the supervision of an authorized user named on the license in accordance with the requirements of 7.10.

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

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

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

7.11.1.2 Any therapeutic dosage of radioactive material, or

7.11.1.3 Any therapeutic dose of radiation from radioactive material.

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

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

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

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

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

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

7.11.2.5 For permanent implant brachytherapy:

(1) Before implantation: the treatment site, the radionuclide, and the total source strength: and

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

7.11.2.~~5~~**6** For all other brachytherapy, including LDR, MDR, and PDR:

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

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

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

7.11.~~4~~3 A written revision to an existing written directive may be made ~~provided that~~**if** the revision is dated and signed by an authorized user ~~prior to~~**before** the administration of the dosage of ~~radioactive~~

Commented [JJ74]: Updated for consistency with the 2018 amendments to 10 CFR 35.40(a).

NRC Compatibility H&S
NRC RATS 2018-1

Commented [JJ75]: 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.

Commented [JJ76]: Added for consistency with the 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 activity (source strength/radioactivity) based criteria.

NRC RATS 2018-1
NRC Compatibility H&S

Commented [JJ77]: This provision is relocated to 7.11.1 for consistency with the flow/format of 10 CFR 35.40.

Commented [JJ78]: Updated for consistency with language of 10 CFR 35.40(c)(1).

NRC Compatibility H&S

~~drug containing~~ **unsealed** radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

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

7.11.~~6~~**4** The licensee shall retain a copy of each written directive and/or written revision to an existing written directive for 3 years.

7.12 Procedures for ~~A~~administrations ~~R~~requiring a ~~W~~written ~~D~~directive.

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

7.12.1.1 The patient's or human research subject's identity is verified before each administration; and

7.12.1.2 Each administration is in accordance with the written directive.

7.12.2 ~~The procedures required by 7.12.1 must, at~~ **At** a minimum, **the procedures required by 7.12.1 must** address the following items that are applicable for the licensee's use of radioactive material:

7.12.2.1 Verifying the identity of the patient or human research subject;

7.12.2.2 Verifying that the ~~specific details of the~~ administration ~~are~~**is** in accordance with the treatment plan, if applicable, and the written directive;

7.12.2.3 Checking both manual and computer-generated dose calculations; ~~and~~

7.12.2.4 Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 7.48 **or 7.62.**

7.12.2.5 Determining if a medical event, as defined in 7.21, has occurred; and

7.12.2.6 Determining, for a permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

7.12.3 A licensee shall retain a copy of the procedures required under 7.12.1 for the duration of the license.

7.13 Duties of ~~A~~authorized ~~U~~user and ~~A~~authorized ~~M~~medical ~~P~~physicist.

7.13.1 A licensee shall assure that only authorized users for the type of radioactive material used:

7.13.1.1 Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

Commented [JJ79]: Updated for consistency with 10 CFR 35.40(c)(2).

NRC Compatibility H&S

Commented [JJ80]: Updated for consistency with wording of 10 CFR 35.41(b).

Commented [JJ81]: Updated for consistency with wording of to 10 CFR 35.41(b)(5).

10 CFR 35.41(b)(2).

Commented [JSJ82]: Consistent with the reformatting of 7.62, a reference to 7.62 is added.

Ref: NRC Letter 02/20/2020

Commented [JJ83]: Added for consistency with 2018 changes to 10 CFR 35.41(b)(5). This is a new provision in the CFR.

Requiring licensees to establish procedures to help evaluate for and report medical events allows the Department (and nationally, the NRC) to identify if similar issues/errors are occurring across facilities.

NRC RATS 2018-1
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CROSS REFERENCE: 7.21 = 10 CFR 35.3045

Commented [JJ84]: Added for consistency with 2018 changes to 10 CFR 35.41(b)(6). This is a new provision in the CFR.

This requires licensees to include in their procedures, an evaluation of whether the placement of implanted sources is consistent with the post-implantation portion of the written directive.

NRC RATS 2018-1
NRC Compatibility H&S

Commented [JSJ85]: 35.41
Added for consistency with 10 CFR 35.41(c) and the recordkeeping requirements of 10 CFR 35.2041. This provision was previously omitted from the rule.

NRC Compatibility D
[Non-RATS item]

7.13.1.2 Direct, as specified in 7.10 and 7.12, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

7.13.1.3 Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with ~~7.3.2~~**7.3.1.2(1)**, ~~7.3.3~~**7.3.1.2(2)** and 7.10;

7.13.2 A licensee shall assure that only authorized medical physicists perform, as applicable:

7.13.2.1 Measurements and calculations as described in 7.41;

7.13.2.2 Full calibration measurements as described in 7.54, 7.55, and 7.56;

7.13.2.3 Periodic spot checks as described in 7.58, 7.59 and 7.61; and

7.13.2.4 Radiation surveys as described in 7.57.

7.14 ~~Suppliers for Sealed Sources or Devices for Medical Use.~~**Suppliers for sealed sources or devices for medical use.**

For medical use, a licensee may only use:

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

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

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

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

7.15 Quality Control of Diagnostic Equipment.

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

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

7.15.2.1 Those recommended by equipment manufacturers; or

7.15.2.2 Procedures which have been approved by the Department.

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

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

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

Commented [JJ86]: Updated to correct prior cross-reference errors and align with the renumbering of section 7.3.1.

Commented [JSJ87]: Minor changes to this provision, consistent with 10 CFR 35.49.

NRC Compatibility C
[NON-RATS ITEM]

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

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

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

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

7.16.4.1 Model and serial number of the instrument;

7.16.4.2 Date of the calibration and other tests;

7.16.4.3 Results of the calibration and other tests; and

7.16.4.4 Name of the individual who performed the calibration and other tests.

7.17 ~~Calibration of Survey Instruments.~~**Calibration of survey instruments.**

7.17.1 A licensee shall ~~ensure that~~**calibrate** the survey instruments used to show compliance with Part 4 and Part 7 ~~have been calibrated~~ before first use, annually **at intervals not to exceed 12 months**, and following a~~ny~~ repair that ~~will~~ affect**s** the calibration. **A licensee shall:**

7.17.1.1 Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

7.17.1.2 Calibrate two separate readings on each scale or decade that will be used to show compliance; and

7.17.1.3 Conspicuously note on the instrument the date of calibration.

~~7.17.2 To satisfy the requirements of 7.17.1 the licensee shall:~~

~~7.17.2.1 Calibrate all required scale readings up to 10 mSv (1 rem) per hour with a radiation source;~~

~~7.17.2.2 Have each radiation survey instrument calibrated as follows, or by acceptable equivalent methods:~~

~~(1) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;~~

~~(2) For linear scale instruments, at 2 points located approximately one-third and two-thirds of full-scale on each scale;~~

~~(3) For logarithmic scale instruments, at mid-range of each decade and at 2 points of at least one decade;~~

~~(4) For digital instruments, at 3 points between 0.02 and 10 mSv (2 and 1000 mrem) per hour; and~~

Commented [JSJ88]: Language and format/flow is updated for consistency with 10 CFR 35.61 except as indicted 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 [JSJ89]: The requirement in 7.17.2.1 is replaced by 7.17.1.1 (above).

Commented [JSJ90]:
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.

~~(5) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.~~

~~7.17.2.3 Conspicuously note on the instrument the date of calibration.~~

Commented [JSJ91]: The requirement in 7.17.2.3 is replaced by 7.17.1.3 (above).

7.17.~~3~~2 ~~The~~**A** licensee ~~shall~~**may** not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is ~~greater~~**more** than 20 percent.

7.17.~~4~~3 ~~The~~**A** licensee shall retain a record of each survey instrument calibration required by 7.17 for 3 years. The record shall include the:

7.17.~~4~~3.1 Model and serial number of the instrument;

7.17.~~4~~3.2 Date of the calibration;

7.17.~~4~~3.3 Results of the calibration; and

7.17.~~4~~3.4 Name of the individual who performed the calibration.

7.18 ~~Determination of Dosages of Radioactive Material for Medical Use.~~**Determination of dosages of unsealed radioactive material for medical use.**

7.18.1 A licensee shall determine and record the activity of each dosage ~~prior to~~**before** medical use.

7.18.1.1 For photon-emitting radioactive material, this determination shall be within 30 minutes prior to medical use.

7.18.1.2 For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the radioactive material.

7.18.2 For a unit dosage, the determination required by 7.18.1 shall be made by:

7.18.2.1 ~~d~~**D**irect measurement of radioactivity; or

7.18.2.2 ~~a~~**A** decay correction, based on the measurement made by:

(1) ~~a~~**A** manufacturer or preparer licensed pursuant to Part 3 of these regulations or equivalent provisions of an~~other~~ Agreement State, or NRC; or

(2) ~~an~~**An** NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

(3) A PET radioactive drug producer licensed under Part 3, Section 3.8.10 or equivalent NRC or Agreement State requirements.

Commented [JSJ92]: Added, consistent with the requirements of 10 CFR 35.63(b)(2)(iii). This provision has been in federal rule for a number of years, but was omitted during prior rule amendments.

NRC Compatibility H&S

7.18.3 For other than ~~a~~ unit dosage**s**, the determination by 7.18.1 shall be made by:

7.18.3.1 ~~d~~**D**irect measurement of radioactivity; or

7.18.3.2 ~~by a c~~**C**ombination of measurement~~s~~ of radioactivity and mathematical calculations; or

7.18.3.3 ~~by a c~~**C**ombination of volumetric measurements and mathematical calculations, based on the measurement made by:

(1) ~~a~~**A** manufacturer or preparer licensed pursuant to Part 3 of these regulations or equivalent provisions of an~~other~~ Agreement State, or NRC.

(2) A PET radioactive drug producer licensed under Part 3, Section 3.8.10 or equivalent NRC or Agreement State requirements.

7.18.4 Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

7.18.5 A license shall retain a record of the each dosage determination required by 7.18.1 for 3 years. The record shall contain the:

7.18.5.1 Name of the radioactive drug;

7.18.5.2 Patient's or human research subject's name, and identification number if one has been assigned;

7.18.~~3.3~~**5.3** Prescribed dosage;

7.18.~~3.4~~**5.4** Determined dosage; or a notation that the total activity is less than 1.1 MBq (30 µCi);

7.18.~~3.5~~**5.5** Date and time of the dosage determination; and

7.18.~~3.6~~**5.6** Name of the individual who determined the dosage.

7.19 ~~Authorization for Calibration, Transmission and Reference Sources.~~**Authorization for calibration, transmission and reference sources.**

7.19.1 Any person authorized by 7.3 for medical use of radioactive material may receive, possess, and use **any of** the following radioactive material for check, calibration**, transmission** and reference use:

~~7.19.1~~**7.19.1.1** ~~Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part 3 of these regulations or equivalent provisions of the another Agreement State, a Licensing State, or NRC, and that do not exceed 1.1 GBq (30 mCi) each;~~**Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Part 3, by NRC under 10 CFR 32.74 or equivalent Agreement State regulations;**

7.19.1.2 Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Part 3, by NRC under 10 CFR 32.74 or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

~~7.19.2~~**7.19.1.3** Any radioactive material with a half-life not longer than 120 days or less in individual amounts not to exceed ~~0.55~~**0.56** GBq (15 mCi);

~~7.19.3~~**7.19.1.4** Any radioactive material with a half life ~~greater~~**longer** than 120 days in individual amounts not to exceed the smaller of **7.4 MBq (200 uCi) or 1000 times the quantities in Part 3 Schedule 3B**~~:~~**; or**

~~7.19.3.1 7.4 MBq (200 µCi);~~

~~7.19.3.2 1000 times the quantities in Part 3 Schedule 3B; and~~

Commented [JSJ93]: Added, consistent with the requirements of 10 CFR 35.63(c)(3)(ii). This provision has been in federal rule for a number of years, but was omitted during prior rule amendments.

NRC Compatibility H&S

Commented [JJ94]: Correction of numbering errors made in this section.

Commented [JSJ95]: Section 7.19 is revised for consistency with the 2018 amendments to 10 CFR 35.65.

NRC Compatibility D
NRC RATS 2018-1

Commented [JSJ96]: This provision is not new to federal rule, but was previously omitted from Colorado rule.

NRC Compatibility D

~~7.19.4~~**7.19.1.5** Technetium-99m in amounts as needed.

7.19.2 Radioactive material in sealed sources authorized by this provision shall not be:

7.19.2.1 Used for medical use as defined in 7.2 except in accordance with the requirements in 7.40; or

7.19.2.1 Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under 7.19.

7.19.3 A licensee using calibration, transmission, and reference sources in accordance with the requirements in 7.19.1 or 7.19.2 need not list these sources on a specific medical use license.

7.20 ~~Requirements for Possession of Sealed Sources and Brachytherapy Sources.~~**Requirements for possession of sealed sources and brachytherapy sources.**

7.20.1 A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Department and shall maintain the instructions for the duration of source use in a legible form convenient to users.

7.20.2 A licensee in possession of a sealed source shall ~~test the source for leakage~~:

7.20.2.1 ~~In accordance with Part 4 of these regulations; and~~**Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the sources was tested within 6 months before transfer to the licensee; and**

7.20.2.2 **Test the source for leakage** ~~At~~**at** intervals not to exceed 6 months or at intervals approved by the Department, an~~other~~ Agreement State, ~~a Licensing State~~ or the NRC in the Sealed Source and Device Registry.

