



COLORADO
Department of Public
Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: James Jarvis, Hazardous Materials and Waste Management Division
Jennifer Opila, Manager, Colorado Radiation Control Program

Through: Gary Baughman, Director, Hazardous Materials and Waste Management Division *JB*

Date: December 1, 2015

Subject: **Rulemaking Hearing**
Proposed Amendments to 6 CCR 1007-1, Part 3, Licensing of Radioactive
Material, for the rulemaking hearing to occur in December of 2015

The Division is proposing amendments to regulatory Part 3, titled *Licensing of Radioactive Material*.

The regulatory part is being amended to ensure consistency with the 2014 and 2015 changes to the Colorado Radiation Control Act (Colorado's the enabling statute). The 2014 changes were initiated by parties external to the Department. Following a 2014 audit of the Radiation Program by the U.S. Nuclear Regulatory Commission (NRC), certain statutory items were found to be incompatible. The Department then initiated changes to the statute which were finalized and approved during the 2015 legislative session. Additional changes to Part 3 are being proposed to address recent NRC comments and to ensure compatibility with federal rule changes that have occurred within the past several years.

The proposed Part 3 changes will provide for: specific requirements and prohibitions pertaining to generally licensed source material; an exemption for common carriers; expansion of considerations for financial surety adjustments; deferral to Part 1 definitions for construction related terms; requirements for the registration of sealed sources and devices not already registered; removal of the term "classified material"; incorporation of current federal licensing requirements for distribution of exempt items; and addition of some low risk items as exempt materials.

In mid-July, 2015, approximately 1,100 stakeholders were notified of the proposed rule amendment and were provided the opportunity to comment over a 60 day period. Additionally, three stakeholder meetings were held in August, 2015 in Denver, Montrose, and Canon City, Colorado to present and discuss the proposed changes. The stakeholder comment period remained open through September 16. To date, the Division has received written comments from six stakeholders pertaining to proposed changes.

Stakeholders involved with community drinking water systems have expressed concern over the limits pertaining to small quantities of source material, since drinking water residuals may contain and can concentrate source material (e.g., uranium and/or thorium). However, as discussed during stakeholder meetings, it is expected that the proposed limits will have minimal impact on drinking water systems since the proposed limit specific to drinking water residuals is slightly higher than the current limit, and the isotope that typically contributes the largest amount of radioactivity during drinking water treatment is radium which is excluded from the source material definition and proposed limits. Additionally, the current

provision in 3.2.1 exempts persons from the requirements where the source material by weight is less than 0.05 %. Most drinking water systems do not produce source material that exceeds this exemption amount. Other stakeholders commented on decommissioning plans, and decommissioning and long term care warranties. The requirements for the decommissioning plans and warranties are consistent with federal rule and state statute.

Further details of the proposed changes are listed in a Statement of Basis and Purpose and Specific Statutory Authority for the proposed rule, which, along with a Regulatory Analysis and supporting information, is available at:

<https://www.colorado.gov/pacific/cdphe/regulations-development-parts-1318>

The Radiation Program requests that the Board of Health approve the rule at the rulemaking hearing on December 16 of 2015.

cc: Deborah Nelson, Administrator, State Board of Health

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STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1, Part 3, Licensing of Radioactive Material

Basis and Purpose.

The Colorado Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes (the Act), requires the State Board of Health to formulate, adopt and promulgate rules and regulations pertaining to radiation control.

Section 25-11-103 of the Act requires the Colorado Department of Public Health and Environment (Department) to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing radiation. Under this authority the Department requires registration of sources of ionizing radiation such as radiation machines and licenses governing the use of radioactive materials.

Section 25-11-104(2) of the Act specifies that Colorado's radiation regulations be consistent with U.S. Nuclear Regulatory Commission (NRC) requirements necessary to maintain compatibility (and status as an Agreement State), and the Suggested State Regulations for Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors, Inc., except when the Board of Health concludes, on the basis of detailed findings, that a substantial deviation from the SSRCR is warranted. Colorado's Part 3 regulation - is based on SSRCR Part "C". With the proposed Part 3 amendments, maintaining exact duplicity with the SSRCR is not feasible and deviation from the SSRCR is necessary. The model regulation - SSRCR Part C - was last amended in 2010 and is not consistent with more recent federal rule changes nor does it contain some provisions specific to state law. The proposed Part 3 amendments add, delete, and modify provisions needed for consistency with federal rule changes and state statute.

The Department is proposing amendments to Part 3 to maintain consistency with the 2014 and 2015 Colorado Radiation Control Act (statutory) changes and to address past comments and federal rule changes of the NRC. The specific proposed Part 3 changes are:

- (1) The addition of specific requirements and prohibitions pertaining to source material allowed under a general license, including:
 - Specific limits for certain types/forms of source material;
 - Prohibitions on administering source material to humans without a specific license;
 - Prohibitions on export of source material without a specific license;
 - Requirements for minimization of contamination; and
 - Requirements for initial distribution of source material to persons generally licensed.
- (2) The addition of an exemption for common carriers involved in the transport of radioactive materials on behalf of licensed entities;
- (3) The deferral to the Part 1 definitions for the terms *commencement of construction* and *construction* and removal of these definitions from Part 3. Note that Part 1 is being amended concurrent with Part 3;
- (4) Modification of the term environmental *report* to environmental *assessment*;
- (5) The addition of licensing requirements for sealed sources and devices which are not listed in the national registry;
- (6) Expansion of the financial assurance/warranty requirements to include:
 - The conditions under which adjustments to financial assurance (decommissioning) warranties must be considered; and
 - The form, maintenance, and accessibility requirements for the financial assurance funds;

- (7) The addition of limitations and requirements associated with bringing additional material onsite where there is a dispute over financial warranty amounts;
- (8) Modification of the assumed interest rate for long-term care warranties from six, to one percent;
- (9) Parallel with Part 18 amendments, the term “classified material” is modified to “radioactive material” or “material”;
- (10) Requirements are added requiring a manufacturer, distributor or initial transferor of a device containing radioactive material above certain quantities to be registered in the (NRC maintained) national registry;
- (11) Provisions are added to provide for inactivation of registration certificates;
- (12) Requirements are added pertaining to the initial transfer of small quantities of source material to general licensees;
- (13) Clarification is added pertaining to the exemptions for certain items containing unimportant quantities of source material;
- (14) Consistent with federal rule, requirements are added which mandate an NRC license for initial sale or distribution of products containing source material to exempt persons;
- (15) The list of low risk items that are exempt from the regulations is expanded for some devices containing small quantities of radioactive material; and
- (16) Minor typographical errors, cross-references and clarifying language are addressed throughout the rule.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutory provisions: 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.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

- Yes, the bill number is HB 15-1145 and SB 14-192 ;
rules are ___ authorized required.
 No

Is this rulemaking due to a federal statutory or regulatory change?

- Yes
 No

Does this rule incorporate materials by reference?

- Yes
 No

Does this rule create or modify fines or fees?

- Yes
 No

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REGULATORY ANALYSIS

for Amendments to

6 CCR 1007-1, Part 3, Licensing of Radioactive Material

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

The Part 3 rule is both a broad and specific rule containing the “base” licensing requirements for radioactive materials use. The proposed amendments will potentially affect:

1. Entities that receive, possess, or transfer small quantities of source material under a general license;
2. Entities that initially transfer or distribute source material to persons generally licensed;
3. Entities that are required to maintain a financial warranty;
4. Entities licensed to manufacture and distribute devices to persons who are generally licensed; and
5. Entities licensed to manufacture and initially transfer devices/items containing source material to persons who are exempt from the regulations.

The proposed changes do not amend Section 3.2.1 of the rule. This provision provides an exemption from the Part 3 requirements for source material meeting the specific criteria (e.g., 0.05 % uranium or thorium by weight) of this provision.

It should be noted that the exemption provided for in 3.2.1 of the rule and the provisions in 3.5 that apply to uranium and thorium content (by weight concentration) does not include the weight of the media in which the uranium or thorium may reside.

The new provisions of Section 3.5 are applicable to small quantities of source material, which by definition include only the radionuclides uranium and thorium. By definition, this would exclude materials such as radium. Although new provisions are being added to Section 3.5, this section also provides for some exceptions for certain uses and/or industries.

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.**

The following describes the potential quantitative and qualitative impacts based on the major elements of the proposed amendments listed in item 1 above.

A. Consistent with federal regulations, one of the proposed amendments adds more restrictive limits for possession of generally licensed source material when it is in a dispersible form. (Source material is material which contains uranium and thorium and is defined in Part 1 of the regulations). Currently, the radiation program is aware of one potential Colorado general licensee in possession of source material in a form which may be considered a dispersible form. Further evaluation is being undertaken to determine the potential impacts to this licensee. Such impacts may include the application for a specific license from the Department and/or the NRC.

In Colorado, there are many entities that treat drinking water for human consumption and/or that treat wastewater. Such facilities may fall within general license requirements for source material or may fall within the exemption provided for in 3.2.1 of the rule. Due to the higher presence of naturally occurring uranium and thorium in Colorado, drinking water treatment systems tend to capture and concentrate these materials, which must be safely managed and properly dispositioned. However, with a few exceptions, the majority of water treatment systems do not generate uranium or thorium quantities greater than the source material exemption limit of 0.05 % uranium or thorium (as specified in Part 3, Section 3.2.1). For non-dispersible source material, the proposed amendment in Section 3.5 provides for a slight increase in the one time and annual limits, allowing a general licensee to possess slightly higher quantities of source material than currently allowed. Based upon the current knowledge of existing drinking water treatment systems, it is believed that there are no quantitative or qualitative impacts on these drinking water treatment facilities as a result of the proposed rule changes.

B. Regarding the proposed requirement pertaining to distribution of source material to general licensees (GL's), the Department is currently unaware of any entities or licensees in Colorado that are initially transferring or distributing source material to persons generally licensed. Therefore the proposed revisions specific to initial distribution of source material to GL's would not have an impact on Colorado entities. Colorado's residents may benefit from the proposed requirements in the future, should an entity wish to initially distribute source materials for general licensee use. The proposed rule contains additional health and safety requirements that would be expected to benefit the regulated entity, workers, and citizens by providing a clearer regulatory structure consistent with the national framework of regulating such materials.

C. With regard to the proposed language pertaining to financial warranties for decommissioning, the current regulations require certain facilities to maintain a financial decommissioning warranty, based on the type of operation or quantities of materials they possess. Consistent with federal rule requirements, the proposed changes expand on the conditions under which a warranty must be modified (increased or decreased) to account for changes and other factors that may arise over the operational lifetime of the facility and which may impact the warranty amount.

Certain facilities must similarly establish a long term care warranty to ensure that funds are adequate to provide surveillance on the site once the facility is decommissioned and the license is terminated. The proposed rule, consistent with recent changes to state statute, assumes a lower interest rate for such funds and therefore will require significantly more "up-front" funding than previously required. The process of determining the specific warranty amounts are complex and are typically determined during the licensing or renewal process and are reevaluated on a periodic basis thereafter to ensure adequate funding.

The case specific warranty amounts and thus the quantitative impacts are difficult to generalize or predict. However, some current facilities requiring warranties may need to increase their amounts under the proposed revised interest rate.

D. Colorado currently has one specific licensee authorized to distribute devices to general licensees. The proposed rule will clarify that such devices are required to be registered in the national registry of such devices. This Colorado licensee currently has their devices registered, consistent with the proposed rule. The proposed rule is believed to have no impact on any current Colorado licensee.

E. Colorado currently has two specific licensees who manufacture and distribute items containing source material to exempt persons (e.g., entities not required to have a license). Current NRC federal rule requires these licensees to obtain an additional specific license for distribution from the U.S. Nuclear Regulatory Commission since only NRC has jurisdiction over the issuance of licenses for such exempt distribution. This NRC license is in addition to the possession and use license issued by Colorado. The incorporation of the federal rule requirements into Colorado rule will not result in overlap of jurisdiction since the requirements focus on different elements of the regulatory program. One of the Colorado licensees was recently issued an NRC exempt distribution license while the other will be required to apply for an NRC license and pay an annual licensing fee to the NRC.

Several other regulatory changes not specifically identified above are technical in nature and most are not expected to have a significant quantitative or qualitative impact. The added or clarified language throughout the rule is expected to enhance the understanding of the rule requirements and maintain Colorado's requirements consistent - notwithstanding differing statutory requirements - with the national regulatory framework for such materials.

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.

The rule requirements are enforced only by the Department. No other agency is expected to encounter costs as a result of the proposed changes.

The costs to the Department or state revenues are not expected to change significantly as a result of the proposed changes.

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

The anticipated/likely probable costs as a result of the proposed rule relate to two primary areas:

- (a) The (federal) licensing requirement for distribution of items containing source material to exempt users; and
- (b) The reduction in the assumed interest rate for financial warranties.

There are two Colorado licensees that would likely be required to obtain a federal license for exempt distribution of source material items. These licensees would encounter additional application and licensing related expenses. The current NRC license application fee for an exempt distribution license for source material is \$6,900 and the annual fee for such license is \$12,500. These additional costs are expected to be realized by these two licensees and are in addition to the Colorado licensing fees. Some additional undetermined costs may also be realized by these licensees due to the associated labeling and periodic reporting requirements imposed by the rule.

The reduction in the assumed interest rate for the long term care financial warranties will impact one or more currently licensed facilities. As discussed previously, the specific amount of such warranty is variable and is dependent upon the site and the materials possessed, among other factors. By statute, a report demonstrating the value of warranty amounts is required to be submitted to the Department annually for review and is adjusted as necessary.

The benefits of amending the rule will be to address outstanding comments and federal rule changes from the NRC such that it is made consistent with the national framework of regulating licensed facilities. The rule amendments will help ensure that Colorado's status as an agreement state is maintained. Additionally, the amended rule will bring the rule requirements into alignment with recent statutory changes.

Inaction on the proposed rule will result in potential conflict with statutory requirements and may jeopardize Colorado's agreement state status. Inaction would also limit Colorado's consistency within the national regulatory framework for radioactive materials regulation, thus creating potential inter-state issues.

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

The purpose of the proposed rule changes is to align the requirements with federal rule and recent statutory changes. There are no less costly or less intrusive methods to achieve the purpose of the proposed changes, short of eliminating some provisions in the rule, which may result in conflict with statutory or federal requirements.

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

The proposed rules are needed to achieve consistency with state statute, and federal rules needed for compatibility as an agreement state. There are no alternate rules or alternatives to rulemaking that will achieve the goals and requirements.

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.

The short and long term consequences of not implementing the proposed requirements will be inconsistency with state law and continued incompatibility with federal rules and requirements needed to maintain status as an agreement state with NRC. Another potential long term consequence - should the proposed amendments not be addressed under state regulation - is the possibility of enhanced oversight by NRC and potential loss of status as an agreement state.

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STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1007-1, Part 3, Licensing of Radioactive Material

The following individuals and/or entities were included in the development of these proposed rules:

On July 17, 2015, a total of ~1,100+ stakeholders were notified of the opportunity to comment on the proposed draft rule over a 60 day period. The entities notified represented:

- Approximately 550+ Stakeholders who have previously participated in stakeholder processes associated with uranium facilities, and Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) groups;
- Approximately 300+ radioactive materials licensees;
- Approximately 278+ “other stakeholders” representing individuals who have specifically signed up to receive notification of proposed radiation regulation changes and who represent a wide variety of interests. These stakeholder entities include: x-ray registrants, radioactive materials licensees; private citizens; private companies; professional organizations; and special interest groups.

Stakeholder meetings were also held mid-way through the comment period in Denver, Montrose, and Canon City, providing stakeholders the opportunity to ask questions and provide comments on the proposed rule changes. A number of stakeholders representing water treatment facilities attended the initial Denver meeting.

Local governments may seek a General License for Small Quantities of Source Material or General License for Radioactive Material other than Source Material. Some local governments may hold a specific license and not fall below the source material exemption provided in the regulation. To the extent there is an impact on local government, the local government is being treated similarly to all other licensees and as required by federal regulation. In addition, the current rule indicates that local governments and Indian nations may be notified of a decommission plan or proposal; the requirement is not being modified by this proposal and the requirement benefits local government and Indian nations as it ensures the local government or Indian nation is made aware of the plan in the event any rights would be potentially affected by the decommissioning.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

In addition to the notice of opportunity to comment on the proposed rule discussed above, stakeholders were provided with the anticipated rulemaking schedule for both the request for rulemaking and the rulemaking hearing dates. This rulemaking timeline information is also posted on the Department website area specific to the rule changes. A formal notice of rulemaking will be issued upon initial approval by the Board of Health during a request for rulemaking hearing.

On November 9-10, 2015 approximately ~1,100 stakeholders were provided notice that this rule-making was proposed for consideration by the Board of Health. The stakeholders comprised the same group of entities as during the initial stakeholder outreach as described above.

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.

Stakeholders have expressed some concern over the potential impacts of the new source material limits on drinking water entities. Although a few water treatment system entities are currently (specifically) licensed under the current requirements, most fall below the source material exemption provided for in the current regulation and would not be affected by the proposed rule. The proposed source material limit requirements are needed to comply with federal rule.

Stakeholders currently licensed by Colorado to possess and use source material for application to certain items (e.g., lenses and mirror coating) have not expressed concern nor provided specific comments during the stakeholder process.

The table below outlines the specific comments received during the stakeholder **comment period**, and the Department’s response to those comments. Due to the parallel rulemaking of this regulatory part with other regulatory parts, and the overlapping nature of certain proposed provisions or topics, some information may overlap and also appear in other rule part documents.

The following table is an outline of the comments received during the stakeholder comment period and the response to those comments.

#	Rule Part(s)	Topic	Summary of Comment(s)	Department Response
3A	Parts 1,3,18	Rules deviate from Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations for Control of Radiation (SSRs)	CDPHE proposes deviation from the model rules but there is no explanation as to what the substantial deviation is for in this rulemaking. A description of what is in the model regulation followed by a description of the deviation is required.	Section 25-11-104 of the Act requires Colorado’s radiation regulations to be consistent with U.S. Nuclear Regulatory Commission (NRC) requirements necessary to maintain compatibility (and status as an Agreement State); and the Suggested State Regulations for Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors, Inc., except when the Board of Health concludes, on the basis of detailed findings, that a substantial deviation from the SSRCR is warranted. In some instances, maintaining consistency with the SSRCR may not be feasible due to the model regulation being out of date with NRC changes, where possible conflicts exist between the SSRCR and state statute, where no model regulation exists, where there are specific programmatic elements or business processes that differ greatly from the SSRCR. The Radiation Control Act (RCA) does not require the Department

				to indicate each deviation from the SSRCR, however in some cases, where staff has found it would be helpful, notes have been provided in the side margins of the proposed revised regulations.
3B	Basis and Purpose for Part 3	“non-exempt source material”	A commenter suggested incorporating the phrase “non-exempt” in front of the phrase source material, such that it reads “non-exempt source material” in the basis and purpose documents which accompany the proposed rule.	The Department disagrees with the inclusion of “non-exempt” in the supporting documents. In the context of federal rule and in the suggested state regulations, the term “non-exempt source material” does not exist. Use of such a term would likely result in confusion as it does not exist within the national framework of radiation regulations applicable to source material. No change to the basis and purpose document was made as a result of this comment.
3C	Basis and Purpose for Part 3	Exemption of source material	The exemption for source material containing < 0.05 percent of uranium and thorium should be emphasized in the basis and purpose/regulatory analysis documents.	The provisions for the exemption from licensing requirements for source material containing <0.05 percent uranium and thorium have not changed as part of this revision. Changes have been made to the basis and purpose/regulatory analysis documents to clarify this exemption.
3D	Part 3	Decommissioning plans	The Department must not allow a tailings impoundment to cease operation and enter closure without an approved closure plan and enforceable reclamation milestones incorporated in the license.	The requirements for closure plans and reclamation milestones have not been changed as part of this rulemaking and are consistent with NRC regulations. No change to the proposed rule was made as a result of this comment.
3E	Part 3	Public process Decommissioning warranty and long term care warranty	A number of stakeholders expressed concern regarding the procedural due process and the public’s ability to participate in the agency’s (Department) hearing process as it pertains to amendments/revisions to a licensed facility decommissioning warranty and long term care warranty.	Section 3.9.5.7 of the regulations requires each licensee’s financial warranty to be subject to annual review by the Department. Public notice of the submittal of the licensee’s annual report is posted on the department’s web site and published by the licensee in the local paper of general circulation. Any person may submit written comments to the Department concerning the adequacy of any financial assurance warranties. However, the act of submitting such comments does not provide a right to administrative appeal concerning the financial assurance warranties. The Radiation Control Act does not authorize appeals in these cases. The Regulations

				cannot authorize an appeal if the statute does not authorize it. No change to the proposed rule was made as a result of this comment.
3F	Non-regulation		A commenter provided numerous documents pertaining to specific facilities in Colorado as well as facilities outside Colorado many of which are not regulated by the Department.	The information provided did not clearly address any specific changes to the proposed rules. No change to the proposed rules was made as a result of the information submitted.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The proposed rule changes are primarily technical in nature and are specific to the requirements of state statute and federal rule. HEEJ is accounted for as current provisions of Part 3 provide considerations for those licensed facilities which potentially will have a more significant impact upon the human environment. No changes to these provisions are being proposed.



COLORADO
Department of Public
Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

December 1, 2015

The Colorado Radiation Advisory Committee would like to express support for the proposed regulatory changes to 6 CCR 1007, Part 1 (*General Provisions*), Part 3 (*Licensing of Radioactive Material*), and Part 18 (*Licensing Requirements for Uranium and Thorium Processing*). The Committee has reviewed and discussed the proposed changes during the August and October 2015 meetings and believes the changes are reasonable and appropriate. The proposed rule changes are complex due to the varying requirements driven by statutory and federal rule changes. We believe the Radiation Program has done an exemplary job in navigating these complexities.

There is consensus from the Radiation Advisory Committee that the proposed changes are reasonable and consistent with recent federal and statutory rule changes. We recognize the value of the Colorado Radiation Program in promoting the safe use of radioactive materials and radiation sources through regulation, and acknowledge the commitment of the staff and Department in developing and promoting safe, reasonable, and scientific and risk based regulatory requirements wherever possible.

In summary, we encourage the State Board of Health to approve the proposed changes to the rules during the rulemaking hearing in December 2015.

With Regards,

Thomas E. Johnson, PhD, CHP, Chair
Colorado Radiation Advisory Committee

Created by the Colorado Radiation Control Act (25-11-105, CRS), the nine-member Radiation Advisory Committee advises the Colorado Department of Public Health and Environment's Radiation Program on radiation safety matters and reviews proposed changes to regulations. The current Committee represents past and present radiation safety personnel and users of radiation sources at state and federally regulated entities associated with institutions of higher learning, medical facilities, industry and consulting.