7.20.2.3 A licensee shall retain records of leak tests required by 7.20.2 for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

7.20.3 To satisfy the leak test requirements of 7.20, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 uCi) of radioactive material in the sample.

7.20.4 If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

7.20.4.1 Immediately withdraw the sealed source from use and store, dispose or cause it to be repaired in accordance with the requirements of these regulations; and

7.20.4.2 File a written report with the Department within 5 days of receiving the leak test result, including the model number and serial number, if assigned, of the leaking source, the radionuclide and its estimated activity, the date and results of the test, and the action taken.

7.20.5 A licensee in possession of a sealed source or brachytherapy source, except for a gamma stereotactic radiosurgery source, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record for 3 years. The inventory records ~~shall~~**must** contain the model number of each source, and serial number if one has been

Commented [JSJ97]: This is a new provision/requirement in federal rule, added for consistency with the 2018 amendments to 10 CFR Part 35.65(b).

The added language clarifies that while sources may be authorized under 7.19 (35.50) they may only be used for medical purposes under the requirements of 7.40 (35.500). The NRC considers the exposure of humans/patients to a radioactive source to be medical use.

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

Commented [JSJ98]: This is a new provision/requirement, added for consistency with the 2018 amendments to 10 CFR Part 35.65(c).

Compatibility D
NRC RATS 2018-1

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

Commented [JSJ99]: Rather than defer to Part 4, the requirements are incorporated into Part 7, consistent with the format of 10 CFR 35.67. These requirements are the same as those currently found in Part 4.

[Non-RATS item]

Commented [JSJ100]: This provision is added for clarity consistent with 10 CFR 35.67(d).

The provision in Part 4 pertaining to recordkeeping for leak test is not specific with regard to the leak testing record. The proposed language adds clarity to the recordkeepoing (and similar to the existing requirement for source inventory in 7.20.5).

The proposed change also provides some regulatory relief by reducing the duration that leak test records must be maintained – from 5 years to 3 years.

[Non-RATS item]

assigned, the identity of each source **by** radionuclide and its estimated activity, the location of each source, and the name of the individual who performed the inventory.

7.21 ~~Reports and Notifications of Misadministrations.~~**Report and notification of a medical event.**

7.21.1 ~~Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:~~**A licensee shall report any event as a medical event, except for an event that results from patient or human research subject intervention, in which:**

7.21.1.1 The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

~~7.21.1.1~~ **(1)** A dose that differs from the prescribed dose **or dose that would have resulted from the prescribed dosage** by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and ~~either~~

~~(1)~~ **(a)** The total dose delivered differs from the prescribed dose by 20 percent or more;

~~(2)~~ **(b)** The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

~~(3)~~ **(c)** The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

~~7.21.1.2~~ **(2)** A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

~~(1)~~ **(a)** An administration of a wrong radioactive drug **containing radioactive material or the wrong radionuclide for a brachytherapy procedure**;

~~(2)~~ **(b)** An administration of a radioactive drug containing radioactive material by the wrong route of administration;

~~(3)~~ **(c)** An administration of a dose or dosage to the wrong individual or human research subject;

~~(4)~~ **(d)** An administration of a dose or dosage delivered by the wrong mode of treatment; or

~~(5)~~ **(e)** A leaking sealed source.

~~7.21.1.3~~ **(3)** A dose to the skin or an organ or tissue other than the treatment site that exceeds by**:**

(a) ~~0.5 Sievert (50 rem) to an organ or tissue and~~**0.5 Sievert (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and**

(b) ~~50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment~~

Commented [JJ101]: Consistent with current NRC language in 10 CFR 35, Part 7 is being modified to change the term “misadministration” to “medical event”.

Commented [JJ102]: Reworded for consistency with 10 CFR 35.3045.

Due to the change in certain requirements related to permanent implant brachytherapy, the requirements pertaining to medical events for these materials are modified in 7.21.

NRC Compatibility C
NRC RATS 2018-1

Commented [JSJ103]: Language pertaining to human research subject intervention is retained from the current rule although it is not found in 10 CFR 35.

Commented [JSJ104]: 35.3045(a)(1)(ii)(A)

NRC Compatibility C

~~site).~~**50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.**

7.21.1.2 For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(1) The total source strength administered differing by 20 % or more from the total source strength documented in the post-implantation portion of the written directive;

(2) The total source strength administered outside of the treatment site exceeding 20 % of the total source strength documented in the post-implantation portion of the written directive; or

(3) An administration that includes any of the following:

(a) The wrong radionuclide;

(b) The wrong individual or human research subject;

(c) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(d) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

7.21.2 A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

7.21.3 The licensee shall notify ~~the Agency~~ by telephone **the Department** no later than the next calendar day after discovery of the ~~misadministration~~**medical event**.

7.21.4 The licensee shall submit a written report to the ~~Agency~~**Department** within 15 days after discovery of the ~~misadministration~~**medical event**.

7.21.4.1 The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual(s) who received the administration;

(6) **What actions**~~Actions~~, if any, ~~that~~ have been taken, or are planned~~,~~ to prevent recurrence; **and**

Commented [JSJ105]: This is a new requirement added consistent with the 2018 amendments to 10 CFR 35.3045(a)(2) pertaining to permanent implant brachytherapy.

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

7.21.4.2 The report may not contain the individual's name or any other information that could lead to identification of the individual.

7.21.5 The licensee shall provide notification of the ~~misadministration~~**medical event** to the referring physician and also notify the individual who is the subject of the ~~misadministration~~**medical event** no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the ~~misadministration~~**medical event**, because of any delay in notification. To meet the requirements of ~~this paragraph~~**7.21.5**, the notification of the individual who is the subject of the ~~misadministration~~**medical event** may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

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

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

Commented [JSJ106]: This provision is replaced by the revised requirements in new 7.21.7 (below).

~~7.21.7.1 The licensee's name;~~

~~7.21.7.1 Names of the individuals involved;~~

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

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

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

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

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

7.21.7 A licensee shall:

Commented [JSJ107]: In part, this provision replaces some requirements of the prior 7.21.7, consistent with 10 CFR 35.3045(g).

7.21.7.1 Annotate a copy of the report provided to the Department with the:

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

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

Commented [JSJ108]: This provision is rephrased to conform to an NRC (federal) rulemaking that is currently in process for 10 CFR 35.3045. The federal rulemaking is intended to provide protection of social security information by limiting its use in regulatory documents where possible.

Proposing this change now is expected to help eliminate the need for a future rulemaking.

Refer to FR 85 33527 for additional information.

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

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

Commented [JSJ109]: This provision is replaced by new 7.21.7.2.

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

7.22.1 The licensee shall notify the Department by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of **Part 4, section** 4.14 as a result of the deceased's body.

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

7.22.2.1 Licensee's name;

7.22.2.2 Date of death;

7.22.2.3 Radionuclide, chemical and physical form and calculated activity at time of death; and

7.22.2.4 Names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 mSv (500 mrem).

7.22.3 The licensee shall retain a record of each written report required by 7.22 for 3 years.

7.23 ~~Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.~~**Report and notification of a dose to an embryo/fetus or a nursing child**

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

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

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

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

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

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

7.23.4.1 The written report must include:

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

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

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

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

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

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

7.23.6 A licensee shall~~: retain a record of a dose to an embryo/fetus or a nursing child for 3 years. The record must contain:~~

~~7.23.6.1 The licensee's name;~~

~~7.23.6.2 Names of all the individuals involved;~~

~~7.23.6.3 Social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event;~~

~~7.23.6.4 A brief description of the event and why it occurred;~~

~~7.23.6.5 The effect, if any, on the embryo/fetus or nursing child;~~

~~7.23.6.6 The actions, if any, taken, or planned, to prevent recurrence; and~~

~~7.23.6.7 Whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

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

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

Commented [JSJ110]: This provision replaces 7.23.6.1 through 7.23.6.7, consistent with the approach and format used in 10 CFR Part 35.3047, and to parallel the changes to 7.21.7.

Current provision 7.23.4 provides requirements for the contents of the specified report, which is largely repeated in the prior language of 7.23.6 that is proposed for deletion. The proposed change to 7.23.6 streamlines the process by requiring the licensee to annotate the existing required report with the specified information.

Proposing this change now is expected to help eliminate the need for a future rulemaking.

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

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

7.24 ~~Vial Shields and Labels.~~**Labeling of vials and syringes.**

7.24.1 A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

7.24.2 Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug, to include the isotope and amount of radioactivity. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

7.25 ~~Surveys for Contamination and Ambient Exposure Rate.~~**Surveys for contamination and ambient exposure rate.**

7.25.1 Surveys required by 7.25.2 and 7.25.3 are in addition to surveys required by Part 4.

7.25.2 Daily Survey Requirements

7.25.2.1 At the end of each day of use, a licensee shall survey with an exposure rate instrument, all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

(1) A licensee does not need to perform the surveys required by 7.25.2.1 in an area where patients or human research subjects are confined when they cannot be released pursuant to 7.26.

7.25.2.2 At the end of each day of use, a licensee shall survey for removable contamination all areas where generators and bulk radioactive drugs are prepared for use. An instrument capable of detecting 33.3 becquerels (2000 dpm) of contamination on each wipe sample shall be used.

7.25.3 Weekly Survey Requirements

7.25.3.1 At least once each week, a licensee shall survey, with an exposure rate instrument, all areas where radioactive drugs or radioactive wastes are stored.

7.25.3.2 At least once each week, a licensee shall survey for removable contamination in all areas where radioactive materials other than sealed sources as defined in Part 7 are stored. An instrument capable of detecting 33.3 becquerels (2000 dpm) of contamination on each wipe sample shall be used.

7.25.4 A licensee shall establish action levels for the surveys required by 7.25.2 and 7.25.3 and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if action levels are exceeded.

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. The record must include:

7.25.5.1 The date of the survey;

7.25.5.2 The results of the survey;

Commented [JSJ111]: This provision is rephrased to conform to an NRC (federal) rulemaking that is currently in process for 10 CFR Part 35.3047. The federal rulemaking is intended to provide protection of social security information by limiting its use in regulatory documents where possible.

Refer to FR 85 33527 for additional information.

7.25.5.3 The instrument used to make the survey (including, if applicable, that the instrument was checked for consistent response with a dedicated check source prior to each daily use); and

7.25.5.4 The name of the individual who performed the survey.

7.26 ~~Release of Individuals Containing Radioactive Drugs or Implants.~~**Release of individuals containing unsealed radioactive material or implants containing radioactive material.**

7.26.1 A licensee may authorize the release from the licensee's control of any individual who has been administered radioactive drugs or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

1 Appendix U of U.S. Nuclear Regulatory Commission NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

7.26.2 A licensee shall provide the released individual or the individual's parent or guardian with instructions, including written instructions on the actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem).

7.26.2.1 If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption in breast-feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

7.26.3 If the total effective dose equivalent to a nursing infant or child could exceed 5 mSv (0.5 rem) from continued breast-feeding, the licensee shall maintain a record that the instructions required by 7.26.2 were provided to a breast-feeding woman.

7.26.4 The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 7.26, if the total effective dose equivalent is calculated by:

7.26.4.1 Using the retained activity rather than the administered activity;

7.26.4.2 Using an occupancy factor less than 0.25 at 1 meter;

7.26.4.3 Using the biological or effective half-live; and

7.26.4.4 Considering the shielding by tissue.

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 of the individual.

7.26.6 Reports of Patient Departure Prior to Authorized Release.

7.26.6.1 The licensee shall notify the Department by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 7.26.

7.26.6.2 The licensee shall submit a written report to the Department within 30 days after discovery of the unauthorized departure. The written report must include:

(1) The licensee's name;

(2) The date and time of the unauthorized departure;

(3) The projected date and time when release would have occurred;

(4) The address of the patient's or human research subject's home or anticipated destination following departure;

(5) The radionuclide, chemical and physical form and calculated activity at time of release;

(6) The apparent reason(s) for the departure prior to authorized release; and

(7) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

7.27 ~~Mobile Nuclear Medicine Service Technical Requirements.~~**Mobile nuclear medicine service technical requirements.**

A licensee providing mobile nuclear medicine service shall:

7.27.1 Transport to each client’s address of use only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

7.27.2 Bring into each client’s address of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

7.27.3 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client’s address of use;

7.27.4 Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;

7.27.5 Check survey instruments for consistent response with a dedicated check source before use at each client's address;

7.27.6 Prior to leaving a client’s address of use, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Part 4 of these regulations; and

7.27.7 Retain a record of each survey required by 7.27.6 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

7.28 Storage of Volatiles and Gases.

7.28.1 A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.

7.28.2 A licensee shall store and use a multi-dose container in a properly functioning fume hood.

7.28.3 A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Part 4 of these regulations.

7.28.3.1 The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

7.28.3.2 A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.

7.29 ~~Decay-In-Storage.~~**Decay-in-storage.**

7.29.1 A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard ~~for~~**to** its radioactivity if ~~the licensee~~**it**:

7.29.1.1 Monitors radioactive material at the ~~container~~ surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with ~~a~~**an appropriate** radiation detection survey ~~instrument~~**meter** set on its most sensitive scale and with no interposed shielding; **and**

7.29.1.~~3~~**2** Removes or obliterates all radiation labels, except for **radiation labels on** material**s** that **are within containers and that** will be ~~handled~~**managed** as biomedical waste after **they have been** release**d from the licensee**; and

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

7.29.2 Records of Decay-in-Storage.

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

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

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

Section D – Unsealed Radioactive Material – Written Directive Not Required

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

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

7.30.1.1 ~~Is obtained from~~**Obtained from:**

(1) ~~a~~**A** manufacturer or preparer licensed ~~pursuant to~~**under Part 3, Section** 3.12.10 or equivalent regulations of an~~other~~ Agreement State~~, a Licensing State~~, or NRC; or;

Commented [JSJ112]: Wording and formatting/alignment modifications were made for consistency with 10 CFR 35.92.

Commented [JSJ113]:
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 [JSJ114]: Modified format to "sentence case" for consistency with 10 CFR Part 35.

Commented [JSJ115]: 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)

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

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

7.30.1.2 Excluding production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F and Section 7E3.1(2)(g) of Appendix 7E; or

(3) An individual under the supervision, as specified in 7.10, of the authorized nuclear pharmacist in 7.30.1.2(1) or the physician who is an authorized user in 7.30.1.2(2); or

7.30.1.3 ~~Is o~~**O**btained from and prepared by a Department, Agreement State, ~~Licensing State~~ or NRC licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

7.30.1.4 ~~Is p~~**P**repared by the licensee **for use in research** in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA ~~for use in research~~.

7.30.2 ~~Authorized User~~ Training For Uptake, Dilution, And Excretion Studies.

The licensee shall require an authorized user of ~~an~~ unsealed radioactive material for the uses authorized under 7.30 to meet the requirements of Appendix 7D.

7.31 ~~Possession of Survey Instrument.~~**Reserved**

~~A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with 7.17.~~

~~**SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL - WRITTEN DIRECTIVE NOT REQUIRED**~~

7.32 ~~Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required.~~**Use of unsealed radioactive material for imaging and localizations studies for which a written directive is not required.**

Except for quantities that require a written directive under 7.11, a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

~~7.32.1 A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive, as described in 7.11, that:~~

7.32.1 Obtained from:

Commented [JSJ116]:
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

Commented [JSJ117]: 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 [JSJ118]:
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)

7.32.1.1 ~~Is obtained from a~~ **A** manufacturer or preparer licensed pursuant to **Part 3, Section** 3.12.10 or equivalent regulations of an~~other~~ Agreement State, ~~a Licensing State,~~ or NRC; or~~;~~

7.32.1.2 A PET radioactive drug producer licensed under Part 3, Section 3.8.10; or

~~7.32.1.2 Excluding production of PET radioactive material, is prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F and Appendix 7E3.1(2)(g), or an individual under the supervision of either as specified in 7.10.~~

Commented [JSJ119]: This provision is replaced with the reformatted requirements of 7.32.2 below.

7.32.2 Excluding production of PET radionuclides, prepared by:

Commented [JSJ120]:
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

7.32.2.1 An authorized nuclear pharmacist;

7.32.2.2 A physician who is an authorized user and who meets the requirements specified in Appendix 7E, or Appendix 7F and 7E3.1(2)(g); or

7.32.2.3 An individual under the supervision, as specified in 7.10, of the authorized nuclear pharmacist in 7.32.2.1 or the physician who is an authorized user in 7.32.2.2;

~~7.32.1.3~~**7.32.3** ~~Is o~~**O**btained from and prepared by a Department, Agreement State, ~~Licensing State~~ or NRC licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

~~7.32.1.4~~**7.32.4** ~~Is p~~**P**repared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

7.32.~~2~~**5** Authorized User Training for Imaging and Localization Studies for which a Written Directive is Not Required.

The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.32 to meet the requirements of Appendix 7E.

7.33 ~~Radionuclide Contaminants.~~**Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**

7.33.1 A licensee ~~shall~~**may** not administer to humans a radioactive drug ~~containing~~**that contains**:

Commented [JSJ121]:
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.

7.33.1.1 More than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 µCi of ^{99}Mo per mCi of ^{99m}Tc)~~.~~**; or**

7.33.1.2 More than 0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection (0.02 µCi of ^{82}Sr per mCi of ^{82}Rb chloride); **or more than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of ^{85}Sr per mCi of ^{82}Rb).**

~~7.33.1.3 More than 0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection (0.2 µCi of ^{85}Sr per mCi of ^{82}Rb).~~

Commented [JSJ122]: This provision is combined with 7.33.1.2 (above) consistent with the formatting of 10 CFR 35.204(a)(2).

~~7.33.2 To demonstrate compliance with 7.33.1, the licensee preparing radioactive drugs from radionuclide generators shall measure the concentration of radionuclide contaminant in:~~

~~7.33.2.1 Each eluate after receipt of a molybdenum-99/technetium-99m generator;~~

~~7.33.2.2 Each eluate or extract, before the first patient use of the day, as appropriate for other than molybdenum-99/technetium-99m generator systems.~~

7.33.2 A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radioactive drug shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with 7.33.1.

7.33.3 A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radioactive drug shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with 7.33.1.

~~7.33.3 Records of Radionuclide Purity.~~
~~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 (µCi/ 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

Commented [JSJ123]: Language is revised 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 [JSJ124]: Revised language for consistency with 10 CFR 35.204(c).

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Commented [JSJ125]: This provision is replaced by 7.33.4.

Commented [JSJ126]: 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.

NRC Compatibility H&S
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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 [JSJ127]: Reporting language is updated for consistency with the 2018 changes to 10 CFR 35.

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.

The proposed language provides some regulatory relief by specifying that the Department and distributor be notified by telephone within 7 days (rather than immediately) when a generator elution exceeds the specific criteria. The licensee must follow up within 30 days with a written report.

While Colorado rule has required notification to the Department (per prior 7.33.4) when generator contamination exceeds specific limits, federal rule prior to the 2018 amendment did not have such notification requirement.

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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.~~

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

7.34 Aerosols and ~~G~~gases.

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

7.35 ~~Radiation Detection Capability.~~**Reserved**

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

Commented [JSJ128]: Provision is 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.

~~**SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL - WRITTEN DIRECTIVE REQUIRED**~~

Section E – Unsealed Radioactive Material – Written Directive Required

Commented [JSJ129]: Section header added for consistency with 10 CFR Part 35.

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

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

Commented [JSJ130]: Section has been reformatted for alignment and consistency with 10 CFR 35.300.

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

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

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)

7.36.1.1 Obtained from:

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

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

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

Commented [JSJ131]: This is a change in formatting only – no requirements are changing.

(1) An authorized nuclear pharmacist;

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

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

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

7.36.1.4 ~~Is prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.~~**Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.**

7.36.2 ~~Authorized User~~ Training For Use Of Any Unsealed Radioactive Material For Diagnostic Or Therapeutic Medical Use For Which A Written Directive Is Required.

The licensee shall require an authorized user of an unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required under 7.36 to meet the requirements of Appendix 7F.

7.36.3 ~~Authorized User~~ Training For Oral Administration of < / = 1.22 GBq ^{131}~~I~~ (33 mCi) Sodium Iodide Requiring A Written Directive.

The licensee shall require an authorized user of an unsealed radioactive material for oral administration of < / = 1.22 GBq ^{131}~~I~~ (33 mCi) sodium iodide requiring a written directive under 7.36 to meet the requirements of Appendix 7G.

7.36.4 ~~Authorized User~~ Training For Oral Administration Of > 1.22 GBq ^{131}~~I~~ (33 mCi) Sodium Iodide Requiring A Written Directive.

The licensee shall require an authorized user of an unsealed radioactive material for oral administration of > 1.22 GBq ^{131}~~I~~ (33 mCi) sodium iodide requiring a written directive under 7.36 to meet the requirements of Appendix 7H.

7.36.5 ~~Authorized User~~ Training For Parenteral Administration Requiring A Written Directive.

The licensee shall require an authorized user of an unsealed radioactive material for parenteral administration requiring a written directive under 7.36 to meet the requirements of Appendix 7I.

7.37 Safety ~~i~~instruction.

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

7.37.1 ~~The~~**A** licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects ~~that have received therapy with a radioactive drug, and~~ **who** cannot be released in accordance with 7.26. **To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:**

~~7.37.2 The instruction required by 7.37.1 shall be appropriate for the duties of the personnel and include:~~

7.37.~~2~~1.1 Patient or human research subject control;

7.37.~~2~~1.2 Visitor control, ~~to include the following;~~**including:**

Commented [JSJ132]: Consistent with federal rule in 10 CFR Part 35.300(c), the reference to the Radioactive Drug Research Committee is deleted.

Ref: NRC Letter 02/20/2020

Commented [JSJ133]: 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 [JSJ134]: This requirement is incorporated into 7.37.1.

Commented [JSJ135]: Visitation requirements are clarified, consistent with 10 CFR Part 35.310.

(1) Routine visitation to hospitalized individuals in accordance with Part 4**, Section 4.14.1.1** of these regulations; **and**

(2) Visitation authorized in accordance with Part 4, Section 4.14.2;

7.37.1.3~~(2)~~ Contamination control;

7.37.1.4~~(3)~~ Waste control; and

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

7.37.~~3~~2 A licensee shall ~~keep~~**retain** a record of individuals receiving **safety** instruction**s** required by 7.37.~~1~~ and maintain such records for 3 years. The record ~~shall~~**must** include a list of the topics covered, the date of **the** instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who ~~gave~~**provided** the instruction.

7.38 Safety ~~P~~**p**recautions.

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

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

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

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

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

7.38.1.3 **N**~~n~~ote on the door or ~~on~~**in** the patient's or the human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; **and**

7.38.1.~~3~~**4** Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle ~~such~~**the** materials and items as radioactive waste.

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

7.39 ~~Emergency Notification.~~**Reserved.**

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

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

Section F – Sealed Sources for Diagnosis

Commented [JSJ136]: 7.37.2 combines the requirements of 10 CFR 35.310 and the recordkeeping requirements of 10 CFR 35.2310.

NRC Compatibility D

Commented [JSJ137]: 7.38 is revised for consistency with 10 CFR 35.315.

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

NRC Compatibility H&S (7.38)

CROSS REFERENCES:
7.26 = 10 CFR 35.75

Commented [JSJ138]: This provision is redundant with the requirements of 7.22 and is therefore deleted here.

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

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

~~7.40.1.1 Approved in the Sealed Source and Device Registry; and~~

~~7.40.1.2 Handled in accordance with the manufacturer's radiation safety and handling instructions:~~

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

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

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

7.40.~~24~~ ~~Authorized User Training For Use Of Sealed Sources For Diagnosis.~~**Training for use of sealed sources and medical devices for diagnosis.**

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

~~**SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR MANUAL BRACHYTHERAPY**~~

Section G – Manual Brachytherapy

7.41 ~~Calibration Measurements of Brachytherapy Sealed Sources.~~**Calibration measurements of brachytherapy sources.**

7.41.1 ~~Prior to~~**Before** the first medical use of a brachytherapy ~~sealed~~ source ~~on or after October 25, 2005~~, a licensee shall ~~perform the following~~**have**:

7.41.1.1 Determine**d** the source output or activity using a dosimetry system that meets the requirements of 7.53;

7.41.1.2 Determine**d** source positioning accuracy within applicators; and

7.41.1.3 Use**d** published protocols **currently** accepted by nationally recognized bodies to meet the requirements of 7.41.1.1 and 7.41.1.2.

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

Commented [JSJ139]: 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)

Commented [JSJ140]: 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)

7.41.3 A licensee shall mathematically correct the outputs or activities determined in 7.41.1 for physical decay at intervals consistent with 1~~.0~~ percent physical decay.

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

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

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

7.41.5.2 The record must include:

(1) The date of the calibration;

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

(3) The source output or activity;

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

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

7.41.6 Strontium-90 sources for ophthalmic treatments.

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

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

(1) An authorized medical physicist; or

(2) An individual who:

(a) Is identified as an ophthalmic physicist on a specific medical use license issued by NRC or an Agreement State; permit issued by a NRC or Agreement State broad scope medical use licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material licensee broad scope medical use permittee; and

(b) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(c) Has successfully completed 1 year full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(d) Has documented training in:

Commented [JSJ141]: Provision revised for consistency with 10 CFR 35.432(d). This provision replaces (prior) 7.41.6.

10 CFR 35.432(d) references 10 CFR 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 [JSJ142]: Language in this section is amended and expanded for consistency with the 2018 amendments to 10 CFR 35.433 as related to the new term and requirements associated with an ophthalmic physicist.

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

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CROSS REFERENCES:
7.41.6.2 = 10 CFR 35.433(b)

Commented [JSJ143]: This provision is revised and replaced by the added language in 7.41.6.2.

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in 7.41.1 through 7.41.5.

7.41.6.2 The individuals who are identified in 7.41.6.1 must:

(1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 7.41.1 through 7.41.5; and

(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in 7.41.6.1 will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

7.41.6.3 Licensees must retain a record of the activity of each strontium-90 source as follows:

(1) A licensee shall maintain a record of the activity of a strontium-90 source required by 7.41.6 for the life of the source.