November 10, 2015

Jennifer T. Opila, MPA
Program Manager
Radiation Program
Department of Public Health & Environment
4300 Cherry Creek Dr. So.
Denver, CO 80246

Dear Ms. Opila,

We realize we are well past the deadline for official comment on changes to the Radiation Control Act, but still want to pass along a few thoughts.

Western Colorado Congress' Uranium Committee wishes to thank you, Mr. Smith and Mr. Jarvis for your very informative presentation in Montrose on the proposed changes to the RCA. And we also wish to thank you for making Montrose one of your presentations sites. This greatly facilitated our committee members being able to attend your presentation.

Our committee was very pleased to find out that you had reduced the long-term care warranty interest rate for cleanups and reclamations from 6 percent to 1 percent under Section 3.9.5.15. This will definitely help protect the taxpayers of Colorado from the long-term financial liabilities caused by uranium facilities.

The committee was also pleased with the groundwater protections added to the RCA with respect to uranium and thorium processing, especially the requirements for restoration of groundwater to historic use levels, expedited remediation of groundwater contamination and the reporting of any spill of toxic or radioactive materials.

Our committee members were also pleased that a visual narrative timeline was included in your presentation and on your website for new licenses, renewals or amendments for receipt of material. This will be very helpful to the general public in following the steps and time limits that need to be taken in these processes.

It was also very helpful to find out that all hearings are now following the requirements of the Administrative Procedures Act. And finally, thank you for producing a clean non-redlined version of 6 CCR 1007-1 Parts 01, 03 and 18 and placing it on your website.

Again, thank you for coming to Montrose and making such a well-prepared presentation,


Jennifer Parker, Chair
WCC Uranium Committee

1 **DRAFT 1 10/07/15**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **RADIATION CONTROL - LICENSING OF RADIOACTIVE MATERIAL**

5 **6 CCR 1007-1 PART 03**

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

7

8 **Adopted by the Board of Health on December 16, 2015.**

9 **LICENSING OF RADIOACTIVE MATERIAL**

10 **3.1 Purpose and Scope**

11 3.1.1 Authority.

12 3.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of sections
13 25 1 108, 25 1.5 101(1)(k) and (1)(l), and 25 11 104, CRS.

14 3.1.2 Basis and Purpose.

15 3.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these
16 regulations; a copy may be obtained from the Department.

17 3.1.3 Scope.

18 3.1.3.1 This part, and Parts 5, 7, 14, 16, 17, 18, and 19 of these regulations, provide for the
19 licensing of radioactive material.

20 3.1.3.2 No person shall receive, possess, own, acquire, process, use, store, transfer, or dispose
21 radioactive material except as authorized pursuant to this part or Parts 5, 7, 14, 17, 18, or
22 19 of these regulations, or as otherwise provided in these parts.

23 3.1.4 Applicability.

24 3.1.4.1 In addition to the requirements of this part, all licensees are subject to the requirements
25 of Parts 1, 4, 10, 12 and 17.

26 3.1.4.2 Furthermore:

- 27 (1) Licensees engaged in industrial radiographic operations are subject to the
28 requirements of Part 5.
- 29 (2) Licensees using radionuclides in the healing arts are subject to the requirements
30 of Part 7.
- 31 (3) Licensees engaged in land disposal of radioactive material are subject to the
32 requirements of either Part 14 or Part 18, as appropriate.
- 33 (4) Licensees engaged in source material milling are subject to the requirements of
34 Part 18.
- 35 (5) Licensees engaged in wireline and subsurface tracer studies are subject to the
36 requirements of Part 16.

Comment [JJ1]:
EDITORIAL NOTE 1: ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DOCUMENT ARE FOR INFORMATION PURPOSES ONLY TO PROVIDE ADDITIONAL INFORMATION AND TO AID THE READER IN UNDERSTANDING THE PROPOSED RULE DURING THE DRAFT REVIEW PROCESS.

THESE COMMENTS ARE **NOT** PART OF THE RULE AND ALL COMMENTS WILL BE DELETED PRIOR TO FINAL SUBMISSION.

EDITORIAL NOTE 2: THE ACRONYM "CRCPD" IN THE SIDE MARGIN NOTES REFERS TO THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS (CRCPD), INC., WHICH DEVELOPS SUGGESTED STATE REGULATIONS FOR CONTROL OF RADIATION (KNOWN AS SSRCR'S). UNLESS OTHERWISE DETERMINED BY THE BOARD OF HEALTH, COLORADO'S RULES ARE TO BE CONSISTENT WITH NRC REGULATIONS AND THE SSRCR REGULATIONS. THE SSRCRS MAY BE FOUND ONLINE AT: <http://www.crcpd.org/ssrcrs/default.aspx>

THIS PROPOSED AMENDMENT IS IN PART BASED ON THE CRCPD SSRCR PART C DATED MARCH 2010 AND THE NRC REGULATIONS THAT HAVE BEEN UPDATED SINCE PART C WAS LAST AMENDED.

COMPATIBILITY WITH FEDERAL U.S. NUCLEAR REGULATORY COMMISSION REGULATIONS IS REQUIRED TO MAINTAIN AGREEMENT STATE STATUS.

INFORMATION ON NRC COMPATIBILITY CATEGORIES MAY BE FOUND AT: <https://scp.nrc.gov/regresources.html>

EDITORIAL NOTE 3: INFORMATION ON THE NRC REGULATORY ACTION TRACKING SYSTEM (RATS) MAY BE FOUND AT: https://scp.nrc.gov/rss_regamendents.html

EDITORIAL NOTE 4: SOME UNAFFECTED SECTIONS OF THE RULE HAVE BEEN OMITTED. SUCH SECTIONS ARE DELINIATED BY " * * * * ".

Comment [JJ2]: This reflects the date of anticipated approval by the Colorado Board of Health. The effective date is typically 60 days beyond this date.

37 (6) Panoramic or underwater irradiator licensees are subject to the requirements of
38 Part 19.

39 3.1.5 Definitions

40 3.1.5.1 Definitions of general applicability to these regulations are in Part 1, Section 1.2.

41 3.1.5.2 As used in Part 3, each term below has the definition set forth.

42
43 "Consortium" means an association of medical use licensees and a Positron Emission Tomography (PET)
44 radionuclide production facility in the same geographical area that jointly own or share in the operation
45 and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use
46 in producing radioactive drugs within the consortium for noncommercial distributions among its
47 associated members for medical use. The PET radionuclide production facility within the consortium must
48 be located at an educational institution or a Federal facility or a medical facility.

49
50 3.1.6 The Department may engage the services of qualified persons in order to assist the Department
51 in meeting the requirements of these regulations, including, but not limited to, evaluating information that
52 may be required under 3.8.8.

53 3.1.6.1 Fees for these services may be charged by the Department as a part of fees charged for
54 radiation control services under Part 12.

55 EXEMPTIONS FROM THE REGULATORY REQUIREMENTS

56 3.2 Exemption Of Source Material

57 3.2.1 Any person is exempt from this part to the extent that such person receives, possesses, uses,
58 owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which
59 the source material is by weight less than 1/20th of 1 percent (0.05 percent) of the mixture,
60 compound, solution, or alloy.

61 3.2.2 Any person is exempt from this part to the extent that such person receives, possesses, uses, or
62 transfers unrefined and unprocessed ore containing source material; provided that, except as
63 authorized in a specific license, such person shall not refine or process such ore.

64 3.2.3 Any person is exempt from this part to the extent that such person receives, possesses, uses, or
65 transfers an item containing uranium or thorium listed in Schedule 3C, Sections 3C.1 through
66 ~~3C.10, 3C.2, 3C.3, 3C.4, 3C.5, 3C.6, 3C.7, 3C.8 or 3C.9.~~

Comment [JJ3]: Language is updated and simplified, consistent with the addition of 3C.10.

67 3.2.3.1 The exemptions listed in Schedule 3C do not authorize the manufacture of any of the
68 products described.

69 3.3 Exemption Of Radioactive Material Other Than Source Material.

70 3.3.1 Exempt Concentrations.

71 3.3.1.1 Except as provided in 3.3.1.2, any person is exempt from this part to the extent that such
72 person receives, possesses, uses, transfers, or acquires products containing radioactive
73 material introduced in concentrations not in excess of those listed in Schedule 3A.

74 (1) A ~~manufacturer~~, processor, or producer that transfers a product or material is
75 exempt so long as concentrations less than those listed in schedule 3A were
76 introduced under an NRC license so authorizing.

Comment [JJ4]: Correction of typographical error.

77 (2) Transfer of radioactive material contained in any food, beverage, cosmetic, drug,
78 or other commodity or product designed for ingestion or inhalation by, or
79 application to, a human being, is not exempt under 3.3.1.1(1).

- 80 3.3.1.2 No person may introduce radioactive material into a product or material knowing or
 81 having reason to believe that it will be transferred to persons exempt under 3.3.1.1 or
 82 equivalent regulations of NRC or any Agreement State, except in accordance with a
 83 specific license issued consistent with 3.12.1 or the general license provided in 3.24.
- 84 3.3.2 Exempt Quantities.
- 85 3.3.2.1 Except as provided in 3.3.2.3 and 3.3.2.4, any person is exempt from these regulations to
 86 the extent that such person receives, possesses, uses, transfers, owns, or acquires
 87 radioactive material in individual quantities each of which does not exceed the applicable
 88 quantity set forth in Schedule 3B.
- 89 3.3.2.2 Any person who possesses radioactive material received or acquired under the general
 90 license formerly provided under 10 CFR 31.4 before September 25, 1971 is exempt from
 91 the requirements for a license set forth in this part to the extent that such person
 92 possesses, uses, transfers or owns such radioactive material.
- 93 3.3.2.3 Section 3.3.2 does not authorize the production, packaging or repackaging of radioactive
 94 material for purposes of commercial distribution, or the incorporation of radioactive
 95 material into products intended for commercial distribution.
- 96 3.3.2.4 No person may, for purposes of commercial distribution, transfer radioactive material in
 97 the individual quantities set forth in Schedule 3B, knowing or having reason to believe
 98 that such quantities of radioactive material will be transferred to persons exempt under
 99 3.3.2 or equivalent regulations of NRC or any Agreement State except in accordance with
 100 a specific license issued by NRC pursuant to Section 32.18 of 10 CFR Part 32 (January
 101 1, 2013¹⁵), which license states that the radioactive material may be transferred by the
 102 licensee to persons exempt under 3.3.2 or the equivalent regulations of NRC or an
 103 Agreement State.¹
- 104 ¹ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
 105 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 106 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 107 20555.
- 108 3.3.2.5 No person may, for purposes of producing an increased radiation level, combine
 109 quantities of radioactive material covered by this exemption so that the aggregate
 110 quantity exceeds the limits set forth in Schedule 3B, except for a device placed in use
 111 before May 3, 1999, or as otherwise permitted by these regulations.

112 3.3.3 Exempt Items.

- 113 3.3.3.1 Any person is exempt from this part to the extent that such person receives, possesses,
 114 uses, or transfers an item containing radioactive material which is listed in Schedule 3C,
 115 Sections ~~3C.10, 3C.11 through, 3C.12, OR~~ 3C.13¹⁴.

Comment [JJ5]: Renumbered due to renumbering of Schedule 3C.

116 LICENSES

117 3.4 Types of Licenses.

118 Licenses for radioactive materials are of two types: general and specific.

- 119 3.4.1 A general license is provided by regulation and grants authority to a person for certain activities
 120 involving radioactive material.
- 121 3.4.1.1 A general license is effective without the filing of an application with the Department or
 122 the issuance of a licensing document to a particular person.
- 123 3.4.1.2 However, registration or filing of a certificate with the Department may be required by the
 124 particular general license.

125 3.4.1.3 The general licensee is subject to all other applicable portions of these regulations and
126 any limitations of the general license.

127 3.4.2 A specific license requires the submission of an application to the Department and the issuance
128 of a licensing document by the Department.

129 3.4.2.1 The licensee is subject to all applicable portions of these regulations as well as any
130 limitations specified in the licensing document.

131 GENERAL LICENSES

132 3.5 General Licenses — Small Quantities Of Source Material.

133 **3.5.1** A general license is hereby issued authorizing commercial and industrial firms; research,
134 educational and medical institutions; and **Federal**, State and local government agencies to
135 **receive, possess, use and transfer uranium and thorium, in their natural isotopic**
136 **concentrations and in the form of depleted uranium, not more than 6.82 kg (15 pounds) of**
137 **source material at any one time** for research, development, educational, commercial, or
138 operational purposes **in the following forms and quantities:-**

139 **3.5.1.1 No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g.,**
140 **gaseous, liquid, powder, etc.) at any one time. Any material processed by the**
141 **general licensee that alters the chemical or physical form of the material**
142 **containing source material must be accounted for as a dispersible form. A person**
143 **authorized to possess, use, and transfer source material under 3.5.1.1 may not**
144 **receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one**
145 **calendar year. Persons possessing source material in excess of these limits as of**
146 **August 27, 2016, may continue to possess up to 7 kg (15.4 lb) of uranium and**
147 **thorium at any one time for one year beyond this date, or until the Department**
148 **takes final action on a pending application submitted on or before August 27, 2017,**
149 **for a specific license for such material; and receive up to 70 kg (154 lb) of uranium**
150 **or thorium in any one calendar year until December 31, 2017, or until the**
151 **Department takes final action on a pending application submitted on or before**
152 **August 27, 2017, for a specific license for such material; and**

153 **3.5.1.2 No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A**
154 **person authorized to possess, use, and transfer source material under 3.5.1.2 may**
155 **not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one**
156 **calendar year. A person may not alter the chemical or physical form of the source**
157 **material possessed under 3.5.1.2 unless it is accounted for under the limits of**
158 **3.5.1.1; or**

159 **3.5.1.3 No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking**
160 **water, at any one time. A person may not remove more than 70 kg (154 lb) of**
161 **uranium from drinking water during a calendar year under 3.5.1.3; or**

162 **3.5.1.4 No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose**
163 **of determining the concentration of uranium and thorium contained within the**
164 **material being analyzed at any one time. A person authorized to possess, use, and**
165 **transfer source material under 3.5.1.4 may not receive more than a total of 70 kg**
166 **(154 lb) of source material in any one calendar year.**

167 **3.5.1.1 A person authorized to use or transfer source material, pursuant to this general license,**
168 **may not receive more than a total of 68.2 kg (150 pounds) of source material in any one**
169 **calendar year.**

170
171
172
173
174

Comment [JJ6]:

The added language, consistent with federal rule of 10 CFR 40.22(a), places limits upon the form and quantities of source material that can be possessed by a general license.

The Part 3 rule as currently written does not specify a limit on the form/isotopic abundance of material. A lack of such limits has been determined by NRC to present additional security and health and safety concerns as certain isotopes such as Th228 in larger quantities present higher potential for radiation doses and risk if they are not properly controlled. Quantities above those specified in the proposed rule changes would require a specific license.

This provision is required for compatibility with NRC requirements.

NRC Compatibility = B
NRC RATS = 2013-2

Comment [JJ7]:

Language added in 3.5.1 is added consistent with 10 CFR 40.22(a)(1) through 40.22(a)(4).

3.5.1.1 places additional limits on the amount of dispersible source material that entities may possess and use under a general license. Source material is defined in Part 1 of the Colorado regulations.

This provision is required for compatibility with NRC requirements. The dates are consistent with the 3 year timeframe allotted for implementation of agreement state rules.

NRC Compatibility = B
NRC RATS = 2013-2

Comment [JJ8]:

This provision places a broad and annual limit on the amount of source material that entities may possess and use under a general license.

The annual receipt amount is approximately the same as under current rule (see prior 3.5.1.1 below). The total possession limit is reduced from the current amount for security and health and safety reasons.

Possession and use of quantities greater than this would require a specific radioactive materials license.

This provision is required for compatibility with NRC requirements and is equivalent to that found in 10 CFR 40.22(a)(2).

NRC Compatibility = B
NRC RATS = 2013-2

Comment [JJ9]: This provision is required for compatibility with NRC requirements and is equivalent to that found in 10 CFR 40.22(a)(3).

NRC Compatibility = B
NRC RATS = 2013-2

Comment [JJ10]: This provision in Colorado rule is deleted consistent with the elimination of an equivalent provision/requirement in 10 CFR 40.22(a).

The more specific and limiting provisions of new 3.5.1.1, etc. (above) replace this provision.
NRC Compatibility = B
NRC RATS = 2013-2

175 ~~3.5.1.22~~ ~~Any Ppersons who receives, possesses, uses or transfers source material in~~
 176 ~~accordance with pursuant to the general license in 3.5.1: are prohibited from administering~~
 177 ~~source material, or the radiation therefrom, either externally or internally, to human beings except~~
 178 ~~as may be authorized in a specific license.~~

Comment [JJ11]:
 Language is added consistent with 10 CFR 40.22(b).
 NRC Compatibility = B
 NRC RATS = 2013-2

180 ~~3.5.2.1~~ ~~Is prohibited from administering source material, or the radiation therefrom, either~~
 181 ~~externally or internally, to human beings except as may be authorized by the NRC~~
 182 ~~in a specific license.~~

Comment [JJ12]:
 Language in 3.5.2.1 through 3.5.2.3 is added consistent with the language and requirements of 10 CFR 40.22(b)(1) through (b)(3). These provisions are new to the federal rule which became effective August 27, 2013.

184 ~~3.5.2.2~~ ~~Shall not abandon such source material. Source material may be disposed of as~~
 185 ~~follows:~~
 186 ~~(1) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible~~
 187 ~~form may be transferred each calendar year, by a person authorized to receive,~~
 188 ~~possess, use, and transfer source material under this general license to persons~~
 189 ~~receiving the material for permanent disposal. The recipient of source material~~
 190 ~~transferred under the provisions of this paragraph is exempt from the~~
 191 ~~requirements to obtain a license under this part to the extent the source material is~~
 192 ~~permanently disposed. This provision does not apply to any person who is in~~
 193 ~~possession of source material under a specific license issued under this chapter;~~
 194 ~~or~~
 195 ~~(2) In accordance with 4.33.~~

NRC Compatibility = B
 NRC RATS = 2013-2
Comment [JJ13]: The mass limit applies to the mass of the U or Th only and not the material that contains the source material.

197 ~~3.5.2.3~~ ~~Is subject to the provisions in 3.1, 3.14.2, 3.15.1 through 3.15.3, 3.15.2.1, 3.15.4.2,~~
 198 ~~through 3.15.4.4, 3.22, 3.23, 4.40, 4.50, 4.52, and 10.5.1.~~

Comment [JJ14]:
 This provision is added for consistency with NRC requirements in 10 CFR 40.22(b)(4) and program needs but is compatibility "D" and is not required for compatibility.

200 ~~3.5.2.4~~ ~~Shall respond to written requests from the Department to provide information~~
 201 ~~relating to the general licensee within 30 calendar days of the date of the request,~~
 202 ~~or other time specified in the request. If the person cannot provide the requested~~
 203 ~~information within the allotted time, the person shall, within that same time period,~~
 204 ~~request a longer period to supply the information by providing the Department a~~
 205 ~~written justification for the request;~~

Comment [JJ15]:
 Language in 3.5.2.5 is added consistent with the language and requirements of 10 CFR 40.22(b)(5).
 This provision is new to the federal rule which became effective August 27, 2013.
 NRC Compatibility = B
 NRC RATS = 2013-2

207 ~~3.5.2.5~~ ~~Shall not export such source material except in accordance with a license issued~~
 208 ~~by NRC pursuant to 10 CFR Part 110.~~

Comment [JJ16]:
 Language in 3.5.3 is added consistent with the language and requirements of 10 CFR 40.22(c).

210 ~~3.5.3~~ ~~Any person who receives, possesses, uses, or transfers source material in accordance with~~
 211 ~~3.5.1 shall conduct activities so as to minimize contamination of the facility and the~~
 212 ~~environment. When activities involving such source material are permanently ceased at~~
 213 ~~any site, if evidence of significant contamination is identified, the general licensee shall~~
 214 ~~notify the Department about such contamination and may consult with the Department as~~
 215 ~~to the appropriateness of sampling and restoration activities to ensure that any~~
 216 ~~contamination or residual source material remaining at the site where source material was~~
 217 ~~used under this general license is not likely to result in exposures that exceed the limits in~~
 218 ~~4.61.2.~~

The proposed requirements place requirements on the general licensee to ensure that they minimize contamination, and that where contamination is present following cessation of operations, they notify the Department.
 NRC Compatibility = C
 NRC RATS = 2013-2

219 ~~3.5.24~~ ~~Any Ppersons who receives, possesses, uses, or transfers source material in accordance with~~
 220 ~~pursuant to the general license granted issued in 3.5.1 are exempt from the provisions of Parts~~
 221 ~~4 and 10 to the extent that such receipt, possession, use, and transfer are within the terms of~~
 222 ~~such general license, except that such person shall comply with the provisions of 4.61.2~~
 223 ~~and 4.33; to the extent necessary to meet the provisions of 3.5.2.2 and 3.5.3 provided,~~
 224 ~~however, that this exemption shall not be deemed to apply to any such person who is also in~~
 225 ~~possession of source material under a specific license issued pursuant to this part. However, this~~
 226 ~~exemption does not apply to any person who also holds a specific license issued under~~
 227 ~~Part 3.~~

Comment [JJ17]:
 Language in 3.5.4 is added consistent with the language and requirements of 10 CFR 40.22(d).
 This provision is new to federal rule changes in 10 CFR 40 which became effective August 27, 2013.
 NRC Compatibility = B
 NRC RATS = 2013-2

229 ~~3.5.5~~ ~~No person may initially transfer or distribute source material to persons generally licensed~~
 230 ~~under 3.5.1.1 or 3.5.1.2, or equivalent regulations of an Agreement State or NRC, unless~~
 231 ~~authorized by a specific license issued in accordance with 3.22.6 or equivalent provisions~~
 232 ~~of an Agreement State or NRC. This prohibition does not apply to analytical laboratories~~
 233 ~~returning processed samples to the client who initially provided the sample. Initial~~
 234 ~~distribution of source material to persons generally licensed under 3.5.1 before August 27,~~

Comment [JJ18]: Language in 3.5.5 is added consistent with the language and requirements of 10 CFR 40.22(e).
 This provision is new to federal rule changes in 10 CFR 40 which became effective August 27, 2013.
 NRC Compatibility = B
 NRC RATS = 2013-2

235 | **2016, without specific authorization may continue for 1 year beyond this date. Distribution**
236 | **may also be continued until the Department takes final action on a pending application for**
237 | **license or license amendment to specifically authorize distribution submitted on or before**
238 | **August 27, 2017.**

239 | 3.5.36 A general license is hereby issued authorizing the receipt of title to source material without regard
240 | to quantity.