(2) The record must include:

(a) The date and initial activity of the source as determined under 7.41.1 through 7.41.5; and

(b) For each decay calculation, the date and the source activity as determined under 7.41.6.

~~7.41.6 A licensee shall retain a record of each calibration on brachytherapy sources required by 7.41.1 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.~~

~~7.41.7 A licensee shall retain a record of decay calculations required by 7.41.5 for the life of the source. The record must include the date and initial activity of the source as determined under 7.41, and for each decay calculation, the date, the source activity and the signature of the authorized medical physicist.~~

7.42 Use of ~~S~~sealed ~~S~~sources ~~F~~for ~~M~~manual ~~B~~brachytherapy.

~~7.42.1 A licensee shall use for manual brachytherapy only sealed sources:~~**A licensee must use only brachytherapy sources:**

7.42.1.1 Approved in the Sealed Source and Device Registry~~; or~~ **for manual brachytherapy use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the**

Commented [JSJ144]: 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 [JSJ145]: This provision is replaced by 7.41.5 (above) to better align with the format and wording of 10 CFR 35.

Commented [JSJ146]: This provision is replaced by 7.41.6.3 (above).

Commented [JSJ147]: This provision is updated for consistency with the 2018 amendments to 10 CFR 35.400.

Similar to the proposed requirements in 7.40, the language here is modified to clarify that sources may be used for purposes not explicitly listed in the Sealed Source and Device Registry.

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radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

7.42.1.2 In research **to deliver therapeutic doses for medical use** in accordance with an ~~effective~~**active** Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 7.14.1 are met.

7.42.2 Authorized User Training For Use Of Sealed Sources For Manual Brachytherapy.

The licensee shall require an authorized user under 7.42 to meet the requirements of Appendix 7K.

7.42.3 Authorized User Training For Use Of Strontium-90 Sealed Sources For Ophthalmic Uses.

The licensee shall require an authorized user of strontium-90 sealed sources for ophthalmic uses under 7.42 to meet the requirements of Appendix 7L.

7.43 Safety ~~i~~instruction.

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

7.43.1 The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 7.26.

7.43.2 The instruction required by 7.43.1 shall be commensurate with the duties of the personnel and include:

7.43.2.1 Size and appearance of the brachytherapy sources;

7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;

7.43.2.3 Patient or human research subject control;

7.43.2.4 Visitor control, including both;

(1) Routine visitation to hospitalized individuals in accordance with 4.14.1.1; and

(2) Visitation authorized in accordance with 4.14.3; and

7.43.2.5 Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

7.43.3 A licensee shall ~~keep~~**retain** a record of individuals receiving **safety** instruction**s** required by 7.43.1 and maintain such records for 3 years. The record ~~shall~~**must** include a list of the topics covered, the date of **the** instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who ~~gave~~**provided** the instruction.

Commented [JSJ148]: 7.43.3 combines the requirements of 10 CFR 35.410 and 10 CFR 35.2310.

NRC Compatibility D

7.44 Safety ~~P~~precautions.

7.44.1 For each patient or the human research subject that is receiving brachytherapy and cannot be released in accordance with 7.26, a licensee shall:

7.44.1.1 Not place the patient or the human research subject in the same room with a patient who is not receiving radiation therapy;

7.44.1.2 Visibly post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

7.44.2 A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

7.44.2.1 Dislodged from the patient; or

7.44.2.2 Lodged within the patient following removal of the source applicators.

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

Commented [JSJ149]: 7.39 is proposed for deletion due to overlap/redundancy with 7.22, so the reference to that section is deleted here.

7.45 Brachytherapy ~~S~~sources ~~I~~inventory.

7.45.1 A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

7.45.2 ~~Promptly~~**As soon as possible** after removing brachytherapy sources from a patient **or a human research subject**, a licensee shall return brachytherapy sources to a secure storage area and count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

Commented [JSJ150]: Some language updated for consistency with 10 CFR 35.406(b).

7.45.3 A licensee shall maintain a record of brachytherapy source accountability for 3 years.

Commented [JSJ151]: Section 7.45.3 has been formatted for alignment.

Provisions reworded for consistency with the format of 10 CFR 35.2406.

7.45.3.1 For temporary implants, the record must include~~: the number and activity of sources:~~

(1) **The number and activity of sources** ~~R~~removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

(2) **The number and activity of sources returned to storage**~~Not implanted~~, the time and date they were returned to storage, and the name of the individual who returned them to storage.

7.45.3.2 For permanent implants, the record must include~~: the number and activity of sources:~~

(1) **The number and activity of sources** ~~R~~removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

(2) **The number and activity of sources not implanted, the date they were** ~~R~~returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

(3) **The number and activity of sources** ~~P~~permanently implanted in the patient or human research subject.

7.46 ~~Surveys After Source Implant and Removal.~~**Surveys after source implant and removal.**

7.46.1 Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

7.46.2 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

7.46.3 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.46.1 and ~~7.6.2~~**7.46.2** for 3 years. Each record ~~shall~~**must** include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Commented [JJ152]: Correction of numbering error.

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

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

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

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

7.47.2.~~1~~**2** The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.47.2.~~1~~**3** The accuracy of isodose plots and graphic displays; and

7.47.2.~~1~~**4** The accuracy of the software used to determine radioactive source positions from radiographic images.

Section H - Photon Emitting Remote Afterloader Units, Teletheraphy Units, and Gamma Stereotactic Radiosurgery Units

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

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

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

Commented [JSJ153]: Due to changes in wording this provision is replaced in its entirety by new provision 7.48.1.

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

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

7.48.1 A licensee must only use sealed sources:

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

7.48.1.2 In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the

Commented [JSJ154]: As a result of the 2018 amendments to 10 CFR 35.600, this provision is revised.

Consistent with federal rule, the revised provision makes a distinction between the devices (afterloader, teletherapy, gamma stereotactic radiosurgery units) and the radioactive sources contained within these units as there is typically a separate sealed source and device registry (SSDR) for each. Additionally, the wording is revised to allow the units to be used for medical uses that are not explicitly listed in the SSDR.

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CROSS REFERENCES:
7.14.1 = 10 CFR 35.49(a)

U.S. Food and Drug Administration provided the requirements of 7.14.1 are met.

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

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

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

~~7.48.2~~**7.48.3** ~~Authorized User~~ Training For Use of a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

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

7.49 Installation, ~~M~~maintenance, ~~A~~adjustment, and ~~R~~repair.

7.49.1 Only a person specifically licensed by the Department, an~~other~~ Agreement State, or the NRC shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

7.49.2 Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, an~~other~~ Agreement State, ~~a Licensing State,~~ or the NRC shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

7.49.3 For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, an~~other~~ Agreement State, ~~a Licensing State,~~ or the NRC, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

7.49.4 A licensee shall retain a record of the installation, maintenance, adjustment and repair ~~done on~~**of** remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years. **For each installation, maintenance, adjustment and repair,** ~~T~~the record ~~shall~~**must** include the date, description of the service, and name(s) of the individual(s) who performed the work.

Commented [JSJ155]: Language modified for consistency with 10 CFR 35.2605.

7.50 ~~Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.~~**Surveys of patients and human research subjects treated with a remote afterloader.**

7.50.1 Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe~~,~~ shielded position.

7.50.2 A licensee shall maintain a record of patient surveys which demonstrate compliance with 7.50.1 for 3 years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

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

7.51.1 A licensee shall:

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

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

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

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

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

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

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

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

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

7.51.3.1 The location of the procedures required by 7.51.1.4; and

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

7.51.4 Operational and safety training.

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

7.51.4.**2** A licensee shall provide **operational and safety** instruction**s**, initially and at least annually, to all individuals who operate ~~a~~**the** unit **at the facility**, as appropriate to

Commented [JSJ156]: Reformatted to remove capitalization and for consistency with wording of 10 CFR 35.610. Section has been formatted for alignment.

Commented [JSJ157]: Provision revised to fit the format of 10 CFR 35.610(c).

Commented [JSJ158]: This sub-section heading is added for formatting and numbering purposes to parallel/maintain consistency with the flow and format of 10 CFR 35.610(d).

Commented [JSJ159]: This is a new provision added for consistency with the 2018 amendments/additions to 10 CFR 35. 610(d).

This requirement specifies that training must be provided by the vendor or individual certified by the device manufacturer following an upgrade impacting the operation and safety of the unit and prior to the first use on a patient. Also see NRC FAQ #51, #52 for further information.

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the individual's assigned duties.~~, in:~~ **The instructions shall include instruction in:**

~~7.51.4.1~~**(1)** The procedures identified in 7.51.1.4; and

~~7.51.4.2~~**(2)** The operating procedures for the unit.

7.51.5 A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

7.51.6 A licensee shall ~~keep~~**retain** a record of individuals receiving instruction required by 7.51.4 **in accordance with the following:**~~and maintain such records for 3 years. The record shall include a list of the topics covered, the date of instruction, the names(s) of the attendee(s), and the name(s) of the individual(s) who gave the instruction.~~

(1) A licensee shall maintain a record of the operational and safety instructions required by 7.51.4 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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 the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

7.52 ~~Doors, Interlocks, and Warning Systems.~~**Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.**

7.52.1 A licensee shall control access to the treatment room by a door at each entrance.

7.52.2 A licensee shall equip each entrance to the treatment room with an electrical interlock system that ~~shall~~**will**:

7.52.2.1 Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

7.52.2.2 Cause the source(s) to be shielded ~~promptly~~ when an entrance door is opened; and

7.52.2.3 Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s)' on/off control is reset at the console.

7.52.3 A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

7.52.4 Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

7.52.5 For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

7.52.6 In addition to the requirements specified in 7.52.1 through 7.52.5, a licensee shall:

7.52.6.1 For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

Commented [JSJ160]: 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.

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NRC Compatibility D (for 35.610(f) and 35.2310)

Commented [JSJ161]: 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.

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Commented [JSJ162]: 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.

(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

(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.

7.52.6.2 For high dose-rate remote afterloader units, require:

(1) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(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.

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.

7.52.6.4 If a patient or research subject suffers a medical emergency during radiation therapy:

(1) Cease the therapy immediately;

(2) Remove the source(s); and

(3) Provide appropriate care to the patient or research subject.

7.52.6.5 If the patient expires during treatment, remove the source(s) before further actions are taken.

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.

7.52.7 A licensee shall have **applicable** emergency response equipment available near each treatment room~~,~~ to respond to a ~~situation in which a source inadvertently~~**source**:

7.52.7.1 ~~Remains~~**Remaining** in the unshielded position; or

7.52.7.2 Lodge~~s~~**d** within the patient following completion of the treatment.

7.53 Dosimetry ~~E~~**e**quipment.

7.53.1 Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions ~~shall~~**must** be met:

7.53.1.1 The system ~~shall~~**must** have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory

accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

7.53.1.2 The system ~~shall~~**must** have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

7.53.2 The licensee shall have available for use a dosimetry system for spot-check output measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 7.53.1. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 7.53.1.

7.53.3 The licensee shall ~~maintain~~**retain** a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record ~~shall~~**must** include:

7.53.3.1 The date;

7.53.3.2 The manufacturer’s name, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 7.53.1 and 7.53.2;

7.53.3.3 The correction factor that ~~were~~**was** determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison;

7.53.3.4 The names of the individuals who performed the calibration, intercomparison, or comparison.

7.54 Full ~~C~~**c**alibration ~~M~~**m**easurements on ~~T~~**t**eletherapy ~~U~~**u**nits.

7.54.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

7.54.1.1 Before the first medical use of the unit;

7.54.1.2 Before medical use under the following conditions:

(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;

(2) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

(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

7.54.1.3 At intervals not exceeding 1 year.

7.54.2 To satisfy the requirement of 7.54.1, full calibration measurements shall include determination of:

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;

7.54.2.2 The coincidence of the radiation field and the field indicated by the light beam localizing device;

7.54.2.3 The uniformity of the radiation field and its dependence on the orientation of the useful beam;

7.54.2.4 Timer accuracy, constancy, and linearity;

7.54.2.5 “On off” error; and

7.54.2.6 The accuracy of all distance measuring and localization devices in medical use.

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.

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.

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.

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.

7.54.7 A licensee shall maintain a record of each calibration for the duration of the license. The record shall include:

7.54.7.1 The date of the calibration;

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;

7.54.7.3 The results and assessments of the full calibrations; and

7.54.7.4 The signature of the authorized medical physicist who performed the full calibration.

7.55 Full ~~C~~calibration ~~M~~measurements on ~~R~~remote ~~A~~afterloader ~~U~~units.

7.55.1 A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

7.55.1.1 Before the first medical use of the unit;

7.55.1.2 Before medical use under the following conditions:

(1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(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

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

7.55.1.4 At intervals not exceeding 1 year for low dose-rate remote afterloader units.

7.55.2 To satisfy the requirement of 7.55.1, full calibration measurements must include, as applicable, determination of:

7.55.2.1 The output within +/- 5 percent;

7.55.2.2 Source positioning accuracy to within +/- 1 millimeter;

7.55.2.3 Source retraction with backup battery upon power failure;

7.55.2.4 Length of the source transfer tubes;

7.55.2.5 Timer accuracy and linearity over the typical range of use;

7.55.2.6 Length of the applicators; and

7.55.2.7 Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

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.