241 | 3.5.36.1 ~~————~~ This general license does not authorize any person to receive, possess, use, or
242 | transfer source material.

243 | 3.5.47 A general license is hereby issued authorizing the possession of source material involved in
244 | mining operations provided such operations meet the regulatory requirements of the Division of
245 | Reclamation, Mining and Safety, Colorado Department of Natural Resources, or any successor
246 | thereto, and, except as authorized in a specific license, such mining operations shall not refine or
247 | process such ore.

248 | 3.5.58 Depleted Uranium in Industrial Products and Devices.

249 | 3.5.58.1 ~~————~~ A general license is hereby issued to receive, acquire, possess, use, or transfer,
250 | in accordance with the provisions of 3.5.58.2, 3.5.58.3, and 3.5.58.4, ~~and 3.5.5.5,~~
251 | depleted uranium contained in industrial products or devices for the purpose of providing
252 | a concentrated mass in a small volume of the product or device.

253 | 3.5.58.2 ~~————~~ The general license in 3.5.58.1 applies only to industrial products or devices
254 | which have been manufactured either in accordance with a specific license issued to the
255 | manufacturer of the products or devices pursuant to 3.12.13 or in accordance with a
256 | specific license issued to the manufacturer by NRC or an Agreement State which
257 | authorizes manufacture of the products or devices for distribution to persons generally
258 | licensed by NRC or an Agreement State.

259 | (1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the
260 | general license established by 3.5.58.1 shall file Department Form R-52,
261 | "Registration Certificate - Use of Depleted Uranium Under General License", with
262 | the Department.

263 | (a) The form shall be submitted within 30 days after the first receipt or
264 | acquisition of such depleted uranium.

265 | (b) The general licensee shall furnish on Department Form R-52 the
266 | following information and such other information as may be required by
267 | that form:

268 | (i) Name and address of the general licensee;

269 | (ii) A statement that the general licensee has developed and will
270 | maintain procedures designed to establish physical control over
271 | the depleted uranium described in 3.5.58.1 and designed to
272 | prevent transfer of such depleted uranium in any form, including
273 | metal scrap, to persons not authorized to receive the depleted
274 | uranium; and

275 | (iii) Name and title, address, and telephone number of the individual
276 | duly authorized to act for and on behalf of the general licensee in
277 | supervising the procedures identified in 3.5.58.32(1)(b)(ii).

278 | (2) The general licensee possessing or using depleted uranium under the general
279 | license established by 3.5.58.1 shall report in writing to the Department any
280 | changes in information furnished by him in Department Form R-52, "Registration

- 281 Certificate - Use of Depleted Uranium Under General License". The report shall
282 be submitted within 30 days after the effective date of such change.
- 283 3.5.85.43 A person who receives, acquires, possesses, or uses depleted uranium pursuant
284 to the general license established by 3.5.58.1:
- 285 (1) Shall not introduce such depleted uranium, in any form, into a chemical, physical,
286 or metallurgical treatment or process, except a treatment or process for repair or
287 restoration of any plating or other covering of the depleted uranium;
- 288 (2) Shall not abandon such depleted uranium;
- 289 (3) Shall transfer or dispose of such depleted uranium only by transfer in accordance
290 with the provisions of 3.22.
- 291 (a) In the case where the transferee receives the depleted uranium pursuant
292 to the general license established by 3.5.58.1, the transferor shall furnish
293 the transferee a copy of this regulation and a copy of Department Form
294 R-52.
- 295 (b) In the case where the transferee receives the depleted uranium pursuant
296 to a general license contained in NRC's or Agreement State's regulation
297 equivalent to 3.5.58.1, the transferor shall furnish the transferee a copy
298 of this regulation and a copy of Department Form R-52 accompanied by
299 a note explaining that use of the product or device is regulated by NRC
300 or Agreement State under requirements substantially the same as those
301 in this regulation;
- 302 (4) Within 30 days of any transfer, shall report in writing to the Department the name
303 and address of the person receiving the depleted uranium pursuant to such
304 transfer, and
- 305 (5) Shall not export such depleted uranium except in accordance with a license
306 issued by NRC pursuant to 10 CFR Part 110 (January 1, 2013).
- 307 3.5.58.54 Any person receiving, acquiring, possessing, using, or transferring depleted uranium
308 pursuant to the general license established by 3.5.58.1 is exempt from the
309 requirements of Parts 4 and 10 with respect to the depleted uranium covered by that
310 general license.

311 3.6 General Licenses ² - Radioactive Material Other Than Source Material.

312 ² Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

313 3.6.1 ~~Certain Devices and Equipment~~ Reserved.

314 ~~3.6.1.1 A general license is hereby issued to transfer, receive, acquire, own, possess, and use~~
315 ~~radioactive material incorporated in the following devices or equipment which have been~~
316 ~~manufactured, tested and labeled by the manufacturer in accordance with a specific~~
317 ~~license issued to the manufacturer by NRC for use pursuant to Section 31.3 of 10 CFR~~
318 ~~Part 31 (January 1, 2013).~~

319 ~~(1) Devices designed for use as static eliminators which contain, as a sealed source~~
320 ~~or sources, radioactive material consisting of a total of not more than 18.5 MBq~~
321 ~~(500 µCi) of polonium-210 per device.~~

322 ~~(2) Devices designed for ionization of air which contain, as a sealed source or~~
323 ~~sources, radioactive material consisting of a total of not more than 18.5 MBq (500~~
324 ~~µCi) of polonium-210 per device or a total of not more than 1.85 GBq (50 mCi) of~~
325 ~~hydrogen-3 (tritium) per device.~~

Comment [JJ19]:

Section 3.6.1 is removed and reserved, consistent with the deletion of an equivalent provision from 10 CFR 31.3.

NRC Compatibility = B

326 ~~3.6.1.2 This general license is subject to the provisions of 1.4 through 1.9, 3.3.1.2, 3.15, 3.22,~~
327 ~~and 3.23, part 4^a, part 10 and part 17.~~

328 ~~3 Attention is directed particularly to the provisions of Part 4 which relate to the labeling of containers. Reserved~~

329 3.6.2 Reserved.

330 3.6.3 Reserved.

331 3.6.4 Certain Measuring, Gauging or Controlling Devices.

332 3.6.4.1 A general license is hereby issued to commercial and industrial firms and to research,
333 educational and medical institutions, individuals in the conduct of their business, and
334 State or local government agencies to receive, acquire, possess, use or transfer, in
335 accordance with the provisions of 3.6.4.2, 3.6.4.3, and 3.6.4.4, radioactive material,
336 excluding special nuclear material, contained in devices designed and manufactured for
337 the purpose of detecting, measuring, gauging or controlling thickness, density, level,
338 interface location, radiation, leakage, or qualitative or quantitative chemical composition,
339 or for producing light or an ionized atmosphere.

340 3.6.4.2 The general license in 3.6.4.1 applies only to radioactive material contained in devices
341 which have been:

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

345 (a) The Department pursuant to 3.12.4 or

346 (b) By NRC or an Agreement State ⁴

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

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

351 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers
352 radioactive material in a device pursuant to the general license in 3.6.4.1:

353 (1) Shall assure that all labels affixed to the device at the time of receipt, and bearing
354 a statement that removal of the label is prohibited, are maintained thereon and
355 shall comply with all instructions and precautions provided by such labels;

356 (2) Shall assure that the device is tested for leakage of radioactive material and
357 proper operation of the "on-off" mechanism and indicator, if any, at no longer
358 than 6-month intervals or at such other intervals as are specified in the label,
359 however;

360 (a) Devices containing only krypton need not be tested for leakage of
361 radioactive material; and

362 (b) Devices containing only tritium or not more than 3.7 MBq (100 µCi) of
363 other beta- and/or gamma-emitting material or 0.37 MBq (10 µCi) of
364 alpha-emitting material and devices held in storage in the original
365 shipping container prior to initial installation need not be tested for any
366 purpose.

367 (3) Shall assure that the tests required by 3.6.4.3(2) of this section and other testing,
368 installation, servicing, and removal from installation involving the radioactive
369 material, its shielding or containment, are performed:

- 370 (a) In accordance with the instructions provided by the labels; or
- 371 (b) By a person holding an applicable specific license from the Department,
372 NRC or an Agreement State to perform such activities;
- 373 (4) Shall maintain records showing compliance with the requirements of 3.6.4.3(2)
374 and 3.6.4.3(3).
- 375 (a) The records shall show the results of tests.
- 376 (b) The records also shall show the dates of performance of, and the names
377 of persons performing, testing, installation, servicing, and removal from
378 installation concerning the radioactive material, its shielding or
379 containment.
- 380 (c) Records of tests for leakage of radioactive material required by 3.6.4.3(2)
381 shall be maintained for 3 years after the next required leak test is
382 performed or until the sealed source is transferred or disposed of.
- 383 (d) Records of tests of the "on-off" mechanism and indicator required by
384 3.6.4.3(2) shall be maintained for 3 years after the next required test of
385 the "on-off" mechanism and indicator is performed or until the sealed
386 source is transferred or disposed of.
- 387 (e) Records which are required by 3.6.4.3(3) shall be maintained for a period
388 of 3 years from the date of the recorded event or until the device is
389 transferred or disposed of;
- 390 (5) Upon the occurrence of a failure of or damage to, or any indication of a possible
391 failure of or damage to, the shielding of the radioactive material or the "on-off"
392 mechanism or indicator, or upon the detection of 185 Bq (0.005 μ Ci) or more
393 removable radioactive material, shall immediately suspend operation of the
394 device and shall:
- 395 (a) Not operate the device until it has been repaired by the manufacturer or
396 other person holding an applicable specific license from the Department,
397 NRC or an Agreement State to repair such devices;
- 398 (b) Ensure that, if dispositioned, the device and any radioactive material
399 from the device is disposed of by transfer to a person authorized by an
400 applicable specific license to receive the radioactive material contained
401 in the device;
- 402 (c) Within 30 days, furnish to the Department a report containing a brief
403 description of the event and the remedial action taken; and
- 404 (d) In the case of detection of 185 Bq (0.005 microcurie) or more removable
405 radioactive material or failure of or damage to a source likely to result in
406 contamination of the premises or the environs, furnish to the Director of
407 the Hazardous Materials And Waste Management Division, within 30
408 days, a plan for ensuring that the premises and environs are acceptable
409 for unrestricted use.
- 410 (i) Under these circumstances, the criteria set out in 4.61.2,
411 "Radiological Criteria For Unrestricted Use," may be applicable,
412 as determined by the division on a case by case basis;
- 413 (6) Shall not abandon the device containing radioactive material;

- 414 (7) Shall not export the device except in accordance with 10 CFR Part 110 (January
415 1, 2015) and shall obtain written approval from NRC before transferring the
416 device to any other specific licensee not specifically identified in 3.6.4.3(8);
- 417 (8) Except as provided in 3.6.4.3(9), shall transfer or dispose of the device
418 containing radioactive material:
- 419 (a) Only by transfer to a specific licensee of the Department, NRC or an
420 Agreement State whose specific license authorizes receipt of the device;
421 and
- 422 (b) Within 30 days after transfer or export, shall furnish to the Department a
423 report containing:
- 424 (i) Identification of the device by manufacturer's (or initial
425 transferor's) name, model number and serial number;
- 426 (ii) The name, address and license number of the person receiving
427 the device;
- 428 (iii) The date of the transfer;
- 429 (iv) The identity of the radionuclide(s) present and activity present,
430 by assay or calculation;
- 431 (c) **Comply with 10 CFR 31.5(c)(8)(iii), as applicable. Shall obtain written
432 Department approval before transferring the device to any other
433 specific licensee not specifically identified in 3.6.4.3(8). However, a
434 holder of a specific license may transfer a device for possession
435 and use under its own specific license without prior approval, if, the
436 holder:-**
- 437 (i) **Verifies that the specific license authorizes the possession
438 and use, or applies for and obtains an amendment to the
439 license authorizing the possession and use;**
- 440 (ii) **Removes, alters, covers, or clearly and unambiguously
441 augments the existing label (otherwise required by 3.6.4.3(1)
442 of this part) so that the device is labeled in compliance with
443 Part 4, Section 4.30; however the manufacturer, model
444 number, and serial number must be retained;**
- 445 (iii) **Obtains the manufacturer's or initial transferor's information
446 concerning maintenance that would be applicable under the
447 specific license (such as leak testing procedures); and**
- 448 (iv) **Reports the transfer under 3.6.4.3(8)(b).**
- 449 (9) Shall transfer the device to another general licensee only:
- 450 (a) Where the device remains in use at a particular location.
- 451 In such case the transferor shall give the transferee a copy of this
452 regulation and any safety documents identified in the label on the device
453 and within 30 days of the transfer, report to the Department the
454 manufacturer's (or initial transferor's) name and model number and serial
455 number of device transferred, the identity of the radionuclide(s) present
456 and assayed or calculated activity present, the transferee's name and
457 mailing address for the location of use, and the name title, and phone
458 number of the responsible individual identified by the transferee in

Comment [JJ20]:

This is not a new provision and there are no changes to the requirements. This provision has been in place for a number of years through incorporation by reference to the federal rule.

For ease of use and in lieu of cross-reference to the federal rule (e.g., incorporation by reference), the full language of 10 CFR 31.5(c)(8)(iii) is added into the Part 3 rule.

SSRCR Cross Reference

= C.22d.iii(8)(c) [2010]

NRC Cross Reference = 10 CFR 31.5(c)(8)(iii)

NRC Compatibility = C

- 459 accordance with 3.6.4.3(12) to have knowledge of and authority to take
460 actions to ensure compliance with the appropriate regulations and
461 requirements; or
- 462 (b) Where the device is held in storage by an intermediate person in the
463 original shipping container at its intended location of use prior to initial
464 use by a general licensee; and
- 465 (10) Shall comply with the provisions of 4.51 and 4.52 for reporting radiation incidents,
466 theft, or loss of licensed material, but shall be exempt from the other
467 requirements of Parts 4 and 10;
- 468 (11) Shall respond to written requests from the Department to provide information
469 relating to the general license within 30 calendar days of the date of the request,
470 or other time specified in the request.
- 471 (a) If the general licensee cannot provide the requested information within
472 the allotted time, it shall, within that same time period, request a longer
473 period to supply the information by providing the director of the
474 Hazardous Materials and Waste Management Division a written
475 justification for the request;
- 476 (12) Shall appoint an individual responsible for having knowledge of the appropriate
477 regulations and requirements and the authority for taking required actions to
478 comply with appropriate regulations and requirements.
- 479 (a) The general licensee, through this individual, shall ensure the day-to-day
480 compliance with appropriate regulations and requirements; this
481 appointment does not relieve the general licensee of any of its
482 responsibility in this regard;
- 483 (13) Shall register each device annually in accordance with 3.6.4.3(13)(a) and
484 3.6.4.3(13)(b), and shall pay the fee required by Part 12, if in possession of a
485 device containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of
486 strontium-90, 37 MBq (1 mCi) of cobalt-60, 3.7 MBq (0.1 mCi) of radium-226, or
487 37 MBq (1 mCi) of americium 241 or any other transuranic (i.e., element with
488 atomic number greater than uranium (92)), based on the activity indicated on the
489 label. Each address for a location of use, as described in 3.6.4.3(13)(b)(iv) of this
490 section, represents a separate general licensee and requires a separate
491 registration and fee.
- 492 (a) Registration must be done by verifying, correcting, and/or adding to the
493 information provided in a request for registration received from the
494 Department.
- 495 (i) The registration information must be submitted to the
496 Department within 30 days of the date of the request for
497 registration or as otherwise indicated in the request.
- 498 (b) In registering devices, the general licensee shall furnish the following
499 information and any other information specifically requested by the
500 Department:
- 501 (i) Name and mailing address of the general licensee;
- 502 (ii) Information about each device: the manufacturer (or initial
503 transferor), model number, serial number, the radioisotope and
504 activity (as indicated on the label);

- 505 (iii) Name, title, and telephone number of the responsible person
506 designated as a representative of the general licensee under
507 3.6.4.3(12);
- 508 (iv) Address or location at which the device(s) are used and/or
509 stored; for portable devices, the address of the primary place of
510 storage;
- 511 (v) Certification by the responsible representative of the general
512 licensee that the information concerning the device(s) has been
513 verified through a physical inventory and checking of label
514 information; and
- 515 (vi) Certification by the responsible representative of the general
516 licensee that they are aware of the requirements of the general
517 license.
- 518 (c) A general licensee holding devices meeting the criteria of 3.6.4.3(13) is
519 subject to the bankruptcy notification requirement in 3.15.5.
- 520 (d) Persons generally licensed by an Agreement State with respect to
521 devices meeting the criteria in paragraph 3.6.4.3(13) are not subject to
522 U.S. Nuclear Regulatory Commission registration requirements if the
523 devices are used in areas subject to NRC jurisdiction for a period less
524 than 180 days in any calendar year. The Commission will not request
525 registration information from such licensees.
- 526 (14) Shall report changes to the mailing address for the location of use (including
527 change in name of general licensee) to the director of the hazardous materials
528 and waste management division within 30 days of the effective date of the
529 change.
- 530 (a) For a portable device, a report of address change is only required for a
531 change in the device's primary place of storage.
- 532 (15) May not hold a device that is not in use for longer than 2 years.
- 533 (a) If a device with shutters is not being used, the shutter must be locked in
534 the closed position.
- 535 (b) The testing required by 3.6.4.3(2) need not be performed during the
536 period of storage only.
- 537 (c) However, when a device is put back into service or transferred to another
538 person, and has not been tested within the required test interval, the
539 device must be tested for leakage before use or transfer and the shutter
540 tested before use.
- 541 (d) A device kept in standby for future use is excluded from the two-year
542 time limit if the general licensee performs quarterly physical inventories
543 of the device while the device is in standby.
- 544 3.6.4.4 The general license in 3.6.4.1 does not authorize the manufacture of devices containing
545 radioactive material.
- 546 3.6.4.5 The general license provided in 3.6.4.1 is subject to the provisions of 1.4 through 1.9,
547 3.15, 3.22, 3.23 and Part 17.
- 548 3.6.5 Luminous Safety Devices for Aircraft.

- 549 3.6.5.1 A general license is hereby issued to receive, acquire, possess, and use tritium or
550 promethium-147 contained in luminous safety devices for use in aircraft, provided:
- 551 (1) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300
552 mCi) of promethium-147; and
- 553 (2) Each device has been manufactured, assembled or imported in accordance with
554 a specific license issued by NRC or each device has been manufactured or
555 assembled in accordance with the specifications contained in a specific license
556 issued by the Department or any Agreement State to the manufacturer or
557 assembler of such device pursuant to licensing requirements equivalent to those
558 in Section 32.53 of 10 CFR Part 32 (January 1, 2013~~15~~).
- 559 3.6.5.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to
560 the general license in 3.6.5.1 are exempt from the requirements of Parts 4 and 10 except
561 that they shall comply with the provisions of 4.51 and 4.52.
- 562 3.6.5.3 This general license does not authorize the manufacture, assembly, or repair of luminous
563 safety devices containing tritium or promethium-147.
- 564 3.6.5.4 This general license does not authorize the ownership, receipt, acquisition, possession or
565 use of promethium-147 contained in instrument dials.
- 566 3.6.5.5 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22, 3.23, and
567 Part 17.
- 568 3.6.6 Ownership of Radioactive Material.
- 569 3.6.6.1 A general license is hereby issued to own radioactive material without regard to quantity.
- 570 3.6.6.2 Notwithstanding any other provisions of this part, this general license does not authorize
571 the manufacture, production, transfer, receipt, possession or use of radioactive material.
- 572 3.6.7 Calibration and Reference Sources.
- 573 3.6.7.1 A general license is hereby issued to those persons listed below to own, receive, acquire,
574 possess, use, and transfer, in accordance with the provisions of 3.6.7.4 and 3.6.7.5,
575 americium-241 in the form of calibration or reference sources:
- 576 (1) Any person who holds a specific license issued by the Department which
577 authorizes him to receive, possess, use, and transfer radioactive material; and
- 578 (2) Any person who holds a specific license issued by NRC which authorizes him to
579 receive, possess, use, and transfer special nuclear material.
- 580 3.6.7.2 A general license is hereby issued to receive, possess, use, and transfer plutonium in the
581 form of calibration or reference sources in accordance with the provisions of 3.6.7.4 and
582 3.6.7.5 to any person who holds a specific license issued by the Department which
583 authorizes him to receive, possess, use, and transfer radioactive material.
- 584 3.6.7.3 A general license is hereby issued to own, receive, possess, use, and transfer radium
585 226 in the form of calibration or reference sources in accordance with the provisions of
586 3.6.7.4 and 3.6.7.5 to any person who holds a specific license issued by the Department
587 which authorizes him to receive, possess, use, and transfer radioactive material.
- 588 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
589 sources which have been manufactured in accordance with the specifications contained
590 in a specific license issued to the manufacturer or importer of the sources by NRC
591 pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70
592 (January 1, 2013~~15~~) or which have been manufactured in accordance with the

593 specifications contained in a specific license issued to the manufacturer by the
 594 Department or any Agreement State pursuant to licensing requirements equivalent to
 595 those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70
 596 (January 1, 20~~13~~15).

597 3.6.7.5 The general licenses provided in 3.6.7.1, 3.6.7.2, and 3.6.7.3 are subject to the
 598 provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and 3.24, and Parts 4 and 10. In addition,
 599 persons who own, receive, acquire, possess, use, or transfer one or more calibration or
 600 reference sources pursuant to these general licenses, shall:

601 (1) Not possess at any one time, at any one location of storage or use, more than
 602 185 kBq (5 μ Ci) of americium-241, 185 kBq (5 μ Ci) of plutonium, or 185 kBq
 603 (5 μ Ci) of radium-226 in such sources;

604 (2) Not receive, possess, use, or transfer such source unless the source, or the
 605 storage container, bears a label which includes one of the following statements,
 606 as appropriate, or a substantially similar statement which contains the
 607 information called for in one of the following statements, as appropriate:

608 (a) The receipt, possession, use and transfer of this source, Model ____,
 609 Serial No.__ are subject to a general license and the regulations of the
 610 U.S. Nuclear Regulatory Commission or an Agreement State. Do not
 611 remove this label.

612 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
 613 (AMERICIUM-241) (PLUTONIUM) (RADIUM-226). ⁵ DO NOT TOUCH
 614 RADIOACTIVE PORTION OF THIS SOURCE.

615 _____
 616 Name of manufacturer or importer

617 ⁵ Showing only the name of the appropriate material.

618 (3) Not transfer, abandon, or dispose of such source except by transfer to a person
 619 authorized by a license from the Department, NRC or an Agreement State to
 620 receive the source;

621 (4) Store such source, except when the source is being used, in a closed container
 622 adequately designed and constructed to contain americium-241, plutonium, or
 623 radium-226 which might otherwise escape during storage; and

624 (5) Not use such source for any purpose other than the calibration of radiation
 625 detectors or the standardization of other sources.

626 3.6.7.6 These general licenses do not authorize the manufacture of calibration or reference
 627 sources containing americium-241, plutonium or radium-226.

628 3.6.8 Reserved.

629 3.6.9 General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing.

630 ⁶
 631 ⁶ The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific
 632 diagnostic drugs in interstate commerce.

633 3.6.9.1 A general license is hereby issued to any physician, veterinarian, clinical laboratory or
 634 hospital to receive, acquire, possess, transfer or use, for any of the following stated tests,
 635 in accordance with the provisions of 3.6.9.2, 3.6.9.3, 3.6.9.4, 3.6.9.5, and 3.6.9.6, the
 636 following radioactive materials in prepackaged units for use in *in vitro* clinical or
 637 laboratory tests not involving internal or external administration of radioactive material, or
 638 the radiation therefrom, to human beings or animals:

- 639 (1) Carbon-14, in units not exceeding 370 kBq (10 μ Ci) each;
- 640 (2) Cobalt-57, in units not exceeding 370 kBq (10 μ Ci) each;
- 641 (3) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 μ Ci) each;
- 642 (4) Iodine-125, in units not exceeding 370 kBq (10 μ Ci) each;
- 643 (5) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85
644 kBq (0.05 μ Ci) of iodine-129 and 185 Bq (0.005 μ Ci) of americium-241 each;
- 645 (6) Iodine-131, in units not exceeding 370 kBq (10 μ Ci) each;
- 646 (7) Iron-59, in units not exceeding 740 kBq (20 μ Ci) each; or
- 647 (8) Selenium-75, in units not exceeding 370 kBq (10 μ Ci) each.
- 648 3.6.9.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant
649 to the general license established by 3.6.9.1 until the person has filed Department Form
650 R-27, "Certificate - *In Vitro* Testing with Radioactive Material Under General License",
651 with the Department and received from the Department a validated copy of Department
652 Form R-27 with certification number assigned. The physician, veterinarian, clinical
653 laboratory or hospital shall furnish on Department Form R-27 the following information
654 and such other information as may be required by that form:
- 655 (1) Name and address of the physician, veterinarian, clinical laboratory or hospital;
- 656 (2) The location of use; and
- 657 (3) A statement that the physician, veterinarian, clinical laboratory or hospital has
658 appropriate radiation measuring instruments to carry out *in vitro* clinical or
659 laboratory tests with radioactive material as authorized under the general license
660 in 3.6.9.1 and that such tests will be performed only by personnel competent in
661 the use of such instruments and in the handling of the radioactive material.
- 662 3.6.9.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the
663 general license established by 3.6.9.1 shall comply with the following requirements.
- 664 (1) The general licensee shall not possess at any one time, pursuant to the general
665 license in 3.6.9.1, at any one location of storage or use, a total amount of iodine
666 125, iodine 131, selenium 75, iron 59, and/or cobalt 57 in excess of 7.4 MBq (200
667 μ Ci).
- 668 (2) The general licensee shall store the radioactive material, until used, in the
669 original shipping container or in a container providing equivalent radiation
670 protection.
- 671 (3) The general licensee shall use the radioactive material only for the uses
672 authorized by 3.6.9.1.
- 673 (4) The general licensee shall not transfer the radioactive material to a person who is
674 not authorized to receive it pursuant to a license issued by the Department, NRC
675 or any Agreement State nor transfer the radioactive material in any manner other
676 than in the unopened, labeled shipping container as received from the supplier.
- 677 (5) The general licensee shall dispose of the Mock Iodine 125 reference or
678 calibration sources described in 3.6.9.1(5) as required by 4.33.
- 679 3.6.9.4 The general licensee shall not receive, acquire, possess, or use radioactive material
680 pursuant to 3.6.9.1:

681 (1) Except as prepackaged units which are labeled in accordance with the provisions
 682 of an applicable specific license issued pursuant to 3.12.8 or in accordance with
 683 the provisions of a specific license issued by NRC or any Agreement State which
 684 authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14,
 685 hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to
 686 persons generally licensed under 3.6.9 or its equivalent; and

687 (2) Unless one of the following statements, as appropriate, or a substantially similar
 688 statement which contains the information called for in one of the following
 689 statements, appears on a label affixed to each prepackaged unit or appears in a
 690 leaflet or brochure which accompanies the package:

691 (a) This radioactive material shall be received, acquired, possessed, and
 692 used only by physicians, veterinarians, clinical laboratories or hospitals
 693 and only for *in vitro* clinical or laboratory tests not involving internal or
 694 external administration of the material, or the radiation therefrom, to
 695 human beings or animals. Its receipt, acquisition, possession, use, and
 696 transfer are subject to the regulations and a general license of the U.S.
 697 Nuclear Regulatory Commission or an Agreement State.

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699 Name of manufacturer

700 3.6.9.5 The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive
 701 material under the general license of 3.6.9.1 shall report in writing to the Department, any
 702 changes in the information furnished by him in the "Certificate - *In Vitro* Testing with
 703 Radioactive Material Under General License", Department Form R-27. The report shall
 704 be furnished within 30 days after the effective date of such change.

705 3.6.9.6 Any person using radioactive material pursuant to the general license of 3.6.9.1 is
 706 exempt from the requirements of Part 4 and 10 with respect to radioactive material
 707 covered by that general license, except that such persons using the Mock Iodine-125
 708 described in 3.6.9.1(5) shall comply with the provisions of 4.33, 4.51 and 4.52.

709 3.6.10 Ice Detection Devices.

710 3.6.10.1 A general license is hereby issued to receive, acquire, possess, use, and transfer
 711 strontium-90 contained in ice detection devices, provided each device contains not more
 712 than 1.85 MBq (50 μ Ci) of strontium-90 and each device has been manufactured or
 713 imported in accordance with a specific license issued by NRC or each device has been
 714 manufactured in accordance with the specifications contained in a specific license issued
 715 by the Department or an Agreement State to the manufacturer of such device pursuant to
 716 licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 (January
 717 1, 2013~~15~~).

718 3.6.10.2 Persons who own, receive, acquire, possess, use, or transfer strontium-90
 719 contained in ice detection devices pursuant to the general license in 3.6.10.1:

720 (1) Shall, upon occurrence of visually observable damage, such as a bend or crack
 721 or discoloration from overheating to the device, discontinue use of the device
 722 until it has been inspected, tested for leakage and repaired by a person holding a
 723 specific license from NRC or an Agreement State to manufacture or service such
 724 devices; or shall dispose of the device pursuant to the provisions of 4.33;

725 (2) Shall assure that all labels affixed to the device at the time of receipt, and which
 726 bear a statement which prohibits removal of the labels, are maintained thereon;
 727 and

- 728 (3) Are exempt from the requirements of Parts 4 and 10 except that such persons
729 shall comply with the provisions of 4.33, 4.51, and 4.52.
- 730 3.6.10.3 This general license does not authorize the manufacture, assembly, disassembly
731 or repair of strontium-90 in ice detection devices.
- 732 3.6.10.4 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22,
733 3.23 and Part 17.

734 ADDITIONAL EXEMPTIONS

735 3.7 Reserved Carriers

736 **Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal**
737 **Service are exempt from the regulations in this Part and Parts 5, 7, 16, 19, and 22 and the**
738 **requirements for a license set forth in section 81 of the Atomic Energy Act to the extent**
739 **that they transport or store radioactive material in the regular course of carriage for**
740 **another or storage incident thereto.**

741 SPECIFIC LICENSES

742 3.8 Filing An Application for A Specific License.

- 743 3.8.1 Applications for specific licenses shall be filed on a form prescribed by the Department.
- 744 3.8.2 The Department may at any time after the filing of the original application, and before the
745 expiration of the license, require further statements in order to enable the Department to
746 determine whether the application should be granted or denied or whether a license should be
747 modified or revoked.
- 748 3.8.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act
749 for and on the applicant's or licensee's behalf.
- 750 3.8.4 An application for a license may include a request for a license authorizing one or more activities.
- 751 3.8.5 In the application, the applicant may incorporate by reference information contained in previous
752 applications, statements, or reports filed with the Department provided such references are clear
753 and specific.
- 754 3.8.6 Applications and documents submitted to the Department may be made available for public
755 inspection except that the Department may withhold any document or part thereof from public
756 inspection pursuant to 24-72-204, CRS.
- 757 3.8.7 Pre-licensing Construction
- 758 3.8.7.1 An application for a license, or to amend or renew an existing license, for (1) source
759 material milling, (2) commercial waste storage, treatment or disposal by incineration, (3)
760 transfer for disposal of wastes from treatment or incineration, (4) commercial waste
761 disposal by land burial or by underground injection, or the (5) conduct of any other activity
762 within the licensing authority of the Department which the Department determines will
763 significantly affect the radiological quality of the human environment, shall be filed with
764 the Department at least nine (9) months prior to the anticipated commencement of
765 construction of the plant or facility in which the activity will be conducted or in accordance
766 with the requirements of Part 18 if applicable, and shall be accompanied by the
767 environmental **reportassessment** required by 3.8.8, unless an exemption from the
768 requirement of furnishing such **a-reportassessment** has been obtained from the
769 Department.
- 770 3.8.7.2 No construction shall be commenced until the license has been issued.

Comment [JJ21]:

This exemption provision was inadvertently excluded from Colorado regulations sometime in the past, and is required for compatibility with federal rule. The federal rule language in 10 CFR 30.13 was updated in 2013 concurrent with the issuance of the new rule in 10 CFR Part 37. (Colorado's equivalent to 10 CFR 37 is Part 22 became effective July 15, 2015.)

SSRCR Cross-reference: C.2 [2010]
NRC RATS: 2013-1
NRC Cross-reference: 10 CFR 30.13
NRC Compatibility = B
NRC Correspondence dated 4/13/15

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3.8.7.3 For the purpose of 3.8.7 the terms **"construction" and "commencement of construction", are defined in Part 1, 1.2. means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site; this term does not include changes desirable for the temporary use of the land for public recreational uses, limited borings to determine site characteristics as necessary for environmental assessment of other pre-construction monitoring to establish background information related to the suitability of a site, or to the protection of environmental values.**

Comment [JJ22]:
Language is modified to defer to the proposed definitions for "construction" and "commencement of construction" in Part 1 which are consistent with the language of 10 CFR Part 150.31 (and other federal rule parts).

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3.8.8 Environmental Impact Assessment.

3.8.8.1 In the case of an application for a license, or to amend or renew an existing license, for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of any other activity which will affect the quality of the human environment by reason of exposure to radiation, before "commencement of construction", as defined in 3.8.7.3, of the plant or facility in or at which the activity will be conducted, or in case of a renewal of such a license, the applicant shall submit all information required under these regulations and such other material as the Department may deem necessary.

Comment [JJ23]: Wording is modified, consistent with the language used in the Colorado Radiation Control Act for the document(s) submitted by the applicant which pertains to environmental concerns. This section pertains to the assessment generated by the licensee/applicant.

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(1) Such information shall include the environmental **reportassessment** and other information required by 3.8.8.2 to be submitted to assist the Department in the evaluation of the short-term and long-range environmental impact of the project and activity so that the Department may weigh environmental, economic, technical, and other benefits against environmental costs, while considering available alternatives.

Comment [JJ24]: Wording is modified here and in later sections of draft part 3 consistent with the language used in the Colorado Radiation Control Act for the document(s) submitted by the applicant which pertaining to their environmental evaluation document(s).

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(2) In the event that an environmental **reportassessment** acceptable to the Department is on file with the Department in regard to the specific licensed activity authorized under an existing license, and upon request of the applicant to amend or renew an existing license or at the initiation of the Department, the Department may grant an exemption of the requirement to submit an additional environmental **report-assessment** or require such amendment of the existing environmental **report-assessment** as will demonstrate the environmental impact to result from the proposed activity.

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(3) The request for exemption shall provide the Department with such information as the Department requires of the applicant to demonstrate that no significant environmental impact will result from the licensed activity.

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3.8.8.2 An environmental **reportassessment** shall be required of the applicant and shall contain all information deemed necessary by the Department as required by the Act.

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(1) Upon receipt of the environmental **report-assessment** or any amendment thereto, and of any other documents required, the Department shall determine the necessity to transmit and, if appropriate, shall transmit the same for review and comment to Federal, State, and local agencies having expertise in and jurisdiction over the proposed project and activity.

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(2) Written comments and reports of reviewing agencies shall be considered by the Department in its decision-making review process on the license application request.

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(3) If an environmental impact statement (EIS) is required of a Federal agency pursuant to the National Environment Policy Act of 1969 (NEPA) and is provided by such Federal agency, it shall be used by the Department in its decision-making review process on the license application request.

820 (4) The Department shall consider applicable regulations of Federal, State, and local
821 regulatory agencies and permit requirements thereof.

822 3.8.9 **Except as provided in 3.8.9.3, 3.8.9.4, and 3.8.9.5, An** application for a specific license to use
823 radioactive material in the form of a sealed source or in a device that contains the sealed source
824 **shall** must either:

Comment [JJ25]:
The language of 3.8.9 and subsections is modified
and updated for consistency with 10 CFR 30.32(g).

NRC RATS = 2012-4
NRC Compatibility = C

825 3.8.9.1 Identify the source or device by manufacturer and model number as registered with the
826 NRC under 10 CFR 32.210 or with an Agreement State, or for a source or a device
827 containing radium-226 or accelerator produced radioactive material with an Agreement
828 State under provisions comparable to 10 CFR 32.210; or

829 3.8.9.2 Contain the information ~~contained~~**identified** in ~~10 CFR 32.210(e)~~**3.12.14.3**; or

830 3.8.9.3 For sources or devices ~~containing naturally occurring or accelerator produced radioactive~~
831 ~~material~~ manufactured ~~before prior to November 30, 2007~~ **October 23, 2012** that are not
832 registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which
833 the applicant is unable to provide all categories of information specified in ~~40 CFR~~
834 ~~32.210(e)~~**3.12.14.3**, the ~~applicant~~**application** must ~~provide~~**include**:

835 (1) All available information identified in ~~10 CFR 32.210(e)~~**3.12.14.3** concerning the
836 source, and, if applicable, the device; and

837 (2) Sufficient additional information to demonstrate that there is reasonable
838 assurance that the radiation safety properties of the source or device are
839 adequate to protect health and minimize danger to life and property. Such
840 information must include a description of the source or device, a description of
841 radiation safety features, the intended use and associated operating experience,
842 and the results of a recent leak test.

843 **3.8.9.4 For sealed sources and devices allowed to be distributed without registration of**
844 **safety information in accordance with 3.12.14.7(1), the applicant may supply only**
845 **the manufacturer, model number, and radionuclide and quantity.**

846 **3.8.9.5 If it is not feasible to identify each sealed source and device individually, the**
847 **applicant may propose constraints on the number and type of sealed sources and**
848 **devices to be used and the conditions under which they will be used, in lieu of**
849 **identifying each sealed source and device.**

850 3.8.10 An application from a medical facility, educational institution, or Federal facility to produce
851 Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees
852 in its consortium authorized for medical use under Part 7 of these regulations or equivalent
853 Agreement State requirements shall include:

854 3.8.10.1 A request for authorization for the production of PET radionuclides or evidence of
855 an existing license issued under this Part or Agreement State requirements for a PET
856 radionuclide production facility within its consortium from which it receives PET
857 radionuclides.

858 3.8.10.2 Evidence that the applicant is qualified to produce radioactive drugs for medical
859 use by meeting one of the criteria in 3.12.10.1(2).

860 3.8.10.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if
861 the applicant is a pharmacy, and documentation that each individual meets the
862 requirements of an authorized nuclear pharmacist as specified in 3.12.10.2(2).

863 3.8.10.4 Information identified in 3.12.10.1(3) on the PET drugs to be noncommercially
864 transferred to members of its consortium.

865 **3.9 General Requirements for the Issuance of Specific Licenses.**

866 A license application **for a specific license** will be approved if the Department determines that:

Comment [JJ26]: Language added for clarity.

867 3.9.1 The applicant is qualified by reason of training and experience to use the material in question for
868 the purpose requested in accordance with these regulations in such a manner as to minimize
869 danger to public health and safety or property;

870 3.9.2 The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger
871 to public health and safety or property and the applicant's facilities are permanently located in
872 Colorado;

873 3.9.3 The issuance of the license will not be inimical to the health and safety of the public;

874 ~~3.9.4~~ The applicant satisfies any applicable special requirements in ~~3.10, 3.11, or 3.12~~ **parts 3, 5, 7, 16,**
875 **19, and 22;** and

Comment [JJ27]:
Update language for consistency with 10 CFR
30.33(a)(4).

876 3.9.5 The applicant has established Department-approved financial assurance warranties in
877 accordance with the following requirements.

878 3.9.5.1 A signed executed original copy of each warranty required by this part shall be furnished
879 to and approved by the Department prior to the issuance of a new license, or any
880 amendment or renewal of an existing license.

881 **DECOMMISSIONING WARRANTY**

882 3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a
883 dollar amount determined by the agency as necessary to protect public health and safety,
884 to ensure corrective action during operation, to ensure decontamination and
885 decommissioning of a facility and disposal of radioactive materials in the event of
886 abandonment, default or inability of the licensee to meet the requirements of the Act,
887 these regulations, or the license.

888 3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

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

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

893 (a) Greater than 10^3 times the applicable quantity of Schedule 3B in
894 unsealed form. For a combination of isotopes if R divided by 10^3 is
895 greater than 1 (unity rule), where R is defined here as the sum of the
896 ratios of the quantity of each isotope to the applicable value in Schedule
897 3B.

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

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

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

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

908 (5) Radioactive waste disposal licensees;

- 909 (6) Source material milling licensees;
- 910 (7) Ore refineries; and
- 911 (8) Other persons with, or applicants for, a specific license as determined by the
912 agency.
- 913 3.9.5.4 Acceptable Financial Assurance Methods.
- 914 (1) Financial assurance warranties shall contain provisions which are acceptable to
915 the Department for:
- 916 (a) Defining the amount and term of the warranty;
- 917 (b) Providing written notification to the Department by the warrantor at least
918 ninety (90) days prior to cancellation, termination, or revocation of the
919 warranty; and
- 920 (c) Converting the warranty into cash upon forfeiture of the warranty, and
- 921 (2) Financial assurance warranties shall be in the form of a cash deposit,
922 prepayment of a trust, escrow account, government fund, certificate of deposit, or
923 deposit of government securities.
- 924 (a) Prepayment is the deposit prior to the start of operation into an account
925 segregated from licensee assets and outside the licensee's
926 administrative control of cash or liquid assets such that the amount of
927 funds would be sufficient to pay decommissioning costs; or
- 928 (3) Financial assurance warranties which involve a guarantee method to ensure that
929 costs will be paid should the licensee default shall be in a form as described
930 below:
- 931 (a) A bond issued by a fidelity or surety company consistent with the
932 provisions of Section 25-11-110(6)(b)(l), CRS;
- 933 (b) An irrevocable "letter of credit" or "line of credit" issued by a recognized
934 financial institution whose financial condition and commitment are
935 established to the satisfaction of the Department;
- 936 (c) For a decommissioning warranty, a guarantee of funds by the applicant,
937 licensee, or parent company which satisfies the requirements listed
938 below. However, this self-guarantee shall not apply to uranium or thorium
939 milling licensees.
- 940 (i) The Department may accept a parent company guarantee of
941 funds for decommissioning costs based upon a financial test of
942 the parent company and a written guarantee as contained in
943 Appendix 3F.
- 944 (ii) The Department may accept an applicant or licensee guarantee
945 of funds for decommissioning costs based upon a financial test
946 of the applicant or licensee and a written guarantee as contained
947 in Appendix 3G.
- 948 (iii) A guarantee by the applicant, licensee, or parent company may
949 not be used in combination with other financial methods to
950 satisfy the requirements of this section.

- 951 (iv) A guarantee by the applicant or licensee may not be used in any
952 situation where the applicant or licensee has a parent company
953 holding majority control of the voting stock of the company; or
- 954 (4) Financial assurance warranties which involve an external sinking fund shall be in
955 a form in which deposits are made at least annually, coupled with a surety
956 method or insurance, the value of which may decrease by the amount being
957 accumulated in the sinking fund.
- 958 (a) An external sinking fund is a fund established and maintained by setting
959 aside funds periodically in an account segregated from licensee assets
960 and outside the licensee's administrative control in which the total
961 amount of funds would be sufficient to pay decommissioning costs at the
962 time termination of operation is expected.
- 963 (b) An external sinking fund may be in the form of a trust, escrow account,
964 government fund, certificate of deposit, or deposit of government
965 securities; or
- 966 (5) Financial assurance warranties previously provided to any State, Federal and/or
967 local governing bodies concerning activities subject to license under these
968 regulations, where the amount, terms, and conditions of such financial assurance
969 warranties have been established to the satisfaction of the Department and in
970 accordance with the requirements of 3.9.5; or
- 971 (6) Except for the guarantee of funds noted in 3.9.5.4(3), combinations of the above
972 may be used to establish an acceptable financial assurance warranty.
- 973 (7) The term of the financial assurance warranty shall be open-ended or shall have
974 provisions for automatic renewal until termination of the license by the
975 Department, unless it can be demonstrated that another arrangement would
976 provide an equivalent level of assurance.
- 977 (8) The value of the financial assurance warranty must not be dependent upon the
978 success, profitability, or continued operation of the licensed business or
979 operation.
- 980 3.9.5.5 The amount of funds to be provided by such decommissioning warranties shall be based
981 on Department-approved cost estimates and shall
- 982 (1) Include the disposal of radioactive materials;
- 983 (2) Include decontamination and decommissioning of buildings, facilities and the site
984 to levels which would allow unrestricted use of these areas upon
985 decommissioning;
- 986 (3) Include the reclamation of tailings and/or waste disposal areas in accordance
987 with technical criteria delineated in Parts 3, 4 and/or 18, as appropriate;
- 988 (4) Take into account total costs that would be incurred if an independent contractor
989 were hired to dispose of radioactive materials and perform decontamination,
990 decommissioning, and reclamation work, including:
- 991 (a) The cost of removal and/or disposal of radioactive material, or a
992 radioactivity-inducing machine, which is or would be generated, stored,
993 processed or otherwise present at the facility or site; and
- 994 (b) The probable extent of contamination through the possession or use of
995 radioactive material, at or adjacent to the facility or site, and the probable
996 cost of removal of such contamination; and

997 (5) Include reasonable administrative costs, including indirect costs, incurred by the
 998 Department in conducting or overseeing the decontamination, decommissioning,
 999 and disposal activities, and to cover the Department's reasonable attorney costs
 1000 that may be incurred in successfully revoking, foreclosing, or realizing the
 1001 decommissioning warranties established by the licensee in accordance with Part
 1002 3.