7.55.4 A licensee shall use the dosimetry system described in 7.53 to measure the output.

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.

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.

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.

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.

7.55.9 A licensee shall retain a record of each calibration for the duration of the license. The record shall include:

7.55.9.1 The date of the calibration;

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;

7.55.9.3 The results and assessments of the full calibrations;

7. 55.9.4 The results of the autoradiograph required for low dose-rate remote afterloader units; and

7. 55.9.5 The signature of the authorized medical physicist who performed the full calibration.

7.56 Full ~~C~~calibration ~~M~~measurements on ~~G~~gamma ~~S~~stereotactic ~~R~~radiosurgery ~~U~~units.

7.56.1 A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

7.56.1.1 Before the first medical use of the unit;

7.56.1.2 Before medical use under the following conditions:

(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;

(2) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(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

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.

7.56.2 To satisfy the requirement of 7.56.1, full calibration measurements must include determination of:

7.56.2.1 The output within +/-3 percent;

7.56.2.2 Relative helmet factors;

7.56.2.3 Isocenter coincidence;

7.56.2.4 Timer accuracy and linearity over the range of use;

7.56.2.5 On-off error;

7.56.2.6 Trunnion centricity;

7.56.2.7 Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

7.56.2.8 Helmet microswitches;

7.56.2.9 Emergency timing circuits; and

7.56.2.10 Stereotactic frames and localizing devices (trunnions).

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.

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.

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.

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.

7.56.7 A licensee shall retain a record of each calibration for the duration of the license. The record shall include:

7. 56.7.1 The date of the calibration;

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;

7. 56.7.3 The results and assessments of the full calibrations;

7. 56.7.4 The signature of the authorized medical physicist who performed the full calibration.

7.57 Radiation ~~S~~surveys of ~~T~~therapeutic ~~T~~treatment ~~U~~units.

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 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 µSv (1 mrem) per hour to 10 mSv (1 rem) per hour. The instruments shall be operable and calibrated in accordance with 7.17.

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.

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

Records of surveys of therapeutic treatment units

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

7.57.4.1 The date of the measurements;

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

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

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

Commented [JSJ163]: 35.2652(b)(4)

7.58 Periodic ~~s~~Spot ~~C~~checks for ~~T~~teletherapy ~~U~~units.

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

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

7.58.1.2 “On off” error;

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

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

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

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

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

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

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

7.58.4.1 Electrical interlocks at each teletherapy room entrance;

7.58.4.2 Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam “on off” mechanism;

7.58.4.3 Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

7.58.4.4 Viewing and intercom systems;

7.58.4.5 Treatment room doors from inside and outside the treatment room; and

7.58.4.6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned “off”.

7.58.5 If the results of the checks required in 7.58.4 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.

7.58.6 A licensee shall maintain a record of each spot check required by 7.58.1 and 7.58.~~5~~**4, and a copy of the procedures required by 7.58.2** for 3 years. The record shall include:

7.58.6.1 The date of the spot check;

7.58.6.2 The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

7.58.6.3 An assessment of timer linearity and constancy;

7.58.6.4 The calculated “on off” error;

7.58.6.5 A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device

7.58.6.6 The determined accuracy of each distance measuring or localization device;

7.58.6.7 The difference between the anticipated output and the measured output;

7.58.6.8 Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

7.58.6.9 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.

7.59 Periodic ~~S~~spot ~~C~~checks for ~~R~~remote ~~A~~afterloader ~~U~~units.

7.59.1 A licensee authorized to use remote afterloader units for medical use shall perform spot checks of each remote afterloader facility and on each unit:

7.59.1.1 At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

7.59.1.2 Prior to each patient treatment with a low dose-rate remote afterloader unit; and

7.59.1.3 After each source installation.

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.

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.

7.59.4 To satisfy the requirements of 7.59.1, spot checks must, at a minimum, assure proper operation of:

Commented [JSJ164]: Correction of cross-reference error and additional language added for consistency with 10 CFR 35.642(f) to clarify that a copy of the procedures used for spot checks must also be maintained.

7.58.6 combines the provisions of 10 CFR 35.642 and 10 CFR 35.2642.

7.59.4.1 Emergency response equipment;

7.59.4.2 Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;

7.59.4.3 Radiation monitors used to indicate the source position;

7.59.4.4 Electrical interlocks at each remote afterloader unit room entrance;

7.59.4.5 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

7.59.4.6 Timer accuracy;

7.59.4.7 Clock (date and time) in the unit's computer; and

7.59.4.8 Decayed source(s) activity in the unit's computer.

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.

7.59.6 A licensee shall retain a record of each check required by 7.59.4**, and a copy of the procedures required by 7.59.2** for 3 years. The record must include, as applicable:

7.59.6.1 The date of the spot check;

7.59.6.2 The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

7.59.6.3 An assessment of timer accuracy;

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

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.

7.60 Additional ~~T~~technical ~~R~~requirements for ~~M~~mobile ~~R~~remote ~~A~~afterloader ~~U~~units.

7.60.1 A licensee providing mobile remote afterloader service shall:

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

7.60.1.2 Account for all sources before departure from a client's address of use.

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:

7.60.2.1 Electrical interlocks on treatment area access points;

7.60.2.2 Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

Commented [JSJ165]: Additional language added for consistency with 10 CFR 35.643 to clarify that a copy of the procedures used for spot checks must also be maintained.

7.59.6 combines the provisions of 10 CFR 35.643 and 10 CFR 35.2643.

This provision has been formatted and aligned.

Commented [JSJ166]: Select provisions in 7.60 have been formatted for alignment purposes which are not easily reflected by text changes/redlines.

7.60.2.3 Viewing and intercom systems;

7.60.2.4 Applicators, source transfer tubes, and transfer tube-applicator interfaces;

7.60.2.5 Radiation monitors used to indicate room exposures;

7.60.2.6 Source positioning (accuracy); and

7.60.2.7 Radiation monitors used to indicate whether the source has returned to a safe shielded position.

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.

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.

7.60.5 A licensee shall retain a record of each check **for mobile remote afterloader units** required by 7.60.2 for 3 years. The record must include:

7.60.5.1 The date of the check;

7.60.5.2 The manufacturer's name, model number, and serial number of the remote afterloader unit;

7.60.5.3 Notations accounting for all sources before the licensee departs from a facility;

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

7.60.5.5 The signature of the individual who performed the check.

7.61 Periodic ~~S~~spot ~~C~~checks for ~~G~~gamma ~~S~~stereotactic ~~R~~radiosurgery ~~U~~units.

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:

7.61.1.1 Monthly;

7.61.1.2 ~~At the beginning of each day of use~~**Before the first use on a given day**; and

7.61.1.3 After each source installation.

7.61.2 ~~The licensee shall have the authorized medical physicist:~~**A licensee shall:**

7.61.2.1 ~~Establish written procedures for performing the spot checks required in 7.61.1; and~~**Perform the measurements required by 7.61.1 in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.**

7.61.2.2 **Have the authorized medical physicist** ~~R~~review the results of each spot ~~-~~check ~~required by 7.61.1.1~~ within 15 days~~. of the check. The authorized medical physicist need not actually perform the spot-check measurements.~~ The

Commented [JSJ167]: Section 7.61.2 revised for consistency with 10 CFR 35.645. This change is not a RATS item.

Commented [JSJ168]: The language regarding the AMP not being required to perform the spot check is incorporated into 7.61.2.1 (above).

authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of ~~the~~**each** spot-check.

7.61.3 To satisfy the requirements of 7.61.1~~.1~~ spot checks must, at a minimum:

7.61.3.1 Assure proper operation of:

(1) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(2) Helmet microswitches;

(3) Emergency timing circuits; and

(4) Stereotactic frames and localizing devices (trunnions).

7.61.3.2 Determine:

(1) The output for one typical set of operating conditions measured with the dosimetry system described in 7.53.2;

(2) The difference between the measurement made in 7.61.3.2(1) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(3) Source output against computer calculation;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) Trunnion centricity.

7.61.4 To satisfy the requirements of 7.61.1.2 and 7.61.1.3, spot-checks must assure proper operation of:

7.61.4.1 Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

7.61.4.2 Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

7.61.4.3 Viewing and intercom systems;

7.61.4.4 Timer termination;

7.61.4.5 Radiation monitors used to indicate room exposures; and

7.61.4.6 Emergency off buttons.

7.61.5 A licensee shall arrange for prompt repair of any system identified in 7.61.3 that is not operating properly.

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.

7.61.7 A licensee shall retain a record of each **spot**-check **for gamma stereotactic radiosurgery units** required by 7.61.3 and 7.61.4 for 3 years. The record must include:

7.61.7.1 The date of the spot check;

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;

7.61.7.3 An assessment of timer linearity and accuracy;

7.61.7.4 The calculated on-off error;

7.61.7.5 A determination of trunnion centricity;

7.61.7.6 The difference between the anticipated output and the measured output;

7.61.7.7 An assessment of source output against computer calculations;

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

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.

7.61.8 A licensee shall retain a copy of the procedures required by 7.61.2 until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

7.62 Other ~~M~~medical ~~U~~uses of ~~R~~radioactive ~~M~~material or ~~R~~radiation ~~F~~from ~~R~~radioactive ~~M~~material.

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:

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

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

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

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

Commented [JSJ169]: This section has been formatted/aligned for appearance. Alignment corrections may not appear as strike out/changed text.

Clarifying language added for consistency with 10 CFR 35.2645(a).

Commented [JSJ170]: This provision parallels the requirement of 10 CFR 35.2645(c).

Commented [JJ171]: Updated for consistency with changes to 10 CFR 35.655(a).

The title was changed to reflect the revised/extended servicing interval (from 5 years to 7 years) for gamma stereotactic radiosurgery (GSR) units.

In consideration of the 6 month periodic maintenance interval and due to the high cost of source replacement for GSR units, stakeholders (nationally) requested a change in this servicing interval.

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7.63.2 This inspection and servicing shall only be performed by persons specifically licensed to do so by the Department, an~~other~~ Agreement State, ~~a Licensing State,~~ or the NRC.

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

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

7.63.4 The record required by 7.63.3 must contain:

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

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

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

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

7.63.~~3.5~~4.4 A list of components inspected and serviced, and the type of service; **and**

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

~~7.63.3.7 The signature of the inspector.~~

7.63.4.5 The signature of the inspector.

7.64 Therapy-related computer systems.

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

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

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

7.64.2.2 The accuracy of dose, dwell time, and treatment time calculations at representative points;

7.64.2.3 The accuracy of isodose plots and graphic displays; and

7.64.2.4 The accuracy of the software used to determine radioactive source positions from radiographic images.

7.64.2.5 The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Section I – Recentness of training.

7.65 The training and experience specified in 7.65.1 through 7.65.6 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Commented [JSJ172]: Updated for consistency with 10 CFR 35.2655.

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CROSS REFERENCE:
7.63 = 10 CFR 35.655

Commented [JSJ173]: Prior provisions 7.63.3.4 and 7.63.3.5 are replaced by an equivalent requirement in 7.63.4.4.

Commented [JSJ174]: There is no equivalent provision in 10 CFR 35.

Commented [JSJ175]: Prior provision 7.63.3.7 is replaced by an equivalent requirement in 7.63.4.5.

Commented [JSJ176]: Provision added for consistency with 10 CFR 35.657.

With the exception of 7.64.2.5, these requirements are equivalent to those already found in the current 7.47 found in Section G for manual brachytherapy. They are added (repeated) here for consistency with the format of the federal rule which is best suited to the computer based systems used with the afterloader, teletherapy, and GSR devices of Section H. The provision of 10 CFR 35.657(e) is incorporated in 7.64.2.5 as it previously omitted.

This is not a RATS item.

Commented [JSJ177]: This provision parallels requirements in 10 CFR Part 35.59, and replaces and consolidates similar existing requirements that are repeated in the appendices of the current (in effect) rule (now proposed for deletion).

7.65.1 Section B, Section I, Appendix 7A, 7B, 7C, and 7P.

7.65.2 Section D, Appendix 7D, and 7E.

7.65.3 Section E, Appendix 7F, 7G, 7H and 7I.

7.65.4 Section F, Appendix 7J.

7.65.5 Section G, Appendix 7K and Appendix 7L.

7.65.6 Section H, and Appendix 7M.

Commented [JSJ178]: Section B refers to provisions 7.7 through 7.14 (inclusive) pertaining to general administrative requirements which parallels subpart B of 10 CFR 35, with the following exceptions: due to formatting differences and limitations, Section B of Part 7 does not directly include 7.65 (Section I) or specific references to Appendix 7A, 7B, 7C, and 7P. Therefore, these provisions are explicitly listed.

Commented [JSJ179]: Section D refers to provisions 7.30 through 7.34 (inclusive) pertaining to unsealed radioactive material NOT requiring a written directive which parallels subpart D of 10 CFR 35.

Commented [JSJ180]: Section E refers to provisions 7.36 through 7.38 (inclusive) pertaining to unsealed radioactive material requiring a written directive which parallels subpart E of 10 CFR 35.

Commented [JSJ181]: Section F refers to provision 7.40 for sealed sources for diagnosis which parallels subpart G of 10 CFR 35.