1003 3.9.5.6 The licensee shall provide in writing to the Department, no later than June 30th of each
 1004 calendar year, an annual report demonstrating proof of the value of existing financial
 1005 warranties and any licensee-proposed changes to the financial assurance warranties,
 1006 including updated decommissioning funding plans, cost estimates, or the type of
 1007 warranty. The annual report shall describe any changes in operations, estimated costs, or
 1008 any other circumstances that may affect the amount of the required financial assurance
 1009 warranties, including any increased or decreased costs attributable to inflation.

1010 3.9.5.7 Each licensee's financial assurance warranties shall be subject to review annually by the
 1011 Department to assure the continued adequacy of each warranty. Public notice of the
 1012 submittal of the licensee's annual report shall be posted on the Department's web site
 1013 and published by the licensee in the local paper of general circulation. Any person may
 1014 submit written comments to the Department concerning the adequacy of any financial
 1015 assurance warranties. The act of submitting such comments does not provide a right to
 1016 administrative appeal concerning the financial assurance warranties.

1017 **3.9.5.8** The Department will determine if the licensee must adjust the amount of the warranty to
 1018 account for increases or decreases in cost estimates resulting from:

1019 (1) ~~i~~Inflation or deflation;

1020 (2) ~~e~~Changes in engineering plans,;

1021 (3) ~~a~~Activities performed,;

1022 (4) **Spills, leakage or migration of radioactive material producing additional**
 1023 **contamination in onsite subsurface material that must be remediated to meet**
 1024 **applicable remediation criteria;**

1025 (5) **Waste inventory increasing above the amount previously estimated;**

1026 (6) **Waste disposal costs increasing above the amount previously estimated;**

1027 (7) **Facility modifications;**

1028 (8) **Changes in authorized ~~quantities of radioactive material~~possession limits;-or**

1029 (9) **Actual remediation costs that exceed the previous cost estimate;**

1030 (10) **Onsite disposal; and**

1031 (11) ~~e~~Changes in any other conditions affecting disposal, decontamination, and
 1032 decommissioning costs.

1033 **3.9.5.9** **Regardless of whether reclamation (disposal, decontamination and**
 1034 **decommissioning) is phased through the life of the licensed operations or takes**
 1035 **place at the end of operations, an appropriate portion of surety liability must be**
 1036 **retained until final compliance with the reclamation plan is determined by the**
 1037 **Department.**

1038 **3.9.5.10** **The appropriate portion of surety liability retained until final compliance with the**
 1039 **reclamation plan is determined will be at least sufficient at all times to cover the**
 1040 **costs of decommissioning and reclamation of the areas that are expected to be**

Comment [JJ28]: Changes to this section necessary for compatibility with 10 CFR Part 40, Appendix A, Criterion 9 (e), and Criterion 9(f)(1) through (f)(11).

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part040/part040-appa.html>

NRC Compatibility = C
 NRC Ltr dated 11/19/14.

Comment [JJ29]: The original language has been relocated from original section 3.9.5.9 (below) and modified (at the request of NRC) for consistency with 10 CFR Part 40, Appendix A, Criterion 9(g).

NRC Ltr dated 11/19/14
 NRC Compatibility = C

Comment [JJ30]: Provision added at the request of NRC for consistency with 10 CFR Part 40, Appendix A, Criterion 9(h).

NRC Ltr dated 11/19/14
 NRC Compatibility = C

1041 **disturbed before the next license renewal. The term of the surety mechanism**
 1042 **must be open ended, unless it can be demonstrated that another arrangement**
 1043 **would provide an equivalent level of assurance. This assurance would be**
 1044 **provided with a surety instrument which is written for a specified time (e.g., 5**
 1045 **years) and which must be automatically renewed unless the surety notifies the**
 1046 **beneficiary (the NRC or the Department) and the principal (the licensee) with**
 1047 **reasonable time (e.g., 90 days) before the renewal date of their intention not to**
 1048 **renew. In such a situation the surety requirement still exists and the licensee**
 1049 **would be required to submit an acceptable replacement surety within a brief time**
 1050 **to allow at least 60 days for the regulatory agency to collect.**

1051 **3.9.5.11 Proof of forfeiture must not be necessary to collect the surety. In the event the**
 1052 **licensee can not provide an acceptable replacement surety within the required**
 1053 **time, the surety shall be automatically collected before its expiration. The surety**
 1054 **instrument must provide for collection of the full face amount immediately on**
 1055 **demand without reduction for any reason, except for trustee fees and expenses**
 1056 **provided for in a trust agreement, and that the surety will not refuse to make full**
 1057 **payment. The conditions described previously would have to be clearly stated on**
 1058 **any surety instrument which is not open ended, and must be agreed to by all**
 1059 **parties. Financial surety arrangements generally acceptable to the Department**
 1060 **are:**

1061 **(1) Trust funds;**

1062 **(2) Surety bonds;**

1063 **(3) Irrevocable letters of credit; and**

1064 **(4) Combinations of the financial surety arrangements or other types of**
 1065 **arrangements as may be approved by the Department. If a trust is not used,**
 1066 **then a standby trust must be set up to receive funds in the event the NRC or**
 1067 **Department exercises its right to collect the surety. The surety arrangement**
 1068 **and the surety or trustee, as applicable, must be acceptable to the Department.**
 1069 **Self insurance, or any arrangement which essentially constitutes self**
 1070 **insurance (e.g., a contract with a State or Federal agency), will not satisfy the**
 1071 **surety requirement because this provides no additional assurance other than**
 1072 **that which already exists through license requirements.**

1073 **3.9.5.12(1)** — With the approval of the Department, a licensee may reduce the amount of a
 1074 decommissioning warranty as decommissioning activities are completed in accordance
 1075 with an approved decommissioning plan and/or to reflect current site conditions and
 1076 license authorizations.

1077 **3.9.5.13(2)** — The licensee shall have sixty days after the date of written notification by the
 1078 Department of a required adjustment to establish a warranty fulfilling all new
 1079 requirements unless granted an extension by the Department. If the licensee disputes the
 1080 amount of the required financial assurance warranties, the licensee may request a
 1081 hearing to be conducted in accordance with section 24-4-105, CRS.

1082 **3.9.5.14(3)** — If the licensee requests a hearing, no new ~~classified material, as that term is~~
 1083 ~~defined in 1.2.2, ore or other radioactive material~~ may be brought on site **for**
 1084 **processing or disposal** and no ~~classified new radioactive~~ material may be processed
 1085 until the licensee's dispute over the financial assurance warranty is resolved, unless the
 1086 licensee posts a bond in a form approved by the Department equal to the amount in
 1087 dispute.

1088 ~~3.9.5.9~~ ~~Regardless of whether the disposal, decontamination and decommissioning work is~~
 1089 ~~phased through the life of the licensed operations or takes place at the end of the~~
 1090 ~~operation, an appropriate and adequate decommissioning warranty shall be maintained~~

Comment [JJ31]: Provision added at the request of NRC for consistency with 10 CFR Part 40, Appendix A, Criterion 9(i).

NRC Ltr dated 11/19/14
NRC Compatibility = C

Comment [JJ32]: Language is modified here for consistency with 2015 statutory (Radiation Control Act) changes via House Bill 15-1145.

RCA: 25-11-110(5)(e)

Comment [JJ33]: The original language has been modified and relocated (above) to (new) 3.9.5.9 for consistency and alignment with 10 CFR Part 40, Criterion 9.

1091 ~~in good standing by the licensee until termination of the license or as otherwise~~
 1092 ~~authorized by the Department.~~

1093 **LONG-TERM CARE WARRANTY**

Comment [JJ34]:
Header added for clarity.

1094 3.9.5.1~~05~~ In addition to the decommissioning warranty required by 3.9.5.2, the Department
 1095 may require any licensee to provide a long-term care warranty if the licensed facility will
 1096 remain a disposal site for radioactive materials subsequent to the termination of the
 1097 license, or the license will be terminated using criteria in 4.61.3 or 4.61.4.

1098 (1) Except as provided in 3.9.5.1~~59~~(2), the following specific licensees are required
 1099 to provide long-term care warranties:

1100 (a) Radioactive waste disposal licensees;

1101 (b) Commercial radioactive waste handling and/or packaging licensees;

1102 (c) Source material milling licensees; and

1103 (d) Formerly U.S. Atomic Energy Commission or U.S. Nuclear Regulatory
 1104 Commission-licensed facilities;

1105 (2) A long-term care warranty is not required for a licensee identified in 3.9.5.1~~59~~(1)
 1106 if the disposition of radioactive materials by the licensee is made in such a
 1107 manner as the Department determines does not require long-term monitoring
 1108 and maintenance of the site.

1109 (3) The long-term care warranty shall be in a form as described in 3.9.5.4.

1110 (4) The amount of funds to be provided by such long-term care warranties shall be
 1111 based on Department-approved cost estimates and ~~shall~~**must** be enough that
 1112 with an assumed ~~six~~**one** percent annual real interest rate, the annual interest
 1113 earnings will be sufficient to cover the annual costs of site surveillance, including
 1114 reasonable administrative costs incurred, in perpetuity, subsequent to the
 1115 termination of the license.

Comment [JJ35]: Consistent with statutory changes (Radiation Control Act 2015 via House Bill 15-1145) and 10 CFR Part 40, Appendix A, Criterion 10, the assumed interest rate is adjusted to one percent. The adjusted assumed interest rate will help ensure that adequate funds are available for long-term care activities once a site is closed and decommissioned.

1116 (a) For each source material mill licensee, the long-term care warranty must
 1117 have a minimum value equivalent to \$250,000 in 1978 dollars.

NRC Compatibility = C
 NRC Letter dated 11/19/14
 RCA: 25-11-110(4)(d)

1118 (i) The value of the long-term care warranty shall be adjusted
 1119 annually to recognize inflation.

1120 (ii) The inflation rate to be used for this adjustment is that indicated
 1121 by the change in the consumer price index published by the U.S.
 1122 Department of Labor, Bureau of Labor Statistics.

1123 (iii) The Department may use other indicators of the inflation rate if
 1124 reasonable; provided, however, that the license shall not
 1125 terminate unless the amount of the long-term care warranty is
 1126 acceptable to the licensing agency and site caretaker.

1127 (b) Cost estimates for facilities and sites requiring long-term care
 1128 subsequent to license termination are to be based on the final disposition
 1129 of wastes such that ongoing active maintenance is not necessary to
 1130 preserve isolation.

1131 (i) It is expected that, as a minimum, annual site inspections shall
 1132 be conducted to confirm the integrity of the stabilized waste
 1133 systems and to determine the need, if any, for maintenance
 1134 and/or monitoring.

- 1135 (ii) Cost estimates shall be adjusted if more frequent site inspections
1136 are required based on an evaluation of a particular site.
- 1137 (c) For sites decommissioned in accordance with the provisions of 4.61.3 or
1138 4.61.4, cost estimates for long-term care subsequent to license
1139 termination must be sufficient to enable the Department, a responsible
1140 government agency, or an independent third party to:
- 1141 (i) Perform periodic site inspections no less frequently than each
1142 five years;
- 1143 (ii) Assure the continuation of institutional controls; and
- 1144 (iii) Assume responsibilities and carry out any necessary control and
1145 maintenance of the site. Cost estimates shall be adjusted if more
1146 frequent site inspections are required based on an evaluation of
1147 a particular site and the institutional controls established for that
1148 site.
- 1149 (5) Whenever the Department determines that a licensee's disposal,
1150 decommissioning and decontamination requirements have been satisfied,
1151 provisions shall be made for transferring custody of the site and the long-term
1152 care warranty funds for that license in accordance with the act.
- 1153 (a) If the value of the long-term care warranty funds exceeds the amount
1154 required by the government agency overseeing the long-term care of the
1155 site, then all such excess amounts shall be returned to the licensee.

1156 3.9.6 Decommissioning Funding Plan Required.

- 1157 3.9.6.1 Each applicant for and holder of a license authorizing the possession and use unsealed
1158 radioactive materials with half-life greater than 120 days and in quantities greater than 10^5
1159 times the applicable quantity of Schedule 3B, shall establish a Department-approved
1160 decommissioning funding plan to assure the availability of funds for decommissioning
1161 activities conducted over the life of the licensed facility. 370 Bq (0.01 μ Ci) shall be used
1162 as the Schedule 3B value for any alpha emitting radionuclide not listed in Schedule 3B, or
1163 mixtures of alpha emitters of unknown composition. A decommissioning funding plan is
1164 also required for licensees authorized a combination of isotopes if R divided by 10^5 is
1165 greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).
- 1166 3.9.6.2 Each holder of, or applicant for, any specific license authorizing the possession and use
1167 of sealed sources or plated foils of half-life greater than 120 days and in quantities
1168 greater than 10^{12} times the applicable quantity in Schedule 3B shall establish a
1169 Department-approved decommissioning funding plan to assure the availability of funds
1170 for decommissioning activities conducted over the life of the licensed facility. 370 Bq
1171 (0.01 μ Ci) shall be used as the Schedule 3B value for any alpha emitting radionuclide not
1172 listed in Schedule 3B, or mixtures of alpha emitters of unknown composition. The
1173 decommissioning funding plan is also required for licensees authorized for a combination
1174 of isotopes if R divided by 10^{12} is greater than 1 (unity rule), where R is defined as in
1175 3.9.5.3(2)(a).
- 1176 3.9.6.3 Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish
1177 an agency-approved decommissioning funding plan to assure the availability of funds for
1178 decommissioning activities conducted over the life of the licensed facility.
- 1179 (1) The decommissioning funding plan must include the cost of disposal of the
1180 maximum radioactivity (becquerel or curie) of radioactive material permitted by
1181 the license, and the cost of disposal of the maximum quantity, by volume, of
1182 radioactive material that could be present at the licensee's facility at any time, in

1183 addition to the cost to remediate the licensee's site to meet the license
1184 termination criteria of Part 4.

1185 3.9.6.4 Each decommissioning funding plan must be submitted for review and approval by the
1186 Department and must contain:

- 1187 (1) A detailed cost estimate for decommissioning, in an amount reflecting:
- 1188 (a) The cost of an independent contractor to perform all decommissioning
1189 activities;
 - 1190 (b) The cost of meeting the 4.61.2 criteria for unrestricted use, provided that,
1191 if the applicant or licensee can demonstrate its ability to meet the
1192 provisions of 4.61.3 for restricted use, the cost estimate may be based
1193 on meeting the 4.61.3 restricted use criteria;
 - 1194 (c) The volume of onsite subsurface material containing residual
1195 radioactivity that will require remediation to meet the criteria for license
1196 termination; and
 - 1197 (d) An adequate contingency factor.
 - 1198 (i) Identification of and justification for using the key assumptions
1199 contained in the detailed cost estimate;
 - 1200 (ii) A description of the method of assuring funds for
1201 decommissioning as required in this section, including means for
1202 adjusting cost estimates and associated funding levels
1203 periodically over the life of the facility.
 - 1204 (iii) A certification by the licensee that financial assurance for
1205 decommissioning has been provided in the amount of the cost
1206 estimate for decommissioning; and
 - 1207 (iv) A signed original, or if permitted, a copy, of the financial
1208 instrument obtained to satisfy the requirements of this section
1209 (unless a previously submitted and accepted financial instrument
1210 continues to cover the cost estimate for decommissioning).

1211 3.9.6.5 At the time of license renewal and at intervals not to exceed three years, the
1212 decommissioning funding plan must be resubmitted with adjustments as necessary to
1213 account for changes in costs and the extent of contamination. If the amount of financial
1214 assurance will be adjusted downward, this can not be done until the updated
1215 decommissioning funding plan is approved. The decommissioning funding plan must
1216 update the information submitted with the original or prior approved plan, and must
1217 specifically consider the effect of the following events on decommissioning costs:

- 1218 (1) Spills of radioactive material producing additional residual radioactivity in onsite
1219 subsurface material;
- 1220 (2) Waste inventory increasing above the amount previously estimated;
- 1221 (3) Waste disposal costs increasing above the amount previously estimated;
- 1222 (4) Facility modifications;
- 1223 (5) Changes in authorized possession limits;
- 1224 (6) Actual remediation costs that exceed the previous cost estimate;

- 1225 (7) Onsite disposal; and
- 1226 (8) Use of a settling pond.
- 1227 3.9.6.6 The decommissioning funding plan must also include a certification by the licensee that
1228 funding for decommissioning activities has been provided for in the amount of the cost
1229 estimate for decommissioning.
- 1230 (1) For an applicant, this certification may state that the appropriate assurance will
1231 be obtained after the application has been approved and the license issued, but
1232 prior to the receipt or possession of radioactive material.
- 1233 (2) A signed original of the financial instrument shall be submitted to the Department.
- 1234 **3.9.7** In the case of an application for a license for (1) source material milling, (2) commercial waste
1235 storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration,
1236 (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of
1237 any other activity which the Department determines will significantly affect the quality of the
1238 human environment, the Department, **before commencement of construction, on the basis of**
1239 **information filed and evaluations made**, has concluded, **after weighing the environmental,**
1240 **economic, technical and other benefits against environmental costs and considering**
1241 **available alternatives**, that the action called for is the issuance of the proposed license with any
1242 appropriate conditions to protect environmental values.
- 1243 3.9.7.1 ~~Such determination shall be made before c~~Commencement of construction **prior to this**
1244 **conclusion is grounds for denial of a license to possess and use source and**
1245 **byproduct material of** in the plant or facility. ~~in which the activity will be conducted and~~
1246 ~~based on information filed and evaluation made pursuant to 3.8.8.~~
- 1247 3.9.8 Commencement of construction prior to the issuance of a license, or of an amendment or renewal
1248 thereof, or of an exemption under the requirements of 3.8.7, may be grounds for denial of such
1249 license, amendment or renewal. ~~;~~ ~~and~~
- 1250 3.9.9 Reserved.
- 1251 3.9.10 License Hearings.
- 1252 3.9.10.1 There shall be an opportunity for public hearings to be held in the following
1253 circumstances in accordance with the procedures in 24-4-104 and -105, CRS. and this
1254 paragraph:
- 1255 (1) Prior to the licensing or leasing of state-owned property for the concentration,
1256 storage or permanent disposal of radioactive materials.
- 1257 (2) For each proposed license, five-year license renewal, or license amendment
1258 pertaining to a uranium recovery facility's receipt of **classified** material as
1259 specified in Part 18 of these regulations.
- 1260 3.9.11 Contingency Plans
- 1261 3.9.11.1 Each application to possess radioactive materials in unsealed form, on foils or
1262 plated sources, or sealed in glass in excess of the quantities in Schedule 3E - "Quantities
1263 of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for
1264 Responding to a Release", must contain either:
- 1265 (1) An evaluation, as described in 3.9.11.2, showing that the projected dose to a
1266 person offsite due to a release of radioactive materials would not exceed 0.01 Sv
1267 (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- 1268 (2) A contingency plan for responding to a release of radioactive material.

Comment [jsj36]: Language in 3.9.7, and 3.9.7.1 is added/modified consistent with 10 CFR Part 40.32(e).

The current language of 3.9.7 is based upon the format and language in SSR CR Part C (2010) which pre-dates the revision to 40.32(e).

NRC Compatibility = H&S

- 1269 3.9.11.2 In evaluating the total effective dose equivalent to an individual pursuant to
1270 3.9.11.1(1):
- 1271 (1) The radioactive material is physically separated so that only a portion could be
1272 involved in an accident;
- 1273 (2) All or part of the radioactive material is not subject to release during an accident
1274 because of the way it is stored or packaged;
- 1275 (3) The release fraction in the respirable size range is predicted to be lower than the
1276 release fraction shown in Schedule 3E due to the chemical or physical form of
1277 the material;
- 1278 (4) The solubility of the radioactive material would reduce the dose received;
- 1279 (5) Facility design or engineered safety features in the facility would cause the
1280 release fraction to be lower than shown in Schedule 3E.
- 1281 (6) Operating restrictions or procedures would prevent a release fraction as large as
1282 that shown in Schedule 3E.
- 1283 3.9.11.3 A contingency plan for responding to a release of radioactive material submitted
1284 under 3.9.11.1(2) must include the following information, in separate sections having
1285 each page numbered and labeled with a revision date and revision number:
- 1286 (1) Facility description - a brief description of the licensee's facility and surroundings.
- 1287 (2) Types of accidents - a n identification of each type of accident involving
1288 radioactive material for which actions by licensee staff or offsite response
1289 organizations will be needed to protect members of the public.
- 1290 (3) Classification of accidents - a method for classifying and declaring each alert or
1291 site area emergency, as defined in Part 1.
- 1292 (4) Detection of accidents - identification of the means of detecting each type of
1293 accident in a timely manner.
- 1294 (5) Mitigation of consequences - a brief description of the means and equipment for
1295 mitigating the consequences of each type of accident, including those provided to
1296 protect workers onsite, and a description of the program for maintaining the
1297 equipment.
- 1298 (6) Assessment of releases - a brief description of the methods and equipment to
1299 assess releases of radioactive materials.
- 1300 (7) Responsibilities - a brief description of the responsibilities of licensee personnel
1301 should an accident occur, including identification of personnel responsible for
1302 promptly notifying offsite response organizations and the Department; also
1303 responsibilities for developing, maintaining, and updating the plan.
- 1304 (8) Notification and coordination.
- 1305 (a) A commitment to and a brief description of the means to promptly notify
1306 offsite response organizations and request offsite assistance, including
1307 medical assistance for the treatment of contaminated injured onsite
1308 workers when appropriate.
- 1309 (b) A control point must be established.