Commented [JSJ182]: Section G refers to provisions 7.41 through 7.47 (inclusive) pertaining to manual brachytherapy which parallels subpart F of 10 CFR 35.

Commented [JSJ183]: Section H refers to 7.48 through 7.63, and Appendix 7M which parallels subpart H of 10 CFR 35.

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

~~The~~**Except as provided in Appendix 7P, the** licensee shall require ~~the~~**an** 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;

and

Commented [JJ184]: For final publication, insert a page break to ensure each new appendices begins at the top of the page.

Commented [JJ185]: Introductory text modified, consistent with 2018 amendments to 10 CFR 35.50.

The changes incorporate the requirements associated with the new Associate Radiation Safety Officer terminology.

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NOTE: The changes in this and in other subsequent appendices are similar and include the following:

1. Removal of the specific NRC web address (where the accepted board certifications are located) and use a more generic website reference.

2. Relocation of the recentness of training requirements to Section 7.65.

3. Relocation (and revision of) the requirements for an experienced individual to the new (proposed) Appendix 7P.

Commented [JJ186]: 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.

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics~~: that is:~~

(a) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by an Agreement State or NRC;

or

(b) In clinical nuclear medicine facilities providing diagnostic ~~and /~~ or therapeutic services under the ~~general supervision~~ **direction** of physicians who meet the requirements for Authorized Users in ~~7A7~~**Appendix 7P**, Appendix 7E or Appendix 7F;

and

(3) Pass an examination administered by diplomates of the specialty board**,** that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety.

or

7A2 ~~Has satisfied the following criteria:~~

7A2.1 Has completed a structured educational program consisting of **both**:

(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;

(d) Radiation biology; and

(e) Radiation dosimetry;

and

(2) ~~1~~**One** year of full-time radiation safety experience, under the supervision of the individual identified as ~~an~~**the** RSO ~~or Alternate RSO~~, on a~~n~~ **NRC or an** Agreement State **license** or ~~NRC license or~~ permit issued by a NRC master material licensee that authorizes similar type(s) of use**(s)** of radioactive material.~~,~~ ~~involving the following:~~ **An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a NRC or an Agreement State license or permit issued by a NRC master material licensee. The full-time radiation safety experience must involve the following:**

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of ~~dose calibrators~~**instruments used to determine the activity of dosages**, survey meters, and~~, if appropriate,~~ instruments used to measure radionuclides;

(c) Securing and controlling radioactive material;

Commented [JSJ187]: 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.

(d) Using administrative controls to avoid mistakes in the administration of radioactive material;

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(f) Using emergency procedures to control radioactive material; and

(g) Disposing of radioactive material;

and

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

or

7A3 ~~Meets the following requirements:~~

Commented [JJ188]: 35.50(c)

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

or

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

or

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

Commented [JJ189]: 35.50(c)(3).

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~~and~~

~~**7A4** Has provided written attestation(s), signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 7A5 and in 7A1.1(1) and 7A1.1(2) or 7A1.2(1) and~~

~~7A1.2(2) or 7A2.1 or 7A3.1 or 7A3.2, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee;~~

and

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

Commented [JJ190]: This provision is updated for consistency with the 2018 amendment to 10 CFR 35.50(d).

~~and~~

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

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

~~or~~

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

Commented [JJ191]: 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.)

~~or~~

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

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

Commented [JJ192]: 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.

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

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

Commented [JJ193]: For final publication, insert a page break to ensure each new appendices begins at the top of the page.

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

7B1 ~~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 7B2.3 and 7B3 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 7B3 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:**

Commented [JJ194]: Appendix 7B is updated for consistency with the 2018 amendments to 10 CFR 35.51.

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

~~(1)~~**7B1.1** 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;

~~and~~

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

(~~a~~**1**) Under the supervision of a medical physicist who is certified in medical physics by a specialty board **whose certification process has been** recognized **under 7B1** by **the NRC or** an Agreement State ~~or NRC~~;

or

(~~b~~**2**) In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements ~~for authorized users~~ in ~~7B5~~**Appendix 7P**, Appendix 7K or Appendix 7M;

and

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

or

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

7B2.1 Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; **and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be**

conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

~~and~~

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

Commented [JSJ195]: This provision is replaced by the prior updated provision in 7B2.1 in keeping with the format and flow of 10 CFR 35.51.

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

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

(~~a~~**1**) Performing sealed source leak tests and inventories;

(~~b~~**2**) Performing decay corrections;

(~~c~~**3**) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

and

(~~d~~**4**) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable;

and

7B2.3**2** Has obtained written attestation that the individual has satisfactorily completed the requirements in~~:~~ **7B2.1 and 7B3, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in Appendix 7B, Appendix 7P, or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.**

Commented [JJ196]: Updated for consistency with 10 CFR 35.51(b)(2).

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

~~or~~

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

~~and~~

~~(3) Has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this Appendix (7B), 7B5, or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status;~~

and

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

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

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

~~(2) Safety procedures,~~

~~(3) Clinical use,~~

~~and~~

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

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

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

~~or~~

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

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

~~7B4 Meets the following recentness of training requirements:~~

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

~~or~~

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

~~or~~

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

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

~~or~~

~~7B5.2 An experienced medical physicist who has demonstrated to the Department experience in the type(s) of use for which the individual is requesting authorized medical physicist~~

Commented [JSJ197]: 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.

~~status (and thus need not comply with the specific training and experience requirements of 7B1 through 7B4):~~

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

~~(a) Therapeutic radiological physics;~~

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

~~(c) X-ray and radium physics;~~

~~or~~

~~(d) Radiological physics;~~

~~or~~

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

~~and~~

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

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

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

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

7C1 ~~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 7C2.2 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.~~**Is certified by a specialty board 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:**

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

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

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

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

and

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

or

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

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

(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;

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

(e) Radiation biology;

Commented [JJ198]: For final publication, insert a page break to ensure each new appendices begins at the top of the page.

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

NRC RATS 2018-1
NRC Compatibility B

Commented [JJ199]: 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)

and

(2) Supervised practical experience in nuclear pharmacy involving:

(a) Shipping, receiving, and performing related radiation surveys;

(b) Using and performing checks for proper operation of instruments to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(d) Using administrative controls to avoid ~~misadministrations~~**medical events** in the administration of radioactive material;

and

(e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

and

7C2.2 Has ~~provided~~ **obtained** written attestation~~(s)~~, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in ~~7C1.1(1), 7C1.1(2), and 7C1.1(3) or 7C2~~**7C2.1**, and ~~has achieved a level of competency sufficient to function independently~~ **is able to independently fulfill the radiation safety related duties** as an authorized nuclear pharmacist.

~~and~~

~~**7C3** Meets the following recentness of training requirements:~~

~~7C3.1 The training and experience required by Appendix 7C shall have been obtained within the 7 years preceding the date of license application or amendment request;~~

~~or~~

~~7C3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.~~

~~or~~

~~**7C4** Meets the following requirements for an experienced authorized nuclear pharmacist.~~

~~7C4.1 An individual identified as an authorized nuclear pharmacist on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license before October 25, 2005, are not required to comply with the training requirements of 7C1 through 7C3.~~

~~7C4.2 Individuals not required to comply with the training requirements of 7C1 through 7C3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.~~

Commented [JJ200]: 35.55(b)(1)(ii)(A) – (E) = (a) through (e)

Commented [JJ201]: Updated for consistency with 35.55(b)(2).

NRC Compatibility B
RATS 2018-1

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

~~The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.30 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 7.30 to be a physician who:**

7D1 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 7D3.2 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 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:**

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

~~and~~

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

or

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

or

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

7D3.1 Has ~~satisfactorily~~ completed 60 hours of training and experience**,** including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive materials for uptake, dilution, and excretion studies. The training and experience 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;
- (d) Chemistry of radioactive material for medical use; and
- (e) Radiation biology;

and

(2) Work experience under the supervision of an authorized user who meets the requirements ~~of 7D5~~**in Appendix 7P**, 7D, 7E, 7F, or equivalent Agreement State or NRC requirements, involving:
- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (c) Calculating, measuring, and safely preparing patient or human research subject dosages;

Commented [JJ202]: 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 amendments 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 [JSJ203]: Section 7D3 has been realigned/formatted for consistency with other sections of Part 7 and the flow and format of 10 CFR 35.

7D3 is an unnumbered header to align with 10 CFR Part 35 structure.

(d) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of unsealed radioactive material;
(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
(f) Administering dosages to patients or human research subjects;

And

7D3.2 ~~Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements of 7D5, Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in 7D1.1(1) or 7D3.1, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.30.~~**Has obtained written attestation that the individual has satisfactorily completed the requirements in 7D3.1 and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 7.30. The attestation must be obtained from either:**

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7D, Appendix 7E, or Appendix 7F, or equivalent NRC or Agreement State requirements; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7D, Appendix 7E, Appendix 7F, or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7D3.1.

~~**and**~~

~~**7D4 Meets the following recentness of training requirements:**~~

~~**7D4.1 The training and experience required by Appendix 7D shall have been obtained within the 7 years preceding the date of license application or amendment request; or**~~

~~**7D4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.**~~

~~**or**~~

~~**7D5 Meets the following requirements for an experienced authorized user for 7.30 uses:**~~

~~**7D5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7D1 through 7D4.**~~

~~**7D5.2 Individuals not required to comply with the training requirements of 7D1 through 7D4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.**~~

Commented [JSJ204]: Here, and in other appendices governing training requirements for authorized users, the requirements for attestation statements are revised, consistent with the 2018 amendments to 10 CFR 35.

In general, the requirements for a physician to become an authorized user to be named on a license for a specific type of radioactive materials use are through one of three mechanisms:
(1) they are currently a named authorized user on an existing Department, NRC or other agreement state license; OR
(2) they are board certified by a board that has been recognized by the Department, NRC or an agreement state for the particular type of use; OR
(3) they do not yet meet the requirements of (1) or (2) and therefore must demonstrate adequate training and experience through the alternate pathway mechanism and provide a signed preceptor statement.

The proposed language provides some regulatory relief by no longer requiring a preceptor statement for individuals who are board certified by a recognized board.

The revised language of this appendices allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

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

~~The licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under 7.32 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 7.32 to be a physician who:

7E1 ~~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 7E3.2 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.~~ **Is certified by a medical specialty board 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. To have its certification process recognized, a specialty board shall require all candidates for certification to:**

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

~~(1)~~

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

and

~~(2)~~

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

or

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

or

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

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

(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 [JJ205]: For final publication, insert a page break such that each appendix begins on a new page.

This appendix is updated for format and content, consistent with the 2018 amendments to 10 CFR 35.290.

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

(e) Radiation biology;

and

~~(2) Work experience under the supervision of an authorized user who meets the requirements of 7E5, 7E, or 7F and 7E3.1(2)(g), or equivalent Agreement State 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:

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

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of unsealed radioactive material;

(e) Using procedures to **safely** contain spilled radioactive material ~~safely~~ and using proper decontamination procedures; ~~and~~

(f) Administering dosages to patients or human research subjects; **and**

(g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs;

and

7E3.2 ~~Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements of 7E5, Appendix 7E, or Appendix 7F and 7E3.1(2)(g), or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in 7E1.1(1) or 7E3, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.30 and 7.32.~~ **Has obtained written attestation that the individual has satisfactorily completed the requirements in 7E3.1 and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 7.30 and 7.32. The attestation must be obtained from either:**

(1) A preceptor authorized user who meets the requirements in Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement State requirements;

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, 7E, or 7F and 7E3.1(2)(g), or equivalent NRC or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7E3.1.

~~and~~

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

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

~~or~~

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

~~or~~

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

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

Commented [JSJ206]: The requirements for attestation statements are revised, consistent with the 2018 amendments to 10 CFR 35.

The revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

Commented [JSJ207]: Requirements for recentness of training is now addressed in 7.65

Commented [JSJ208]: 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:

~~**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 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~~**Council on Postdoctoral** 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 **and experience** 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;

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

Commented [JJ209]: 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 [JSJ210]:
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.

Commented [JSJ211]:
Revised to use the correct terminology for the residency approval organization of the American Osteopathic Association.

Commented [JSJ212]: Clarifying wording added for consistency with 10 CFR Part 35.390(b)(1).

Ref: NRC Letter 02/20/2020

(e) Radiation biology;

and

(2) Work experience, under the supervision of an authorized user who meets the requirements of ~~7F4~~**Appendix 7P**, ~~or~~ 7F, or equivalent Agreement State or NRC requirements. A supervising authorized user, who meets the requirements in 7F2~~.1~~, must also have experience in administering dosages in the same dosage category or categories (i.e., 7F2.1(2)(f)) as the individual requesting authorized user status. The work experience must involve:

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

(b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(c) Calculating, measuring, and safely preparing patient or human research subject dosages;

(d) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of unsealed radioactive material;

(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

(f) ~~Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status:~~**Administering dosages of radioactive drugs to patients or human research subjects from the three categories in 7F2.1(2)(f). Radioactive drugs containing radionuclides in categories not included in 7F2.1(2)(f) are regulated under 7.62. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:**

(i) Oral administration of less than or equal to 1.22 ~~GBq~~**gigabecquerels** (33 ~~mCi~~**millicuries**) of ~~Na~~**sodium iodide** I-131**,** for which a written directive is required;

(ii) ~~Oral administration of greater than 1.22 GBq (33 mCi) of Na I-131 for which a written directive is required [experience with at least 3 cases in 7F2.1(2)(f)(ii) also satisfies the requirement in category 7F2.1(2)(f)(i)];~~**Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;[2]**

(iii) Parenteral administration of any **radioactive drug that contains a radionuclide that is primarily used for its electron emission,** beta ~~emitter~~**radiation characteristics, alpha radiation characteristics**, or ~~a photon-emitting radionuclide with a~~ photon energy less than 150 keV, for which a written directive is required;

Commented [JJ213]: Updated for consistency with 10 CFR 35.390(b)(1)(ii)(G).