- 1310 (c) The notification and coordination must be planned so that unavailability
1311 of some personnel, parts of the facility, and some equipment will not
1312 prevent the notification and coordination.
- 1313 (d) The licensee shall also commit to notify the Department immediately
1314 after notification of the appropriate offsite response organizations and not
1315 later than one hour after the licensee declares an emergency.
- 1316 (9) Information to be communicated - a brief description of the types of information
1317 on facility status, radioactive releases, and recommended protective actions, if
1318 necessary, to be given to offsite response organizations and to the Department.
- 1319 (10) Training.
- 1320 (a) A brief description of the frequency, performance objectives and plans
1321 for the training that the licensee will provide workers on how to respond
1322 to an emergency including any special instructions and orientation tours
1323 the licensee would offer to fire, police, medical and other emergency
1324 personnel.
- 1325 (b) The training shall familiarize personnel with site-specific emergency
1326 procedures.
- 1327 (c) Also, the training shall thoroughly prepare site personnel for their
1328 responsibilities in the event of accident scenarios postulated as most
1329 probable for the specific site, including the use of team training for such
1330 scenarios.
- 1331 (11) Safe shutdown - a brief description of the means of restoring the facility to a safe
1332 condition after an accident.
- 1333 (12) Exercises.
- 1334 (a) Provisions for conducting quarterly communications checks with offsite
1335 response organizations and biennial onsite exercises to test response to
1336 simulated emergencies.
- 1337 (b) Quarterly communications checks with offsite response organizations
1338 must include the check and update of all necessary telephone numbers.
- 1339 (c) The licensee shall invite offsite response organizations to participate in
1340 the biennial exercises.
- 1341 (d) Participation of offsite response organizations in biennial exercises
1342 although recommended is not required.
- 1343 (e) Exercises must use accident scenarios postulated as most probable for
1344 the specific site and the scenarios shall not be known to most exercise
1345 participants.
- 1346 (f) The licensee shall critique each exercise using individuals not having
1347 direct implementation responsibility for the plan.
- 1348 (g) Critiques of exercises must evaluate the appropriateness of the plan,
1349 emergency procedures, facilities, equipment, training of personnel, and
1350 overall effectiveness of the response.
- 1351 (h) Deficiencies found by the critiques must be corrected.

1352 (13) Hazardous chemicals - a certification that the applicant has met its
 1353 responsibilities under the Emergency Planning and Community Right-To-Know
 1354 Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at
 1355 the proposed place of use of the radioactive material.

1356 3.9.11.4 The licensee shall allow the offsite response organizations expected to respond
 1357 in case of an accident 60 days to comment on the licensee's emergency plan before
 1358 submitting it to the Department.

1359 (1) The licensee shall provide any comments received within 60 days to the
 1360 Department with the emergency plan.

1361

1362 **3.10 Additional Requirements for Issuance of Specific Licenses for Use of Unsealed**
 1363 **Radioactive Material.**

1364
 1365 3.10.1 In addition to the requirements set forth in 3.9, applicants for licenses authorizing the possession
 1366 and use of unsealed radioactive materials shall include in the application a description of the
 1367 facility and procedures for operation which

1368 3.10.1.1 Minimize to the extent practicable, contamination of the facility and environment;

1369 3.10.1.2 Facilitate eventual decommissioning; and

1370 3.10.1.3 Minimize, to the extent practicable, the generation of radioactive waste.

1371 3.10.2 Licensees shall, to the extent practical, conduct operations to minimize the introduction of
 1372 residual radioactivity into the site, including the subsurface, in accordance with the existing
 1373 radiation protection requirements in Part 4, Section 4.5 and radiological criteria for license
 1374 termination in Part 4, Section 4.61 of the regulations.

1375 **3.11 Special Requirements for Specific Licenses of Broad Scope.**

1376

1377 [* * * = Indicates omission of unaffected rule sections]

1378

1379 **3.12 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or**
 1380 **Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

1381 3.12.1 A licensee authorized to introduce radioactive material into a product or material owned by or in
 1382 the possession of the licensee or another to be transferred to persons exempt under 3.3.1.1 shall
 1383 meet the requirements of 10 CFR 32.11 and any other applicable NRC requirement.

1384 3.12.2 No person may introduce byproduct material into a product or material knowing or having reason
 1385 to believe that it will be transferred to persons exempted pursuant to 3.3.2, under 10 CFR 30.14
 1386 or equivalent regulations of an Agreement State, except in accordance with a license issued
 1387 under 10 CFR 32. ⁸

1388 ⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
 1389 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 1390 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 1391 20555.

1392 3.12.2.3 Each person licensed under 3.12.2 shall maintain records identifying, by name
 1393 and address, each person to whom radioactive material is transferred for use under
 1394 3.3.2, and stating the kinds and quantities of radioactive material transferred. An annual
 1395 summary report stating the total quantity of each radionuclide transferred under the

Comment [JJ37]: The language in brackets and subsequent "****" marks are not part of the final rule and will be deleted prior to final submission.

1396 specific license shall be filed with the Department. Each report shall cover the year
 1397 ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive
 1398 material have been made pursuant to 3.12.2 during the reporting period, the report shall
 1399 so indicate.

1400 3.12.3 RESERVED.

1401 3.12.4 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under
 1402 3.6.4.

1403 3.12.4.1 An application for a specific license to manufacture, or **initially transfer** distribute
 1404 devices containing radioactive material, excluding special nuclear material, to persons
 1405 generally licensed under 3.6.4 or equivalent regulations of NRC or an Agreement State
 1406 will be approved if:

Comment [JJ38]: Language updated consistent with 10 CFR 32.51(a).

1407 (1) The applicant satisfies the general requirements of 3.9;

1408 (2) The applicant submits sufficient information relating to the design, manufacture,
 1409 prototype testing, quality control, labels, proposed uses, installation, servicing,
 1410 leak testing, operating and safety instructions, and potential hazards of the
 1411 device to provide reasonable assurance that:

1412 (a) The device can be safely operated by persons not having training in
 1413 radiological protection;

1414 (b) Under ordinary conditions of handling, storage, and use of the device,
 1415 the radioactive material contained in the device will not be released or
 1416 inadvertently removed from the device, and it is unlikely that any person
 1417 will receive in any period of 1 calendar quarter a dose in excess of 10
 1418 percent of the limits specified in 4.6.1; and

1419 (c) Under accident conditions such as fire and explosion associated with
 1420 handling, storage, and use of the device, it is unlikely that any person
 1421 would receive an external radiation dose or dose commitment in excess
 1422 of the following organ doses:

1423 (i) Whole body; head and trunk; active blood-forming organs;
 1424 gonads; or lens of eye: 150 mSv (15 rem)

1425 (ii) Hands and forearms; feet and ankles; localized areas of skin
 1426 averaged over areas no larger than 1 square centimeter: 2 Sv
 1427 (200 rem)

1428 (iii) Other organs: 500 mSv (50 rem); and

1429 (3) Each device bears a durable, legible, clearly visible label or labels approved by
 1430 the Department, which contain in a clearly identified and separate statement:

1431 (a) Instructions and precautions necessary to assure safe installation,
 1432 operation, and servicing of the device; documents such as operating and
 1433 service manuals may be identified in the label and used to provide this
 1434 information;

1435 (b) The requirement, or lack of requirement, for leak testing, or for testing
 1436 any "on-off" mechanism and indicator, including the maximum time
 1437 interval for such testing, and the identification of radioactive material by
 1438 isotope, quantity of radioactivity, and date of determination of the
 1439 quantity; and

1440 (c) The information called for in one of the following statements, as
1441 appropriate, in the same or substantially similar form:

1442 (i) The receipt, possession, use, and transfer of this device, Model
1443 ____, Serial No. ____⁹, are subject to a general license or the
1444 equivalent and the regulations of the U.S. Nuclear Regulatory
1445 Commission or an Agreement State. This label shall be
1446 maintained on the device in a legible condition. Removal of this
1447 label is prohibited.

1448 CAUTION - RADIOACTIVE MATERIAL

1449 _____

1450 Name of manufacturer or distributor

1451 ⁹ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is
1452 elsewhere specified in labeling affixed to the device.

1453 (ii) The receipt, possession, use, and transfer of this device,
1454 Model ____, Serial No. ____¹⁰, are subject to a general license or
1455 the equivalent, and the radiation regulations. This label shall be
1456 maintained on the device in a legible condition. Removal of this
1457 label is prohibited.

1458 CAUTION - RADIOACTIVE MATERIAL

1459 _____

1460 Name of manufacturer or distributor

1461 ¹⁰ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is
1462 elsewhere specified in labeling affixed to the device.

1463 (4) Each device having a separable source housing that provides the primary
1464 shielding for the source also bears, on the source housing, a durable label
1465 containing the device model number and serial number, the isotope and quantity,
1466 the words, "Caution-Radioactive Material," the radiation symbol prescribed in
1467 4.27 and the name of the manufacturer or initial distributor.

1468 (5) **The device has been registered in the Sealed Source and Device Registry.**

1469 3.12.4.2 In the event the applicant desires that the device be required to be tested at
1470 intervals longer than 6 months, either for proper operation of the "on-off" mechanism and
1471 indicator, if any, or for leakage of radioactive material or for both, the applicant shall
1472 include in the application sufficient information to demonstrate that such longer interval is
1473 justified by performance characteristics of the device or similar devices and by design
1474 features which have a significant bearing on the probability or consequences of leakage
1475 of radioactive material from the device or failure of the "on-off" mechanism and indicator.

1476 3.12.4.3 In determining the acceptable interval for the test for leakage of radioactive
1477 material, the Department will consider information which includes, but is not limited to:

- 1478 (1) Primary containment or source capsule;
- 1479 (2) Protection of primary containment;
- 1480 (3) Method of sealing containment;
- 1481 (4) Containment construction materials;
- 1482 (5) Form of contained radioactive material;

Comment [JJ39]:
 Provision added consistent with 10 CFR 32.51(a)(6).

 The sealed source and device registry or SSD registry is a database maintained by the Nuclear Regulatory Commission to help ensure that all devices containing radioactive materials and sold in the U.S. have been evaluated for safety and use considerations. Refer to Part 1 of the Colorado regulations for a definition for sealed source and device registry.

 NRC Compatibility = B
 NRC RATS = 2012-4

- 1483 (6) Maximum temperature withstood during prototype tests;
- 1484 (7) Maximum pressure withstood during prototype tests;
- 1485 (8) Maximum quantity of contained radioactive material;
- 1486 (9) Radiotoxicity of contained radioactive material; and
- 1487 (10) Operating experience with identical devices or similarly designed and
1488 constructed devices.
- 1489 3.12.4.4 — In the event the applicant desires that the general licensee under 3.6.4, or under
1490 equivalent regulations of NRC or an Agreement State, be authorized to install the device,
1491 collect the sample to be analyzed by a specific licensee for leakage of radioactive
1492 material, service the device, test the "on-off" mechanism and indicator, or remove the
1493 device from installation, the applicant shall include in the application written instructions
1494 to be followed by the general licensee, estimated calendar quarter doses associated with
1495 such activity or activities, and bases for such estimates.
- 1496 (1) The submitted information shall demonstrate that performance of such activity or
1497 activities by an individual untrained in radiological protection, in addition to other
1498 handling, storage, and use of devices under the general license, is unlikely to
1499 cause that individual to receive a calendar quarter dose in excess of 10 percent
1500 of the limits specified in 4.6.1.
- 1501 3.12.4.5 — Each person licensed under 3.12.4 to distribute devices to generally licensed
1502 persons shall:
- 1503 (1) Before a device is transferred, furnish information specified in this paragraph to
1504 each person to whom a device is to be transferred, or in the case of a transfer
1505 through an intermediate person, to the intended user prior to initial transfer to the
1506 intermediate person, including:
- 1507 (a) A copy of the general license contained in 3.6.4 and a copy of the
1508 general license contained in the NRC or Agreement State regulation
1509 equivalent to 3.6.4;
- 1510 (b) A copy of sections 3.6 and 4.40 through 4.52;
- 1511 (c) A list of the services that can only be performed by a specific licensee;
- 1512 (d) Information on acceptable disposal options including estimated costs of
1513 disposal;
- 1514 (e) An indication that federal policy is to issue high civil penalties for
1515 improper disposal; and
- 1516 (f) The name or title, address, and phone number of the contact at the
1517 transferee's NRC or Agreement State location.
- 1518 (2) Report to the Department all transfers of such devices to persons for use under
1519 the general license in 3.6.4 and all receipts of such devices.
- 1520 (a) Such a report to the Department shall include:
- 1521 (i) The identity of each general licensee by name and mailing
1522 address for the location of use; if there is no mailing address for
1523 the location of use, an alternate address for the general licensee
1524 shall be submitted along with information on the actual location
1525 of use;

- 1526 (ii) The name, title, and phone number of the person identified by
 1527 the general licensee as having knowledge of and authority to
 1528 take required actions to ensure compliance with the appropriate
 1529 regulations and requirements;
- 1530 (iii) The date of transfer;
- 1531 (iv) The type, model number, and serial number of the device
 1532 transferred; and
- 1533 (v) The quantity and type of radioactive material contained in the
 1534 device.
- 1535 (b) If one or more intermediate persons will temporarily possess the device
 1536 at the intended place of use before its possession by the user, the report
 1537 must include the same information for both the intended user and each
 1538 intermediate person, and clearly designate the intermediate person(s).
- 1539 (c) For devices received from a 3.6.4 general licensee, the report must
 1540 include the identity of the general licensee by name and address, the
 1541 type, model number, and serial number of the device received, the date
 1542 of receipt, and, in the case of devices not initially transferred by the
 1543 reporting licensee, the name of the manufacturer or initial transferor.
- 1544 (d) If the licensee makes changes to a device possessed by a 3.6.4 general
 1545 licensee, such that the label must be changed to update required
 1546 information, the report must identify the general licensee, the device, and
 1547 the changes to information on the device label.
- 1548 (e) The report must cover each calendar quarter, must be filed within 30
 1549 days of the end of the calendar quarter, and must clearly indicate the
 1550 period covered by the report.
- 1551 (f) The report must clearly identify the specific licensee submitting the report
 1552 and include the license number of the specific licensee.
- 1553 (g) If no transfers have been made to or from persons generally licensed
 1554 under 3.6.4 during the reporting period, the report must so indicate.
- 1555 (3) Furnish clear and legible reports to other agencies, containing all of the data
 1556 required by Form 653, "Transfers of Industrial Devices Report", including:
- 1557 (a) Report the information specified in 3.12.4.5(2) to NRC for all transfers of
 1558 such devices to persons for use under NRC general license in Section
 1559 31.5 of 10 CFR Part 31 (January 1, 20~~15~~**15**).
- 1560 (b) Report the information specified in 3.12.4.5 (2) to the responsible State
 1561 agency for all transfers of devices manufactured and distributed pursuant
 1562 to 3.12.4 for use under a general license in that State's regulations
 1563 equivalent to 3.6.4.
- 1564 (4) Maintain all information concerning transfers and receipts of devices that
 1565 supports the reports required by this section for a period of 3 years following the
 1566 date of the recorded event.
- 1567 3.12.5 Special Requirements for the Manufacture, Assembly, ~~or~~ Repair **or Initial Transfer** of Luminous
 1568 Safety Devices for Use in Aircraft.

1569 3.12.5.1 An application for a specific license to manufacture, assemble, ~~or repair or~~
1570 **initially transfer** luminous safety devices containing tritium or promethium-147 for use in
1571 aircraft, for distribution to persons generally licensed under 3.6.5 will be approved if:

1572 (1) The applicant satisfies the general requirements specified in 3.9; and

1573 (2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, **and**
1574 32.56, ~~and 32.101~~ of 10 CFR Part 32 (January 1, 20**13**15), or their equivalent.

1575 (3) **The device has been registered in the Sealed Source and Device Registry.**

1576 3.12.6 Special Requirements for License to Manufacture **or initially transfer** Calibration Sources
1577 Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally
1578 Licensed Under 3.6.7.

1579 3.12.6.1 An application for a specific license to manufacture calibration and reference sources
1580 containing americium-241, plutonium or radium-226 to persons generally licensed
1581 under 3.6.7 will be approved if:

1582 (1) The applicant satisfies the general requirement of 3.9; and

1583 (2) The applicant satisfies the requirements of Sections 32.57, 32.58, **and 32.59,**
1584 ~~and 32.102~~ of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 (January 1,
1585 20**13**15) or their equivalent.

1586 3.12.7 Reserved.

1587 3.12.8 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory
1588 Testing Under General License.

1589 * * *

1590 3.12.9 Licensing the Manufacture **or initial transfer and Distribution** of Ice Detection Devices.

1591 3.12.9.1 An application for a specific license to manufacture and distribute ice detection
1592 devices to persons generally licensed under 3.6.10 will be approved if:

1593 (1) The applicant satisfies the general requirements of 3.9; and

1594 (2) The criteria of Sections 32.61, **and 32.62,** ~~and 32.103~~ of 10 CFR Part 32
1595 (January 1, 20**13**15) are met.

1596 (3) **The device has been registered in the Sealed Source and Device Registry.**

1597 3.12.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for
1598 Medical Use.

1599 * * *

1600 3.12.11 Reserved.

1601 3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical
1602 Use.

1603 3.12.12.1 An application for a specific license to manufacture and distribute sources and
1604 devices containing radioactive material to persons licensed pursuant to Part 7 for use as
1605 a calibration, transmission, or reference source or for the uses listed in 7.19, 7.40, 7.42,
1606 7.48 and 7.62 will be approved if:

1607 (1) The applicant satisfies the general requirements in 3.9 of this part;

Comment [JJ40]:
10 CFR 32.101 (pertaining to prototype testing criteria for luminous safety devices used in aircraft) was deleted from federal rule in 2012 and therefore the reference in Part 3 is deleted.

NRC Compatibility = B
RATS 2012-4

Comment [JJ41]:
Language is added consistent with federal rule in 10 CFR 32.53(f). Although the requirement is currently in place through reference to 32.53 in 3.12.5.1(2), the Radiation Program believes the added language will help clarify the requirements for the regulated community.

Colorado does not currently have any specific licensees who manufacture, assemble, repair or initially transfer luminous safety devices for use in aircraft.

NRC Cross-reference = 10 CFR Part 32.53(f)
NRC Compatibility = B

Comment [JJ42]:
10 CFR 32.102 (pertaining to prototype testing criteria for calibration/reference sources using Am241 or Ra226) was deleted from federal rule in 2012 and therefore the reference in Part 3 is deleted.

NRC Compatibility = B
RATS 2012-4

Comment [JJ43]:
10 CFR 32.103 (pertaining to prototype testing criteria for calibration/reference sources using Am241 or Ra226) was deleted from federal rule in 2012 and therefore the reference in Part 3 is deleted.

NRC Compatibility = B
RATS 2012-4

Comment [JJ44]:
Language is added consistent with federal rule in 10 CFR 32.61(f). Although the requirement is currently in place through reference to 32.61 in 3.12.9.1(2), the Radiation Program believes the added language will help clarify the requirements for the regulated community.

Colorado is not aware of any specific licensees who manufacture, or initially transfer ice detection devices within the state.

NRC Cross-reference = 10 CFR Part 32.61(f)
NRC Compatibility = B

- 1608 (2) The applicant submits sufficient information regarding each type of source or
1609 device pertinent to an evaluation of its radiation safety, including:
- 1610 (a) The radioactive material contained, its chemical and physical form, and
1611 amount,
- 1612 (b) Details of design and construction of the source or device,
- 1613 (c) Procedures for, and results of, prototype tests to demonstrate that the
1614 source or device will maintain its integrity under stresses likely to be
1615 encountered in normal use and accidents,
- 1616 (d) For devices containing radioactive material, the radiation profile of a
1617 prototype device,
- 1618 (e) Details of quality control procedures to assure that production sources
1619 and devices meet the standards of the design and prototype tests,
- 1620 (f) Procedures and standards for calibrating sources and devices,
- 1621 (g) Legend and methods for labeling sources and devices as to their
1622 radioactive content, and
- 1623 (h) Instructions for handling and storing the source or device from the
1624 radiation safety standpoint; these instructions are to be included on a
1625 durable label attached to the source or device or attached to a
1626 permanent storage container for the source or device; provided, that
1627 instructions which are too lengthy for such label may be summarized on
1628 the label and printed in detail on a brochure which is referenced on the
1629 label;
- 1630 (3) The label affixed to the source or device, or to the permanent storage container
1631 for the source or device, contains information on the radionuclide, quantity, and
1632 date of assay, and a statement that the source or device is licensed by the
1633 Department for distribution to persons licensed pursuant to 7.40 and 7.42 or
1634 under equivalent licenses of NRC or an Agreement State, provided that such
1635 labeling for sources which do not require long term storage may be on a leaflet or
1636 brochure which accompanies the source;
- 1637 (4) **The source or device has been registered in the Sealed Source and Device**
1638 **Registry.**
- 1639 3.12.12.2 In the event the applicant desires that the source or device be required to be
1640 tested for leakage of radioactive material at intervals longer than 6 months, the applicant
1641 shall include in the application sufficient information to demonstrate that such longer
1642 interval is justified by performance characteristics of the source or device or similar
1643 sources or devices and by design features that have a significant bearing on the
1644 probability or consequences of leakage of radioactive material from the source; and
- 1645 3.12.12.3 In determining the acceptable interval for test of leakage of radioactive material,
1646 the Department will consider information that includes, but is not limited to:
- 1647 (1) Primary containment or source capsule,
- 1648 (2) Protection of primary containment,
- 1649 (3) Method of sealing containment,
- 1650 (4) Containment construction materials,

Comment [JJ45]:

Language is added consistent with federal rule in 10
CFR 32.74(a)(4).

NRC Cross-reference = 10 CFR Part 2.74(a)(4)
NRC Compatibility = B

- 1651 (5) Form of contained radioactive material,
- 1652 (6) Maximum temperature withstood during prototype tests,
- 1653 (7) Maximum pressure withstood during prototype tests,
- 1654 (8) Maximum quantity of contained radioactive material,
- 1655 (9) Radiotoxicity of contained radioactive material, and
- 1656 (10) Operating experience with identical sources or devices or similarly designed and
- 1657 constructed sources or devices.

1658 3.12.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted
 1659 Uranium for Mass-Volume Applications.

1660

1661 * * *

1662

1663 3.12.14 Registration of Product Information.

1664 **3.12.14.1** Any manufacturer or initial distributor of a sealed source, or ~~of a~~ device containing a
 1665 sealed source, ~~whose product is intended for use under a specific license~~ may submit a
 1666 request to the Department for evaluation of radiation safety information about ~~its~~**the**
 1667 product and for the product registration.

Comment [JJ46]: Language updated, consistent with federal rule 10 CFR 32.210(a).

 Compatibility = B
 NRC RATS 2012-4

1668 3.12.14.2 The request for review must be ~~made in duplicate and~~ sent to the **Radiation Program**
 1669 **Manager**~~Director~~, Hazardous Materials **A**and Waste Management Division, Colorado
 1670 Department of Public Health and Environment, 4300 Cherry Creek Drive South,
 1671 Denver, Colorado 80246-1530.

1672 3.12.14.3 The request for review of a sealed source or device must include sufficient information
 1673 about the design, manufacture, prototype testing, quality control program, labeling,
 1674 proposed uses and leak testing and, for a device, the request must also include
 1675 sufficient information about installation, service and maintenance, operating and safety
 1676 instructions, and its potential hazards, to provide reasonable assurance that the
 1677 radiation safety properties of the source or device are adequate to protect health and
 1678 minimize danger to life and property.

1679 3.12.14.4 The Department normally evaluates a sealed source or device using radiation safety
 1680 criteria in accepted industry standards.

1681 (1) If these standards and criteria do not readily apply to a particular case, the
 1682 Department formulates reasonable standards and criteria with the help of the
 1683 manufacturer or distributor.

Comment [JJ47]: Language updated, consistent with federal rule 10 CFR 32.210(d).

1684 **(2)** The Department shall use criteria and standards sufficient to ensure that the
 1685 radiation safety properties of the device or sealed source are adequate to protect
 1686 health and minimize danger to life and property. **Subpart A of 10 CFR Part 32**
 1687 **includes specific criteria that apply to certain exempt products and 3.12.4,**
 1688 **3.12.5, 3.12.6, 3.12.8, and 3.12.9 of this part includes specific criteria**
 1689 **applicable to certain generally licensed devices. Sections 3.12.10 and**
 1690 **3.12.12 include specific provisions that apply to certain specifically**
 1691 **licensed items.**

Note that certain federal rule provisions are addressed through incorporation by reference in some of the sections referenced.

 Compatibility = B
 NRC RATS 2012-4

1692 **3.12.14.5** After completion of the evaluation, the Department issues a certificate of
 1693 registration to the person making the request. The certificate of registration

Comment [JJ48]:
 Language updated, consistent with federal rule 10 CFR 32.210(e).

 NRC RATS 2012-4
 Compatibility = B

1694 acknowledges the availability of the submitted information for inclusion in an application
 1695 for specific license proposing use of the product **or concerning use under an**
 1696 **exemption from licensing or general license as applicable for the category of**
 1697 **certificate.**

1698 3.12.14.6 The person submitting the request for evaluation and registration of safety
 1699 information about the product shall manufacture and distribute the product in accordance
 1700 with:

1701 (1) The statements and representations, including quality control program, contained
 1702 in the request; and

1703 (2) The provisions of the certificate of registration.

1704 **3.12.14.7 Authority to manufacture or initially distribute a sealed source or device to**
 1705 **specific licensees may be provided in the license without the issuance of a certificate of**
 1706 **registration in the following cases:**

1707 (1) **Calibration and reference sources containing no more than:**

1708 (a) **37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or**

1709 (b) **0.37 MBq (10 µCi), for alpha emitting radionuclides; or**

1710 (2) **The intended recipients are qualified by training and experience and have**
 1711 **sufficient facilities and equipment to safely use and handle the requested**
 1712 **quantity of radioactive material in any form in the case of unregistered sources**
 1713 **or, for registered sealed sources contained in unregistered devices, are**
 1714 **qualified by training and experience and have sufficient facilities and**
 1715 **equipment to safely use and handle the requested quantity of radioactive**
 1716 **material in unshielded form, as specified in their licenses; and**

1717 (a) **The intended recipients are licensed under 3.11 or comparable**
 1718 **provisions of NRC or an Agreement State; or**

1719 (b) **The recipients are authorized for research and development; or**

1720 (c) **The sources and devices are to be built to the unique specifications of**
 1721 **the particular recipient and contain no more than 740 GBq (20 Ci) of**
 1722 **tritium or 7.4 GBq (200 mCi) of any other radionuclide.**

1723 **3.12.14.8 After the certificate is issued, the Department may conduct an additional review**
 1724 **as it determines is necessary to ensure compliance with current regulatory**
 1725 **standards. In conducting its review, the Department will complete its evaluation**
 1726 **in accordance with criteria specified in this section. The Department may request**
 1727 **such additional information as it considers necessary to conduct its review and**
 1728 **the certificate holder shall provide the information as requested.**

1729 **3.12.15 Inactivation of certificates of registration of sealed sources and devices**

1730 **3.12.15.1 A certificate holder who no longer manufactures or initially transfers any of the**
 1731 **sealed source(s) or device(s) covered by a particular certificate issued by the**
 1732 **Department shall request inactivation of the registration certificate. Such a**
 1733 **request must be made to the Department and must normally be made no later**
 1734 **than two years after initial distribution of all of the source(s) or device(s)**
 1735 **covered by the certificate has ceased. However, if the certificate holder**
 1736 **determines that an initial transfer was in fact the last initial transfer more than**
 1737 **two years after that transfer, the certificate holder shall request inactivation of**
 1738 **the registration certificate.**

Comment [JJ49]: New provision 3.12.14.7 is added consistent with the 2012 amendments to 10 CFR Part 32.210(g).

The new provision provides some relief from requiring a sealed source and device evaluation for some types of low activity sources, sources having unique specifications, and under other specific circumstances where the recipient has demonstrated adequate training and experience.

NRC RATS 2012-4
Compatibility = B

Comment [JJ50]: New provision 3.12.14.8 is added consistent with the 2012 amendments to 10 CFR Part 32.210(h).

The new provision allows for the review of additional information as needed following issuance of the certificate, and the licensee must provide the requested information.

NRC RATS 2012-4
Compatibility = C

Comment [JJ51]: New provision 3.12.15 is added consistent with the 2012 amendments to 10 CFR Part 32.211.

The provision outlines the process for inactivation of a sealed source and device registration, license termination, and servicing devices previously distributed under a previous active registration.

NRC RATS 2012-4
Compatibility = B

1740 | the certificate within 90 days of this determination and briefly describe the
1741 | circumstances of the delay.

1742 | **3.12.15.2 If a distribution license is to be terminated in accordance with 3.16 the licensee
1743 | shall request inactivation of its registration certificates associated with that
1744 | distribution license before the Department will terminate the license. Such a
1745 | request for inactivation of certificate(s) must indicate that the license is being
1746 | terminated and include the associated specific license number.**

1747 | **3.12.15.3 A specific license to manufacture or initially transfer a source or device covered
1748 | only by an inactivated certificate no longer authorizes the licensee to initially
1749 | transfer such sources or devices for use. Servicing of devices must be in
1750 | accordance with any conditions in the certificate, including in the case of an
1751 | inactive certificate.**
1752 |
1753 |

1754 | **3.13 Third-Party Method.**

1755 | * * *

1756 | **3.14 Issuance of a Specific License.**

1757 | * * *

1758 | **3.15 Specific Terms and Conditions of License.**

1759 | 3.15.1 Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or
1760 | hereafter in effect, and to all rules, regulations, and orders of the Department.

1761 | 3.15.2 Inalienability of Licenses.

1762 | 3.15.2.1 No license issued or granted under this part and no right to possess or utilize
1763 | radioactive material granted by any license issued pursuant to this part shall be
1764 | transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily,
1765 | directly or indirectly, through transfer of control of any license to any person unless the
1766 | Department shall, after securing full information, find that the transfer is in accordance
1767 | with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations,
1768 | and orders of the Department, and shall give its consent in writing.

1769 | 3.15.2.2 An application for transfer of license must include:

1770 | (1) The identity, technical and financial qualifications of the proposed transferee;

1771 | (2) Financial assurance for decommissioning information required by 3.9.6;

1772 | (3) A description of the acquisition or proposed transfer including dates;

1773 | (4) An updated organizational chart including the proposed transferee's
1774 | management structure for the licensed activities;

1775 | (5) Documentation of registration with the Colorado Secretary of State for the
1776 | proposed transferee;

1777 | (6) A statement from the proposed transferee's management that they will conduct
1778 | business in accord with all of the commitments previously submitted by the
1779 | current licensee;

1780 | (7) A statement from the proposed transferee's management accepting liability for all
1781 | licensed materials that are and have been possessed under the license; and

1782 (8) A copy of the appropriate radioactive materials license application signed by the
1783 RSO and the proposed transferee's management.

1784 3.15.3 Each person licensed by the Department pursuant to this part shall confine use and possession
1785 of the material licensed to the locations and purposes authorized in the license. **Except as**
1786 **otherwise provided in the license, a license issued pursuant to Part 3 shall carry with it the**
1787 **right to receive, possess, and use source or byproduct material. Preparation for shipment**
1788 **and transport of source or radioactive material shall be in accordance with the provisions**
1789 **of Part 17.**

Comment [JJ52]:

Language added consistent with 40.41(c).

NRC Compatibility = C

1790 3.15.4 Notice and Disposition of Records Prior to License Termination.

1791

1792

* * *

1793 **3.16 Expiration, Decommissioning and Termination of Licenses.**

1794 3.16.1 Definition of "principal activity".

1795 3.16.1.1 As used in this regulation, "principal activity" means an activity authorized by the
1796 license which is essential to achieving the purpose(s) for which the license was issued
1797 or amended.

1798 3.16.1.2 Not included as principal activities are:

1799 (1) Radioactive material storage while no licensed material is accessed for use or
1800 disposal; and

1801 (2) Any activity incidental to decontamination or decommissioning.

1802 3.16.2 Expiration.

1803 3.16.2.1 Except as provided in 3.17.2, each specific license shall expire at the end of the
1804 specified day in the month and year stated therein.

1805 3.16.2.2 Each specific license revoked by the Department expires at the end of the day on
1806 the date of final determination to revoke the license, or on the expiration date stated in
1807 the determination, or as otherwise provided by order.

1808 3.16.2.3 With respect to possession of radioactive material and residual radioactive
1809 contamination, each specific license continues in effect beyond the expiration date until
1810 the Department notifies the licensee in writing that the license is terminated, even if:

1811 (1) The licensee decides not to renew the license;

1812 (2) No application for license renewal is submitted;

1813 (3) An application for renewal is denied; or

1814 (4) The Department modifies or suspends a license.

1815 3.16.2.4 No less than 30 days before the expiration date specified in the license, the
1816 licensee shall either:

1817 (1) Submit an application for license renewal under 3.17; or

1818 (2) Notify the Department, in writing, that the licensee has decided not to renew the
1819 license.

- 1820 3.16.2.5 If a licensee does not submit an application for license renewal under 3.17, the
1821 licensee shall, on or before the expiration date specified in the license:
- 1822 (1) Terminate use of radioactive material;
- 1823 (2) Transfer radioactive materials to an authorized recipient and/or properly dispose
1824 of radioactive material;
- 1825 (3) Reduce residual radioactive contamination to levels which are as low as
1826 reasonably achievable (ALARA); and
- 1827 (4) Submit a completed Department Form R-23, *Request for Termination of a*
1828 *Radioactive Materials License*, or equivalent information requesting license
1829 termination, including survey results, leak tests, disposal records, and/or other
1830 documentation which demonstrates acceptable conditions for license termination
1831 as specified in 3.16.6.
- 1832 3.16.2.6 Each licensee who possesses radioactive material, including residual radioactive
1833 contamination attributable to licensed activities, following the expiration date specified in
1834 the license shall:
- 1835 (1) Limit actions involving radioactive material to those related to decontamination
1836 and other activities related to preparation for release for unrestricted use; and
- 1837 (2) Continue to control entry to restricted areas until they are suitable for release for
1838 unrestricted use or the Department notifies the licensee in writing that the license
1839 is terminated.
- 1840 3.16.2.7 Each licensee or person responsible for a facility or site which includes a non-
1841 exempt source of radiation or which may be contaminated by residual radioactivity shall,
1842 no less than 30 days before vacating or relinquishing possession or control of the facility
1843 or site, notify the agency, in writing, of the intent to vacate.
- 1844 3.16.3 Timely Decommissioning.
- 1845 3.16.3.1 Each licensee or person in possession of a non-exempt source of radiation who
1846 decides to terminate all activities involving that source of radiation shall notify the
1847 hazardous materials and waste management division immediately, in writing.
- 1848 3.16.3.2 The licensee shall notify the Hazardous Materials And Waste Management
1849 Division in writing within 60 days of the occurrence of any of the following:
- 1850 (1) The licensee has decided to permanently cease principal activities, as defined in
1851 this part, at the entire site or in any separate building or outdoor area that
1852 contains residual radioactivity such that the building or outdoor area is unsuitable
1853 for unrestricted use in accordance with 4.61; or
- 1854 (2) No principal activities under the license have been conducted for a period of 24
1855 months; or
- 1856 (3) No principal activities have been conducted for a period of 24 months in any
1857 separate building or outdoor area that contains residual radioactivity such that
1858 the building or outdoor area is unsuitable for unrestricted use in accordance with
1859 these regulations.
- 1860 3.16.3.3 Concurrent with the notification of the Hazardous Materials And Waste
1861 Management Division required in 3.16.3.1 and 3.16.3.2, the licensee shall either:
- 1862 (1) Begin decommissioning activities; or,

- 1863 (2) Within 12 months of notification, submit a decommissioning plan if required by
1864 3.16.4, and begin decommissioning upon approval of that plan.
- 1865 3.16.3.4 Licensees shall complete decommissioning of the site or separate building or
1866 outdoor area as soon as practicable but no later than 24 months following the initiation of
1867 decommissioning, unless an alternate schedule addressing the factors in 3.16.4 is
1868 requested and approved by the Department.
- 1869 3.16.3.5 When decommissioning involves the entire site, the licensee shall request
1870 license termination upon completion of decommissioning activities.
- 1871 3.16.3.6 The Department may approve alternate schedules for the submission of plans
1872 and for the completion of decommissioning as required pursuant to 3.16.3.3 and 3.16.3.4
1873 if the Department determines that the alternate schedule:
- 1874 (1) Is necessary to effectively conduct decommissioning;
- 1875 (2) Presents no undue risks to public health and safety; and
- 1876 (3) Is otherwise in the public interest.
- 1877
- 1878 3.16.4 Decommissioning Plan.
- 1879 3.16.4.1 A licensee must submit a decommissioning plan:
- 1880 (1) If the licensee intends to terminate the license using radiological criteria specified
1881 in 4.61.3 or 4.61.4 (the exemption of 4.61.1.1 applies);
- 1882 (2) If required otherwise by these regulations;
- 1883 (3) If required by license condition; or
- 1884 (4) If the procedures and activities necessary to carry out decommissioning of the
1885 site or separate building or outdoor area have not been previously approved by
1886 the Department and these procedures could increase potential health and safety
1887 impacts to workers or to the public, such as in any of the following cases:
- 1888 (a) Procedures would involve techniques not applied routinely during
1889 cleanup or maintenance operations;
- 1890 (b) Workers would be entering areas not normally occupied where surface
1891 contamination and radiation levels are significantly higher than routinely
1892 encountered during operation;
- 1893 (c) Procedures could result in significantly greater airborne concentrations of
1894 radioactive materials than are present during operation; or
- 1895 (d) Procedures could result in significantly greater releases of radioactive
1896 material to the environment than those associated with operation.
- 1897 3.16.4.2 Procedures such as those listed in 3.16.4.1 of this section with potential health
1898 and safety impacts may not be carried out prior to Department approval of the
1899 decommissioning plan.
- 1900 3.16.4.3 The decommissioning plan for the site or separate building or outdoor area must
1901 include:

- 1902
1903
- (1) A description of the conditions of the site, separate buildings, and/or outdoor areas sufficient to evaluate the acceptability of the plan;
- 1904
1905
- (2) A description of planned decommissioning activities and a schedule for completion;
- 1906
1907
- (3) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
- 1908
- (4) A description of the planned final radiation survey;
- 1909
1910
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1912
- (5) A current detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and
- 1913
1914
- (6) A description of the intended final condition of the site, separate buildings, and/or outdoor areas upon completion of decommissioning activities.
- 1915
1916
- (7) Decommissioning plans proposing the use of radiological criteria specified in 4.61.3 or 4.61.4, must also include:
- 1917
1918
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1921
- (a) An analysis demonstrating that reductions in residual radioactivity necessary to comply with the provisions of 4.61.2 would result in net public or environmental harm or were not being made because the residual levels of contamination associated with restricted conditions are ALARA.
- 1922
1923
1924
1925
- (i) Determination of dose and residual radioactivity levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal;
- 1926
1927
1928
1929
- (b) A description of the institutional controls necessary to satisfy the requirements of 4.61.3.2, including a description of how the controls will be enforced and an analysis showing that the controls will not impose undue burdens on the local community or other affected parties;
- 1930
1931
- (c) An analysis demonstrating that if institutional controls were no longer in effect then the dose criteria of 4.61.3.4 will be met;
- 1932
1933
1934
- (d) A detailed cost estimate for a long-term care warranty, and a plan for establishing a Department approved warranty prior to completion of decommissioning activities;
- 1935
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- (e) A description of how the licensee will seek advice from representatives of a broad cross section of community interests who may be affected by the decommissioning and how the licensee will provide participants an opportunity for a comprehensive, collective discussion on key decommissioning issues, including: the adequacy and enforceability of institutional controls, burdens/impacts to local communities and affected parties, and the adequacy of financial assurance; and
- 1942
1943
1944
1945
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1947
- (f) A description of how the licensee will make publicly available a summary of the results of all such discussions, including: a description of the individual viewpoints of the participants on the issues, the extent of agreement and disagreement among the participants on the issues, and a description of how key issues in disagreement will be addressed during decommissioning.

1948 3.16.4.4 For decommissioning plans calling for completion of decommissioning later than
 1949 24 months after plan approval, the plan shall include a justification for the
 1950 decommissioning schedule which addresses the following:

- 1951 (1) Whether it is technically feasible to complete decommissioning within a 24-month
 1952 period;
- 1953 (2) Whether sufficient waste disposal capacity is available to allow completion of
 1954 decommissioning with a 24-month period;
- 1955 (3) Whether a significant volume reduction in wastes requiring disposal will be
 1956 achieved by allowing short-lived radionuclides to decay;
- 1957 (4) Whether a significant reduction in radiation exposure to workers can be achieved
 1958 by allowing short-lived radionuclides to decay; and
- 1959 (5) Other site-specific factors which the Department may consider appropriate on a
 1960 case-by-case basis, such as the regulatory requirements of other government
 1961 agencies, lawsuits, ground-water treatment activities, monitored natural ground-
 1962 water restoration, actions that could result in more environmental harm than
 1963 deferred cleanup, and other factors beyond the control of the licensee.

1964 3.16.4.5 Upon the receipt of a decommissioning plan or proposal by the licensee for
 1965 release of a site pursuant to 4.61.3 or 4.61.4, or whenever the Department deems such
 1966 notice to be in the public interest, the Department shall:

- 1967 (1) Notify and solicit comments from:
 - 1968 (a) Local and state governments in the vicinity of the site and any Indian
 1969 nation or other indigenous people that have treaty or statutory rights that
 1970 could be affected by the decommissioning; and
 - 1971 (b) The environmental protection agency for cases where the licensee
 1972 proposes to release a site pursuant to 4.61.4.
- 1973 (2) Publish a notice in a forum, such as local newspapers, letters to state or local
 1974 organizations, or other appropriate forum, that is readily accessible to individuals
 1975 in the vicinity of the site, and solicit comments from affected parties.

1976 3.16.4.6 The proposed decommissioning plan will be approved by the Department if the
 1977 information therein demonstrates that the decommissioning will be in accordance with the
 1978 requirements of 3.9.5.105, 3.16, and 4.61 (the exemption of 4.61.1.1 applies), completed
 1979 as soon as practicable, and that the health and safety of workers and the public will be
 1980 adequately protected.

1981 3.16.5 Decommissioning Record Keeping.

1982 * * *

1983 3.16.6 Demonstrating Acceptable Conditions for License Termination.

1984 * * *

1985 3.16.6.4 The licensee's report required by 3.16.6.6-3 shall specify, as appropriate:

1986 * * *

1987 3.16.7 License Termination.

1988 3.16.7.1 Specific licenses, including expired licenses, will be terminated by written notice
1989 to the licensee when the Department determines that:

1990 (1) Radioactive materials have been properly disposed and records of disposal
1991 required by 4.48 to be maintained and retained have been forwarded to the
1992 Department as required by 3.15.4;

1993 (2) Reasonable effort has been made to eliminate residual radioactive
1994 contamination, if present;

Comment [JJ53]: Provision added consistent with 10 CFR 40.42(k)(2).

1995 (3) The licensee has demonstrated, by radiation survey results and/or other
1996 appropriate methods, that the license termination will be in compliance with these
1997 regulations;

1998 (34) The licensee has established a Department approved long term care warranty, if
1999 required;

2000 (45) Department approved institutional controls have been implemented to limit public
2001 doses, if required; and

2002 (56) All records required by 3.16.5 have been transferred to the Department.

2003 3.16.8 Additional Cleanup.

2004 3.16.8.1 Except for facilities exempted under 4.61.1.1, after a site has been
2005 decommissioned and the license terminated in accordance with 3.16 and 4.61, the
2006 Department may reinstate the terminated license or issue a new license and require
2007 additional cleanup only if, based on new or previously unknown information, it determines
2008 that the criteria of 4.61 were not met and residual radioactivity remaining at the site could
2009 result in significant threat to public health and safety.

2010 3.17 Renewal of Licenses.

2011 * * *

2012 3.18 Amendment of Licenses at Request of Licensee.

2013 * * *

2014 3.19 Agency Action on Applications to Renew and Amend.

2015 * * *

2016 3.20 Reserved.

2017 3.21 Reserved.

2018 TRANSFER OF MATERIALS

2019 3.22 Transfer of Material.

Comment [JJ54]: Section title added consistent with 10 CFR 40.54.

2020 * * *

2021 REQUIREMENTS FOR LICENSE TO INITIALLY TRANSFER SOURCE MATERIAL FOR USE UNDER
2022 THE SMALL QUANTITIES OF SOURCE MATERIAL GENERAL LICENSE

Comment [JJ55]: Provision in 3.22.6 is added consistent with the language and requirements of 10 CFR 40.54.

2023 3.22.6 An application for a specific license to initially transfer source material for use under 3.5.1,
2024 or equivalent regulations of the NRC or an Agreement State, will be approved if:
2025

This provision is new to the federal rule which became effective August 27, 2013.

2026 3.22.6.1 The applicant satisfies the general requirements specified in 3.9; and
2027
2028

NRC Compatibility = B
NRC RATS = 2013-2

2029 **3.22.6.2** The applicant submits adequate information on, and the Department approves the
 2030 methods to be used for quality control, labeling, and providing safety instructions
 2031 to recipients.
 2032

2033 **3.22.7 License Conditions for Initial Transfer of Source Material**

2034 **Conditions of licenses to initially transfer source material for use under the ‘small**
 2035 **quantities of source material’ general license: Quality control, labeling, safety**
 2036 **instructions, and records and reports.**

2037 **3.22.7.1** Each person licensed under 3.22.6 shall label the immediate container of each
 2038 quantity of source material with the type of source material and quantity of
 2039 material and the words, “radioactive material.”