NRC Compatibility B

Commented [JSJ214]: Note that footnote "2" is associated with this provision.

~~and/or~~

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

and

7F2.2 ~~Has provided written attestation(s), that the individual has satisfactorily completed the requirements in 7F1.1(1) and 7F2.1(2)(f) or 7F2.1, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 7.36. The written attestation must be signed by a preceptor authorized user who:~~**Has obtained written attestation that the individual has satisfactorily completed the requirements in 7F2.1 and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 7.36. The attestation must be obtained from either:**

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

(2) ~~The preceptor authorized user, who meets the requirements in 7F2.1 must have experience in administering dosages in the same dosage category or categories (i.e., 7F2.1(2)(f)) as the individual requesting authorized user status.~~**A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 7P, 7F, or equivalent Agreement State or NRC requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7F2.1.**

[2] Experience with at least three cases in Category 7F2.1(2)(f)(ii) also satisfies the requirement in Category 7F2.1(2)(f)(i).

~~and~~

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

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

~~or~~

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

~~or~~

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

Commented [JSJ215]: This provision is revised, based on the 2018 amendments to 10 CFR 35.390(b)(2)(i) and replaces the language in the current 7F2.2(2).

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. This provision would apply to an individual who may be an authorized user named on a license for other types of use, but would like obtain authorization in 7F.

Commented [JSJ216]: This is a new provision based on the 2018 amendments to 10 CFR 35.390(b)(2)(ii).

For recent graduates of medical training programs, the revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

Commented [JSJ217]: This provision has been replaced by 7.65, which parallels the requirements of 10 CFR 35.59.

Commented [JSJ218]: This provision has been replaced by Appendix 7P, consistent with the format of 10 CFR 35.390.

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

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

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~~gigabeckquerels I (33 ~~mCi~~millicuries) ~~(7.36.3 USES)~~

~~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 NRC or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page;**

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:~~

(~~a~~**1**) Radiation physics and instrumentation;

(~~b~~**2**) Radiation protection;

(~~c~~**3**) Mathematics pertaining to the use and measurement of radioactivity;

(~~d~~**4**) Chemistry of radioactive material for medical use; and

(~~e~~**5**) 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~~.1~~, 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:

(~~a~~**1**) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

Commented [JJ219]: 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.

Commented [JSJ220]: 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.

(~~b~~2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(~~c~~3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(~~d~~4) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of ~~unsealed~~ radioactive material;

(~~e~~5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

(~~f~~6) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

and

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

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

~~and~~**or**

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

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7G, Appendix 7H, or equivalent NRC or Agreement State requirements, has experience in administering dosages as specified in 7F2.1(2)(f)(i) or 7F2.1(2)(f)(ii), and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7G3.1 and 7G3.2.

~~and~~

~~**7G4** Meets the following recentness of training requirements:~~

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

Commented [JSJ221]: The revised provision clarifies that the preceptor must have experience administering materials in the same categories as the individual requesting authorization. This provision would apply to an individual who may be an authorized user named on a license for other types of use, but would like obtain authorization for uses under 7G.

Commented [JSJ222]: This provision is new, based on the 2018 amendments to 10 CFR 35.392(c)(3)(ii).

For recent graduates, the revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

~~or~~

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

~~or~~

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

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

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

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~~GIGABECQUERELS (33 ~~mCi~~millicuries) ~~(7.36.4 USES)~~

~~**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 NRC 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:~~

(~~a~~**1**) Radiation physics and instrumentation;

(~~b~~**2**) Radiation protection;

(~~c~~**3**) Mathematics pertaining to the use and measurement of radioactivity;

(~~d~~**4**) Chemistry of radioactive material for medical use; and

(~~e~~**5**) Radiation biology;

and

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

(~~a~~**1**) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(~~b~~**2**) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

Commented [JJ223]: For final publication, insert a page break such that each appendix begins on a new page.

Appendix 7H is updated for consistency with the format and 2018 updates to 10 CFR 35.394.

(~~c~~**3**) Calculating, measuring, and safely preparing patient or human research subject dosages;

(~~d~~**4**) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of ~~unsealed~~ radioactive material;

(~~e~~**5**) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

(~~f~~**6**) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

~~and~~**and**

7H3.3~~(3) Has provided written attestation(s), that the individual has completed the requirements of 7H3.1(1) and 7H3.1(2), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses of unsealed radioactive materials using Na I-131 in activities greater than 1.22 GBq (33 mCi) authorized under 7.36. The written attestation must be signed by a preceptor authorized user who:~~**Has obtained written attestation that the individual has satisfactorily completed the requirements in 7H3.1 and 7H3.2, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 7.36. The attestation must be obtained from either:**

(1) **A preceptor authorized user who** ~~Meets~~**meets** the requirements in ~~7H5~~**Appendix 7P**, Appendix 7F, or Appendix 7H, or equivalent NRC or Agreement State requirements~~;~~ **and has experience in administering dosages as specified in 7F2.1(2)(f)(ii); or**

~~and~~**and**

~~(2) The preceptor authorized user, who meets the requirements in 7F2.1 must have experience in administering dosages as specified in 7F2.1(2)(f)(ii).~~

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7H, or equivalent NRC or Agreement State requirements, has experience in administering dosages as specified in F2.1(2)(f)(ii), and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7H3.1 and 7H3.2.

Commented [JSJ224]: This provision is new, based on the 2018 amendments to 10 CFR 35.392(c)(3)(ii).

For recent graduates, the revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

~~and~~

~~**7H4** Meets the following recentness of training requirements:~~

~~7H4.1 The training and experience required by Appendix 7H shall have been obtained within the 7 years preceding the date of license application or amendment request;~~

~~or~~

~~7H4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.~~

~~or~~

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

~~7H5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7H1 through 7H4.~~

~~7H5.2 Individuals not required to comply with the training requirements of 7H1 through 7H4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.~~

PART 7, APPENDIX 7I: ~~AUTHORIZED USER~~ TRAINING FOR THE PARENTERAL ADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL REQUIRING A WRITTEN DIRECTIVE ~~(7.36.5 USES)~~

~~The licensee shall require an authorized user for parenteral administration of unsealed radioactive material for which a written directive is required to be a physician who has a current active State of Colorado license and:~~

7I1 Except as provided in Appendix 7P, the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

7I1**.1** Is an authorized user under Appendix 7F for uses listed in 7F2.1(2)(f)(iii) ~~or 7F2.1(2)(f)(iv)~~, or equivalent NRC or Agreement State requirements;

or

7I1.2 Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State requirements and who meets the requirements in 7I2;

or

7I1.3 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under Appendix 7K or Appendix 7M, and who meets the requirements in paragraph 7I2 of this section.

~~or~~

~~7I2 Is an authorized user under Appendix 7K, Appendix 7M, or equivalent NRC or Agreement State requirements and who meets the requirements in 7I4;~~

~~or~~

~~7I3 Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State under Appendix 7K or Appendix 7M, and who meets the requirements in paragraph 7I4 of this section.~~

~~or~~

~~7I4 Has satisfied the following criteria:~~

7I2 The physician:

7I~~4.12~~**.1** Has ~~satisfactorily~~**successfully** completed 80 hours of classroom and laboratory training**,** applicable to parenteral administrations **listed in 7F2.1(2)(f)(iii).** ~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required.~~ **The training must include:**

~~(1) The training must include:~~

~~(a)~~**(1)** Radiation physics and instrumentation;

~~(b)~~**(2)** Radiation protection;

~~(c)~~**(3)** Mathematics pertaining to the use and measurement of radioactivity;

~~(d)~~**(4)** Chemistry of radioactive material for medical use;

and

~~(e)~~**(5)** Radiation biology;

~~and~~**and**

Commented [JJ225]: 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.

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Commented [JSJ226]: Provision replaced by 7I1.2 above.

Commented [JSJ227]: Provision replaced by 7I1.3 above.

~~(2)~~**7I2.2** Has work experience under the supervision of an authorized user who meets the requirements of **Appendix 7P**~~7I6~~, Appendix 7F, Appendix 7I, or equivalent Agreement State or NRC requirements, in the parenteral administration**s listed in 7F2.1(2)(f)(iii).**~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user, who meets the requirements in 7F, must have experience in administering dosages as specified in 7F2.1(2)(f)(iii) and/or 7F2.1(2)(f)(iv).~~ **A supervising authorized user, who meets the requirements in Appendix 7F, 7I, or equivalent Agreement State or NRC requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status.** The work experience must involve:

~~(a)~~**(1)** Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

~~(b)~~**(2)** Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

~~(c)~~**(3)** Calculating, measuring, and safely preparing patient or human research subject dosages;

~~(d)~~**(4)** Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of unsealed radioactive material;

~~(e)~~**(5)** Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

and

~~(f)~~**(6)** Administering dosages to patients or human research subjects that include~~:~~

~~(i) At~~ **at** least 3 cases involving the parenteral administration**s as specified in 7F2.1(2)(f)(iii)**~~, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV;~~

~~and/or~~

~~(ii) At least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required;~~

and

~~(3)~~**7I2.3** Has ~~provided~~**obtained** written attestation~~(s)~~ that the individual has **satisfactorily** completed the requirements in ~~7I2 or 7I3~~**7I2.1 or 7I2.2**, and ~~has achieved a level of competency sufficient to function~~ **is able to** independently **fulfill the radiation safety-related duties** as an authorized user for the parenteral administration of unsealed radioactive material~~s~~ requiring a written directive. ~~The written attestation must be signed by a preceptor authorized user who:~~**The attestation must be obtained from either:**

~~(a) Meets the requirements in 7I6, Appendix F, or Appendix I, or equivalent NRC or Agreement State requirements;~~

~~and~~

~~(b) Meets the requirements in Appendix 7F must have experience in administering dosages as specified in 7F2.1(2)(f)(iii) and/or 7F2.1(2)(f)(iv).~~

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7F, 7I, or equivalent Agreement State or NRC requirements. A preceptor authorized user who meets the requirements in Appendix 7F, 7I, or equivalent Agreement State or NRC requirements, must have experience in administering dosages in the same category or categories as the individuals requesting authorized user status;

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7F, Appendix 7I, or equivalent Agreement State or NRC requirements, has experience in administering dosages in the same dose category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7I2.1 and 7I2.2.

Commented [JSJ228]: For recent graduates, the revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

~~and~~

~~7I5 Meets the following recentness of training requirements:~~

Commented [JSJ229]: The recentness of training requirements have been relocated to a single location in 7.65.

~~7I5.1 The training and experience required by Appendix 7I shall have been obtained within the 7 years preceding the date of license application or amendment request;~~

~~or~~

~~7I5.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.~~

~~or~~

~~7I6 Meets the following requirements for an experienced authorized user for 7.36.5 uses:~~

Commented [JSJ230]: The requirements for an experienced authorized individual have been consolidated in Appendix 7P.

~~7I6.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7I1 through 7I5.~~

~~7I6.2 Individuals not required to comply with the training requirements of 7I1 through 7I5 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.~~

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 7.40 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:~~

(~~a~~**1**) Radiation physics and instrumentation;

(~~b~~**2**) Radiation protection;

(~~c~~**3**) Mathematics pertaining to the use and measurement of radioactivity;

(~~d~~**4**) Radiation biology;

and

7J~~3~~4 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~~

~~**7J5** Meets the following requirements for an experienced authorized user for 7.40 uses:~~

~~7J5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or~~

Commented [JJ231]: 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.

~~Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7J1 through 7J4.;~~

~~7J5.2 Individuals not required to comply with the training requirements of 7J1 through 7J4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.~~

PART 7, APPENDIX 7K: ~~AUTHORIZED USER~~ TRAINING FOR ~~THE~~ USE OF MANUAL BRACHYTHERAPY SOURCES ~~(7.42 USES)~~

~~The licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 7.42 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 of a manual brachytherapy source for the uses authorized under 7.42 to be a physician who:

7K1 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 7K2.3 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 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:**

~~7K1.1 To have its certification process recognized, a specialty board shall require all candidates for certification to:~~

~~(1)~~**7K1.1** Successfully complete a minimum of 3 years of residency training in a radiation oncology 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~~

and

~~(2)~~**7K1.2** Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy;

or

7K2 ~~Has satisfied the following criteria:~~

7K2.1 Has ~~satisfactorily~~ completed a structured educational program in basic radionuclide handling techniques applicable to the ~~medical~~ use of manual brachytherapy sources~~,~~ 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;

(d) Radiation biology;

and

(2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in ~~7K4~~**Appendix 7P**, Appendix 7K, or equivalent NRC or Agreement State requirements at a medical ~~institution~~**facility authorized to use radioactive materials under 7.42**, involving:

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

(b) Checking survey meters for proper operation;

(c) Preparing, implanting, and removing brachytherapy sources;

Commented [JJ232]: 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.

NRC RATS 2018-1
NRC Compatibility B

Commented [JSJ233]: Revised to use the correct terminology for the residency approval organization of the American Osteopathic Association.

Commented [JSJ234]: The change in this provision is updated for consistency with the 2018 amendments to 10 CFR 35.490(b)(1)(ii).

The current term "medical institution" (as specifically defined in 7.2) unnecessarily limits where the work experience for an authorized user can be obtained. The language is modified to "medical facility" which will allow physician authorized users additional flexibility.

(d) Maintaining running inventories of material on hand;

(e) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of radioactive material;

(f) Using emergency procedures to control radioactive material;

and

7K2.2 Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in ~~7K4~~**Appendix 7P**, Appendix 7K, or equivalent Agreement State or NRC requirements, ~~provided that the experience:~~

~~(a)~~ ~~I~~**as** part of a formal training program approved by the Residency Review Committee **for Radiation Oncology** of the Accreditation Council for Graduate Medical Education or **the** Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association.~~;~~ **This experience may be obtained concurrently with the supervised work experience required by 7K2.1**

and

~~(b) May be obtained concurrently with the supervised work experience required by 7K2.1(2).~~

and

7K2.3 ~~Has provided written attestation(s), signed by a preceptor authorized user who meets the requirements in 7K4, Appendix 7K, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in 7K1.1(1), or paragraphs 7K2.1 and 7K2.2, and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 7.42.~~**Has obtained written attestation that the individual has satisfactorily completed the requirements in 7K2.1 and 7K2.2 and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 7.42. The attestation must be obtained from either:**

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7K, or equivalent Agreement State or NRC requirements.

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7K, or equivalent Agreement State or NRC requirements, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7K2.1 and 7K2.2.

~~and~~

~~**7K3** Meets the following recentness of training requirements:~~

Commented [JSJ235]:
For recent graduates, the revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

7K3.1 The training and experience required by Appendix 7K shall have been obtained: within the 7 years preceding the date of license application or amendment request;

or

7K3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

7K4 Meets the following requirements for an experienced authorized user for 7.42 uses:

7K4.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7K1 through 7K3.

7K4.2 Individuals not required to comply with the training requirements of 7K1 through 7K3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

PART 7, APPENDIX 7L: ~~AUTHORIZED USER~~ TRAINING FOR OPHTHALMIC USE OF STRONTIUM-90 ~~(7.42 USES)~~

~~The licensee shall require an authorized user of a Strontium-90 source for ophthalmic radiotherapy authorized under 7.42 to be a physician who has a current active State of Colorado license and:~~**Except as provided in Appendix 7P, the licensee shall require the authorized of strontium-90 for ophthalmic radiotherapy to be a physician who:**

7L1 Is an authorized user under Appendix 7K or equivalent NRC or Agreement State requirements;

or

7L2 ~~Has satisfied the following criteria:~~

7L2.1 Has ~~satisfactorily~~ completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. **The training must include:**

~~(1) The training must include:~~

(~~a~~**1**) Radiation physics and instrumentation;

(~~b~~**2**) Radiation protection;

(~~c~~**3**) Mathematics pertaining to the use and measurement of radioactivity; **and**

(~~d~~**4**) Radiation biology;

and

~~(2)~~**7L2.2** Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals~~.~~**.** This supervised clinical training must involve:

(~~a~~**1**) Examination of each individual to be treated;

(~~b~~**2**) Calculation of the dose to be administered;

(~~c~~**3**) Administration of the dose; and

(~~d~~**4**) Follow-up and review of each individual's case history;

and

~~(3)~~**7L3.3** Has ~~provided~~**obtained** written attestation~~(s)~~, signed by a preceptor authorized user who meets the requirements in ~~7L4~~**Appendix 7P**, Appendix 7K, Appendix 7L, or equivalent NRC or Agreement State requirements, that the individual has satisfactorily completed the requirements of ~~7L2~~**7L2.1 and 7L2.2** and ~~has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic radiotherapy uses authorized under 7.42.~~**is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.**

~~and~~

~~**7L3** Meets the following recentness of training requirements:~~

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10 CFR 35.491

NRC RATS 2018-1
NRC Compatibility B

7L3.1 The training and experience required by Appendix 7L shall have been obtained within the 7 years preceding the date of license application or amendment request;

or

7L3.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.

or

7L4 Meets the following requirements for an experienced authorized user for 7.42 opthalmic radiotherapy uses:

7L4.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7L1 through 7L3.

7L4.2 Individuals not required to comply with the training requirements of 7L1 through 7L3 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.

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:~~

~~(1)~~**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

~~(1)~~**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 source~~s~~ 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 [JJ237]: 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 [JSJ238]: Revised to use the correct terminology for the residency approval organization of the American Osteopathic Association.

(2) 500 hours of ~~supervised~~ work experience, under the supervision of an authorized user who meets the requirements in ~~7M5~~**Appendix 7P**, Appendix 7M, or equivalent Agreement State or NRC requirements at a medical ~~institution~~**facility that is authorized to use radioactive materials in 7.48**, involving:

(a) Reviewing full calibration measurements and periodic spot checks;

(b) Preparing treatment plans and calculating treatment doses and times;

(c) Using administrative controls to prevent a ~~misadministration~~**medical event** involving the use of radioactive material;

(d) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(e) Checking and using survey meters; and

(f) Selecting the proper dose and how it is to be administered;

and

7M2.2 Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in ~~7M5~~**Appendix 7P**, Appendix 7M, or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~**Council** on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by ~~paragraph~~ 7M2.1(2) ~~of this section; and~~**;**

and

7M2.3 ~~Has provided written attestation(s) that the individual has satisfactorily completed the requirements of 7M1 or 7M2.1 and 7M2.2, and 7M3, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 7M5, Appendix 7M, or equivalent Agreement State or NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status;~~ **Has obtained written attestation that the individual has satisfactorily completed the requirements in 7M2.1 and 7M2.2 and 7M3; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:**

(1) A preceptor authorized user who meets the requirements in Appendix 7P, Appendix 7M, or equivalent Agreement State or NRC requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status;

or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Appendix 7P, Appendix 7M, or equivalent Agreement State or NRC requirements, for the type(s) of therapeutic medical unit for which the

Commented [JSJ239]:
"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

Commented [JSJ240]:
For recent graduates, the revised language of this provision allows for residency program directors to sign off/provide the attestations for individuals who are demonstrating training through the alternate pathway.

individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be 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 Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 7M2.1 and 7M2.2.

~~and~~

7M3 Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by~~:~~ **satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.**

~~7M3.1 Satisfactorily completing a vendor training program;~~

~~or~~

~~7M3.2 By receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization;~~

~~and~~

~~**7M4** Meets the following recentness of training requirements:~~

~~7M4.1 The training and experience required by Appendix 7M shall have been obtained within the 7 years preceding the date of license application or amendment request;~~

~~or~~

~~7M4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.~~

~~or~~

~~**7M5** Meets the following requirements for an experienced authorized user for 7.48 uses.~~

~~7M5.1 An individual identified as an authorized user for the medical use of radioactive material on a license issued by the NRC or Agreement State, a permit issued under an NRC or Agreement State broad scope license that authorizes medical use before October 25, 2005, who perform only those medical uses for which they were authorized on that date are not required to comply with the training requirements of 7M1 through 7M4.~~

~~7M5.2 Individuals not required to comply with the training requirements of 7M1 through 7M4 may serve as preceptors for, and supervisors of, applicants seeking authorization on licenses for the same uses for which these individuals are authorized.~~

PART 7, APPENDIX 7N: NUCLEAR MEDICINE TECHNOLOGIST (NMT) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The licensee shall require the nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who can, upon the request of the Department, demonstrate:

7N1 ~~Has provided:~~ **Evidence of:**

7N1.1 ~~Evidence of:(1)~~ Current registration with The American Registry of Radiologic Technologists with competency in Nuclear Medicine (ARRT(N));

or

7N1.2~~(2)~~ Current certification by The Nuclear Medicine Technology Certification Board in Nuclear Medicine (CNMT);

or

7N1.3~~(3)~~ Being board-eligible to take the CNMT or ARRT(N) examination;

or

7N1.4~~(4)~~ Current certification by a ~~recognized~~ specialty board **recognized in writing by the Department**~~(see 7N5)~~;

~~and~~

~~7N1.2 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;~~

~~(1) Each preceptor authorized user supervising the experiential training required by Appendix 7N shall meet the requirements of Appendix 7N, or equivalent Agreement State or NRC requirements.~~

~~or~~

~~**7N2** Has satisfied the following criteria:~~

~~7N2.1 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;~~

~~(b) Radiation protection;~~

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

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

~~(e) Radiation biology; and~~

Commented [JJ241]: There are no equivalent requirements in NRC regulations. NRC does not recognize nuclear medicine technologists.

Also see provision 7.10 of the proposed rule.

Commented [JJ242]: For final publication, insert a page break such that each appendix begins on a new page.

Commented [JSJ243]: This proposed change eliminates the option of an alternate pathway for Nuclear Medicine Technologists, effectively requiring certification.

~~(2) Work experience, involving:~~

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

~~(b) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;~~

~~(c) Calculating, measuring, and safely preparing patient or human research subject dosages;~~

~~(d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;~~

~~(e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and~~

~~(f) Administering dosages to patients or human research subjects;~~

~~7N2.2 Has provided written attestation(s), signed by a preceptor authorized user, that the individual has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;~~

or

7N~~3~~2 ~~Has demonstrated~~**Is able to demonstrate** adequate prior experience as:

7N~~3~~2.1 A full-time nuclear medicine technologist for a minimum of two years ~~performing~~ during the past five-year period **prior to August 14, 2020** under the supervision of an authorized user and ~~has provided written attestation(s), signed by a preceptor authorized user, that the individual~~ has achieved a level of competency sufficient to function independently as a nuclear medicine technologist;

or

7N~~3~~2.2 An experienced nuclear medicine technologist working at a facility holding a Department license before October 25, 2005. ~~(and thus need not comply with the requirements of 7N2);~~

~~**7N4** Meets the following recentness of training requirements:~~

~~7N4.1 The training and experience required by Appendix 7N shall have been obtained within the 7 years preceding the date of license application or amendment request;~~

~~or~~

~~7N4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.~~

~~**7N5** To be recognized by the Department, a specialty board shall require that each candidate for certification as a nuclear medicine technologist satisfactorily complete a certification process that includes all of the training requirements in 7N2.1.~~

PART 7, APPENDIX 7O: ~~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:~~

~~**7O1** Has provided:~~

~~7O1.1 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 7O5);~~

~~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~~

~~7O1.2 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 7O shall meet the requirements of Appendix 7O, or equivalent Agreement State or NRC requirements.~~

~~or~~

~~**7O2** Has satisfied the following criteria:~~

~~7O2.1 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;~~

~~(b) Radiation protection;~~

Commented [JSJ244]:
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.

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

(d) Radiation biology;

and

(2) Work experience, involving:

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

(b) Assisting the authorized user in simulating the patient for treatment;

(c) Preparing the patient for treatment;

(d) Implementing treatment plans as prescribed by the authorized user;

(e) Providing written documentation of treatment setup and patient treatments;

(f) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;

(g) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;

(h) Delivering doses to patients or human research subjects under the supervision of the authorized user;

(i) Maintaining running inventories of radioactive material on hand;

(j) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,

(k) Properly implementing emergency procedures;

7O2.2 Has provided 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;

or

7O3 Has demonstrated adequate prior experience as:

7O3.1 A full-time radiation therapy technologist for a minimum of two years performing during the past five-year period under the supervision of an authorized user and has provided 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;

or

7O3.2 An experienced radiation therapy technologist working at a facility holding a Department license before October 25, 2005 (and thus need not comply with the requirements of 7O2);

~~**7O4** Meets the following recentness of training requirements:~~

~~7O4.1 The training and experience required by Appendix 7O shall have been obtained within the 7 years preceding the date of license application or amendment request;~~

~~or~~

~~7O4.2 The individual must have had related, documented, continuing education and experience since the required training and experience was obtained.~~

~~**7O5** To be recognized by the Department, a specialty board shall require that each candidate for certification as a radiation therapy technologist satisfactorily complete a certification process that includes all of the training requirements in 7O2.1.~~

PART 7, APPENDIX 7P: TRAINING FOR EXPERIENCED RADIATION SAFETY OFFICER, TELETHERAPY OR MEDICAL PHYSICIST, AUTHORIZED MEDICAL PHYSICIST, AUTHORIZED USER, NUCLEAR PHARMACIST, AND AUTHORIZED NUCLEAR PHARMACIST.

7P1

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

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

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

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

7P2

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

Commented [JJ245]:
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.

August 14, 2020 is the anticipated effective date of the Part 7 rule under the current rulemaking schedule.

NRC RATS 2018-1
All provisions are NRC Compatibility B, with the exception of 7P1.4, which is compatibility D.

Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before August 14, 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.

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:

(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;

(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;

(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

(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.

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 period identified in 7P2, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of the regulations.

7P3 Individuals who need not comply with training requirements as described in Appendix 7P may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.