2040 **3.22.7.2** Each person licensed under 3.22.6 shall ensure that the quantities and
 2041 concentrations of source material are as labeled and indicated in any transfer
 2042 records.

2043 **3.22.7.3** Each person licensed under 3.22.6 shall provide the information specified in 3.22.7
 2044 to each person to whom source material is transferred for use under 3.5.1 or
 2045 equivalent provisions in NRC or Agreement State regulations. This information
 2046 must be transferred before the source material is transferred for the first time in
 2047 each calendar year to the particular recipient. The required information includes:

2048 (1) A copy of 3.5.1 and 3.22, or relevant equivalent regulations of the NRC or an
 2049 Agreement State.

2050 (2) Appropriate radiation safety precautions and instructions relating to handling,
 2051 use, storage, and disposal of the material.

2052 **3.22.7.4** Each person licensed under 3.22.6 shall report transfers as follows:

2053 (1) File a report with the Department. The report shall include the following
 2054 information:

- 2055 (a) The name, address, and license number of the person who transferred
 2056 the source material;
 2057 (b) For each general licensee under 3.5.1 or equivalent NRC or Agreement
 2058 State provisions to whom greater than 50 grams (0.11 lb) of source material
 2059 has been transferred in a single calendar quarter, the name and address of
 2060 the general licensee to whom source material is distributed; a responsible
 2061 agent, by name and/or position and phone number, of the general licensee
 2062 to whom the material was sent; and the type, physical form, and quantity of
 2063 source material transferred; and
 2064 (c) The total quantity of each type and physical form of source material
 2065 transferred in the reporting period to all such generally licensed recipients.

2066 (2) File a report with the NRC and each responsible Agreement State agency that
 2067 identifies all persons, operating under provisions equivalent to 3.5.1, to whom
 2068 greater than 50 grams (0.11 lb) of source material has been transferred within
 2069 a single calendar quarter. The report shall include the following information
 2070 specific to those transfers made to the NRC or Agreement State being
 2071 reported to:

- 2072 (a) The name, address, and license number of the person who transferred
 2073 the source material; and
 2074 (b) The name and address of the general licensee to whom source material
 2075 was distributed; a responsible agent, by name and/or position and phone
 2076 number, of the general licensee to whom the material was sent; and the
 2077 type, physical form, and quantity of source material transferred.
 2078 (c) The total quantity of each type and physical form of source material
 2079 transferred in the reporting period to all such generally licensed recipients
 2080 within the Agreement State or under NRC jurisdiction, as appropriate.
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Comment [JJ56]:

Section title in 3.22.7, and language in 3.22.7.1 is added consistent with the language and requirements of 10 CFR 40.55(a).

This provision is new to the federal rule which became effective August 27, 2013.

NRC Compatibility = B
 NRC RATS = 2013-2

Comment [JJ57]:

Provision in 3.22.7.2 is added consistent with the language and requirements of 10 CFR 40.55(b).

This provision is new to the federal rule which became effective August 27, 2013.

NRC Compatibility = B
 NRC RATS = 2013-2

Comment [JJ58]:

Provision in 3.22.7.3 is added consistent with the language and requirements of 10 CFR 40.55(c).

This provision is new to the federal rule which became effective August 27, 2013.

NRC Compatibility = B
 NRC RATS = 2013-2

Comment [JJ59]:

Provision in 3.22.7.4 is added consistent with the language and requirements of 10 CFR 40.55(d).

This provision is new to the federal rule which became effective August 27, 2013.

NRC Compatibility = B
 NRC RATS = 2013-2

2090 (3) Submit each report by January 31 of each year covering all transfers for the
 2091 previous calendar year. If no transfers were made to persons generally
 2092 licensed under 3.5.1 or equivalent NRC or Agreement State provisions during
 2093 the current period, a report shall be submitted to the Department indicating
 2094 so. If no transfers have been made to general licensees under NRC
 2095 jurisdiction or in a particular Agreement State during the reporting period, this
 2096 information shall be reported to the NRC or the responsible Agreement State
 2097 agency upon request of the agency.

2098
 2099 **3.22.7.5** Each person licensed under 3.22.6 shall maintain all information that supports the
 2100 reports required by this section concerning each transfer to a general licensee for
 2101 a period of 1 year after the event is included in a report to the Department, an
 2102 Agreement State agency, or the NRC.

Comment [JJ60]: Provision in 3.22.7.5 is added consistent with the language and requirements of 10 CFR 40.55(e).

 This provision is new to the federal rule which became effective August 27, 2013.

 NRC Compatibility = C
 NRC RATS = 2013-2

2103 **MODIFICATION AND REVOCATION OF LICENSES**

2104 **3.23 Modification and Revocation of Licenses.**

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 2108 **3.24 Reciprocal Recognition of Licenses.**

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2111 **PART 3, SCHEDULE 3A: EXEMPT CONCENTRATIONS (3.3.1)**

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Comment [JJ61]: Page break inserted for formatting purposes to ensure Schedule 3A begins at the top of the page.

There are no changes to the content of Schedule 3A.

2116 **PART 3, SCHEDULE 3B: EXEMPT QUANTITIES (3.3.2)**

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Comment [JJ62]:

Page break inserted for formatting purposes to ensure Schedule 3B begins at the top of the page.

There are no changes to the content of Schedule 3B.

2120 **PART 3, SCHEDULE 3C: UNIMPORTANT QUANTITIES OF SOURCE MATERIAL AND EXEMPT**
 2121 **ITEMS (3.2.3-AND 3.3.3)**

2122 **3C Any person is exempt from the requirements for a license set forth in section 62 of the**
 2123 **Atomic Energy Act and from the regulations in this part 3, and parts 4 and 10, to the**
 2124 **extent that such person receives, possesses, uses, or transfers an item listed below:**

2125 3C.1 Any quantities of thorium contained in:

2126 3C.1.1 Incandescent gas mantles;

2127 3C.1.2 Vacuum tubes;

2128 3C.1.3 Welding rods;

2129 3C.1.4 Electric lamps for illuminating purposes provided that each lamp does not contain more
 2130 than 50 milligrams of thorium;

2131 3C.1.5 Germicidal lamps, sunlamps, and lamps for outdoors or industrial lighting provided that
 2132 each lamp does not contain more than 2 grams of thorium;

2133 3C.1.6 Rare earth metals and compounds, mixtures, and products containing not more than 0.25
 2134 percent by weight thorium, uranium, or any combination of these; or

2135 3C.1.7 Personnel neutron dosimeters provided that each dosimeter does not contain more than
 2136 50 milligrams of thorium.

2137 3C.2 Source material contained in the following products:

2138 3C.2.1 Glazed ceramic tableware **manufactured before August 27, 2013**, provided that the
 2139 glaze contains not more than 20 percent by weight source material;

2140 3C.2.2 Glassware containing not more than **2 percent by weight source material or, for**
 2141 **glassware manufactured before August 27, 2013**, 10 percent by weight source
 2142 material, but not including commercially manufactured glass brick, pane glass, ceramic
 2143 tile or other glass or ceramic used in construction;

2144 3C.2.3 Glass enamel or glass enamel frit containing not more than 10 percent by weight source
 2145 material imported or ordered for importation into the United States, or initially distributed
 2146 by manufacturers in the United States, before July 25, 1983; or

2147 3C.2.4 Piezoelectric ceramic containing not more than 2 percent by weight source material.

2148 3C.3 Photographic film, negatives, and prints containing uranium or thorium.

2149 3C.4 Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium
 2150 alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and
 2151 that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical
 2152 treatment or processing of any such product or part.

2153 3C.5 Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or
 2154 stored or handled in connection with installation or removal of such counterweights, provided that:

2155 ~~3C.5.1 The counterweights are manufactured in accordance with a specific license issued by~~
 2156 ~~NRG, authorizing distribution by the licensee pursuant to 10 CFR Part 40 (January 1,~~
 2157 ~~2010);~~

2158 3C.5.21 Each counterweight has been impressed with the following legend clearly legible through
 2159 any plating or other covering: "Depleted Uranium";¹⁴

Comment [JJ63]:
 For formatting purposes, a page break is inserted such that Schedule 3C begins at the top of the page.

Comment [JJ64]:
 The title section language is added, for consistency with the language in 10 CFR Part 40.13.

Comment [JJ65]:
 Language is added, consistent with the language in 10 CFR Part 40.13(c).
 NRC RATS 2013-2
 Compatibility = B

Comment [JJ66]:
 Language added for consistency with 10 CFR 40.13(c)(2)(i). The added date is consistent with the date shown in 10 CFR Part 40.13.
 The exempt distribution date of August 27, 2013 is reserved to NRC jurisdiction.
 NRC Compatibility = B
 RATS = 2013-2

Comment [JJ67]:
 Language added for consistency with 10 CFR 40.13(c)(2)(iii). The added date is consistent with the date shown in 10 CFR Part 40.13.
 The exempt distribution date of August 27, 2013 is reserved to NRC jurisdiction.
 NRC Compatibility = B
 RATS = 2013-2

Comment [JJ68]:
 The provision in 10 CFR Part 40 (40.13(c)(5)(i) was deleted during the August 27, 2013 amendments to 10 CFR Part 40. The equivalent provision in Colorado rule is therefore deleted.
 NRC Cross-reference = 10 CFR 40.13(c)(5)(i)
 NRC Compatibility = B
 RATS = 2013-2

2160 14 The requirement specified in 3C.5.12 need not be met by counterweights manufactured prior to December 31, 1969; provided,
 2161 that such counterweights **were manufactured under a specific license issued by the Atomic Energy Commission and were**
 2162 impressed with the legend, "CAUTION – RADIOACTIVE MATERIAL – URANIUM", as previously required by the regulations.

Comment [JJ69]:

Language is added to footnote 14 consistent with the revisions to equivalent to footnotes for 10 CFR Part 40.13(c)(5)(i), and (ii).

NRC Compatibility = B
 RATS = 2013-2

2163 3C.5.32 Each counterweight is durably and legibly labeled or marked with the identification of the
 2164 manufacturer and the statement: "Unauthorized Alterations Prohibited" ¹⁵ ; and

2165 15 The requirement specified in 3C.5.23 need not be met by counterweights manufactured prior to December 31, 1969; provided,
 2166 that such counterweights **were manufactured under a specific license issued by the Atomic Energy Commission and were**
 2167 impressed with the legend, "CAUTION – RADIOACTIVE MATERIAL – URANIUM", as previously required by the regulations.

Comment [JJ70]:

Language is added to footnote 15, consistent with the revisions to equivalent to footnotes for 10 CFR Part 40.13(c)(5)(i), and (ii).

NRC Compatibility = B
 RATS = 2013-2

2168 3C.5.43 This exemption shall not be deemed to authorize the chemical, physical, or metallurgical
 2169 treatment or processing of any such counterweights other than repair or restoration of
 2170 any plating or other covering.

2171 3C.6 Natural or depleted uranium used as shielding constituting part of any shipping container,
 2172 provided that:

2173 3C.6.1 The shipping container is conspicuously and legibly impressed with the legend "Caution -
 2174 Radioactive Shielding - Uranium"; and

2175 3C.6.2 The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall
 2176 thickness of 1/8 inch (3.2 mm).

2177 **3C.7** Thorium **or uranium** contained in **or on** finished optical lenses **and mirrors**, provided that each
 2178 lens **or mirror** does not contain more than **10 percent by weight thorium or uranium or, for**
 2179 **lenses manufactured before August 27, 2013**, 30 percent by weight of thorium;; and that
 2180 **the** ~~this~~ exemption **contained in 3C.7** shall not be deemed to authorize either:

Comment [JJ71]:

Language is added to section 3C.7, 3C.7.1, and 3C.7.2 for consistency with 10 CFR 40.13(c)(7). The "grandfathering" date is maintained consistent with the date in 10 CFR Part 40.13 as exempt distribution remains under exclusive NRC jurisdiction.

Based upon industry information obtained during NRC analysis (for Part 40 revisions), there has been a manufacturing shift to coating lenses (on the surface) versus incorporating the material into the lenses. Therefore, language is added to clarify that the exemptions apply to materials contained within and coated on lenses and mirrors.

NRC Compatibility = B
 RATS = 2013-2

2181 3C.7.1 The shaping, grinding, or polishing of such lens or manufacturing processes other than
 2182 the assembly of such lens **or mirror** into optical systems and devices without any
 2183 alteration of the lens **or mirror**; or

2184 3C.7.2 The receipt, possession, use, or transfer of **uranium or** thorium contained in contact
 2185 lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

2186 3C.8 ~~Uranium contained in detector heads for use in fire detection units, provided that each detector~~
 2187 ~~head contains not more than 185 Bq (0.005 µCi) of uranium; or~~ **Reserved**

Comment [JJ72]: This section is deleted, consistent with deletion from federal rule in 10 CFR Part 40.13(d). The NRC determined that this provision was obsolete as fire detection units containing source material have never been manufactured for commercial use. The section is made "reserved" to retain subsequent numbering and cross-references.

[Ref: 78 FR 32319; May 29, 2013]
 NRC Compatibility = B
 RATS = 2013-2

2188 3C.9 Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

2189 3C.9.1 The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria
 2190 (thorium dioxide); and

2191 3C.9.2 The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

2192 **3C.10 No person may initially transfer for sale or distribution a product containing source**
 2193 **material to persons exempt under 3C.1 through 3C.10, or equivalent regulations of the**
 2194 **NRC or an Agreement State, unless authorized by a license issued by NRC under 10 CFR**
 2195 **Part 40.52 to initially transfer such products for sale or distribution.**

2196 **3C.10.1 Persons authorized to manufacture, process, or produce these materials or**
 2197 **products containing source material by an Agreement State, and persons who**
 2198 **import finished products or parts, for sale or distribution are exempt from the**
 2199 **requirements of parts 4, and 10, and 3.9.1 and 3.9.2.**

Comment [JJ73]: Section 3C.10 and 3C.10.1 is added for consistency with an equivalent paragraph added to 10 CFR Part 40 in 40.13(c)(10) and (c)(10)(ii).

[NOTE: A provision equivalent to 40.13(c)(10)(i) – not shown – is excluded from Colorado rule as the date specified in the federal rule provision has passed and is therefore the provision is obsolete and no longer applicable.]

NRC Compatibility = B
 RATS = 2013-2

2200 3C.1140 Except for persons who apply radioactive material to, or persons who incorporate
 2201 radioactive material into, the following products, any person is exempt from these regulations to
 2202 the extent that the person receives, possesses, uses, transfers, owns, or acquires the following
 2203 products ¹⁶ :

2204 16 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or

2205	other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
2206	exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
2207	20555.
2208	3C.4011.1 Timepieces or hands or dials containing not more than the following specified
2209	quantities of radioactive material and not exceeding the following specified radiation dose
2210	rate:
2211	3C.1140.1.1 925 MBq (25 mCi) of tritium per timepiece.
2212	3C.1140.1.2 185 MBq (5 mCi) of tritium per hand.
2213	3C.4011.1.3 555 MBq (15 mCi) of tritium per dial (bezels when used shall be
2214	considered as part of the dial).
2215	3C.40-11.1.4 3.7 MBq (100 µCi) of promethium-147 per watch or 7.4 MBq (200 µCi) of
2216	promethium-147 per any other timepiece.
2217	3C.40-11.1.5 0.74 MBq (20 µCi) of promethium-147 per watch hand or 1.48 MBq (40
2218	µCi) of promethium-147 per other timepiece hand.
2219	3C.40-11.1.6 2.22 MBq (60 µCi) of promethium-147 per watch dial or 4.44 MBq (120
2220	µCi) of promethium-147 per other timepiece dial (bezels when used shall be
2221	considered as part of the dial).
2222	3C.40-11.1.7 The radiation dose rate from hands and dials containing promethium-147
2223	will not exceed, when measured through 50 milligrams per square centimeter of
2224	absorber:
2225	(1) For wristwatches, 1 µGy (0.1 mrad) per hour at 10 centimeters from any
2226	surface.
2227	(2) For pocket watches, 1 µGy (0.1 mrad) per hour at 1 centimeter from any
2228	surface.
2229	(3) For any other timepiece, 2 µGy (0.2 mrad) per hour at 10 centimeters
2230	from any surface.
2231	3C.40-11.1.8 37 kBq (1 µCi) of radium-226 per timepiece in timepieces acquired prior
2232	to the effective date of this regulation;
2233	3C.10-11.2 Static elimination devices and Ion generating tubes
2234	3C.11.2.1 Static elimination devices which contain, as a sealed source or
2235	sources, byproduct material consisting of a total of not more than
2236	18.5 MBq (500 uCi) of polonium-210 per device.
2237	3C.11.2.2 Ion generating tubes designed for ionization of air that contain, as a
2238	sealed source or sources, byproduct material consisting of a total
2239	of not more than 18.5 MBq (500 uCi) of polonium-210 per device or
2240	of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium)
2241	per device.
2242	3C.11.2.3 Such devices authorized before October 23, 2012 for use under the
2243	general license then provided in 3.6 and equivalent regulations of
2244	the NRC and Agreement States and manufactured, tested, and
2245	labeled by the manufacturer in accordance with the specifications
2246	contained in a specific license issued by the NRC.

Comment [JJ74]:

The requirements for (end use) static eliminators and ion generating devices were for the most part, regulated as "generally licensed" devices for many years. Due to their inherent low risk (to end users) the added language puts these items (within the activity levels specified) under an "exempt" material category.

This provision is added consistent with the language of 10 CFR 30.15(a)(2) which became effective in federal rule in October 2012.

NRG Compatibility = B
NRG RATS = 2012-4

- 2247 **3C.11.3** Precision balances containing not more than 37 MBq (1 mCi) of tritium per balance or not
 2248 more than 18.5 MBq (0.5 mCi) of tritium per balance part manufactured before December
 2249 17, 2007;
- 2250 **3C.1140.34** Marine compasses containing not more than 27.8 GBq (750 mCi) of tritium gas
 2251 and other marine navigational instruments manufactured before December 17, 2007
 2252 containing not more than 9.25 GBq (250 mCi) of tritium gas;
- 2253 **3C.1140.45** Ionization chamber smoke detectors containing not more than 1 microcurie (μCi)
 2254 of americium-241 per detector in the form of a foil and designed to protect life and
 2255 property from fires.
- 2256 **3C.1140.56** Electron tubes, provided that:
- 2257 **3C.1140.56.1** Each tube does not contain more than one of the following specified
 2258 quantities of radioactive material:
- 2259 **a.**(1) 0.55 GBq (150 mCi) of tritium per microwave receiver protector tube or
 2260 370 MBq (10 mCi) of tritium per any other electron tube;
- 2261 (2) 37 kBq (1 μCi) of cobalt-60;
- 2262 (3) 185 kBq (5 μCi) of nickel-63;
- 2263 (4) 1.11 MBq (30 μCi) of krypton-85;
- 2264 (5) 185 kBq (5 μCi) of cesium-137;
- 2265 (6) 1.11 MBq (30 μCi) of promethium-147; and further
- 2266 **3C.1140.56.2** The radiation dose rate from each electron tube containing radioactive
 2267 material will not exceed 10 μGy (1 mrad) per hour at 1 centimeter from any
 2268 surface when measured through 7 milligrams per square centimeter of absorber;
 2269 ¹⁷
- 2270 17 For purposes of 3C.4011.56, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving
 2271 tubes, microwave tubes, indicator tubes, pick up tubes, radiation detection tubes, and any other completely sealed tube that is
 2272 designed to conduct or control electrical currents.
- 2273 **3C.4011.67** Ionizing radiation measuring instruments containing, for purposes of internal
 2274 calibration or standardization, one or more sources of radioactive material, provided that:
- 2275 **3C.4011.67.1** Each source contains no more than one exempt quantity set forth in
 2276 Schedule 3B of this part; and
- 2277 **3C.4011.67.2** Each instrument contains no more than 10 exempt quantities. For
 2278 purposes of this requirement, an instrument's source(s) may contain either one or
 2279 different types of radionuclides and an individual exempt quantity may be
 2280 composed of fractional parts of one or more of the exempt quantities in Schedule
 2281 3B of this part, provided that the sum of such fractions shall not exceed unity.
- 2282 **3C.4011.67.3** For americium-241, 1.85 kBq (0.05 μCi) is considered an exempt
 2283 quantity under **3C.40.611.7**;
- 2284 **3C.4412** Self-luminous products containing radioactive material containing tritium, krypton-85, or
 2285 promethium-147.
- 2286 **3C.4412.1** Except for persons who manufacture, process, or produce self-luminous products
 2287 containing tritium, krypton-85, or promethium-147, any person is exempt from these
 2288 regulations to the extent that such person receives, possesses, uses, transfers, owns, or
 2289 acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured,

2290 processed, produced, imported, or transferred in accordance with a specific license
 2291 issued by NRC pursuant to section 32.22 of 10 CFR Part 32 (January 1, 2015), which
 2292 license authorizes the transfer of the product to persons who are exempt from regulatory
 2293 requirements.

2294 **3C.12.2** Any person who desires to manufacture, process, or produce, or initially transfer
 2295 for sale or distribution self-luminous products containing tritium, krypton-85, or
 2296 promethium-147 for use under 3C.12.1, should apply for a license under 32.22 of 10
 2297 CFR Part 32 and for a certificate of registration in accordance with 32.210 of 10
 2298 CFR Part 32.

Comment [JJ75]:
 This provision is added consistent with the language of 10 CFR 30.19(b) which became effective in federal rule in October 2012.

 The provision clarifies that applicants under 10 CFR 32.22 (include those who initially distribute the specified devices) should also apply for a registration certificate. Colorado does not currently have any licensees who manufacture such luminous devices.

 NRC Compatibility = B
 NRC RATS = 2012-4
 NRC Cross-reference = 10 CFR 30.19(b)

2299 **3C.1412.23** — The exemption in this section does not apply to tritium, krypton-85, or
 2300 promethium-147 used in products for frivolous purposes or in toys or adornments.

2301 ~~3C.4213~~ Gas and aerosol detectors containing radioactive material.
 2302 **3C.4213.1** Except for persons who manufacture, process, or produce, or initially transfer
 2303 for sale or distribution gas and aerosol detectors containing radioactive material, any
 2304 person is exempt from the requirements for a license set forth in the Act and from
 2305 these regulations in 3, 4, 5, 7, 10, 16, and 19 to the extent that such person receives,
 2306 possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol
 2307 detectors designed to protect health, life safety, or property from fires and airborne
 2308 hazards provided that detectors containing radioactive material shall have been and
 2309 manufactured, processed, produced, imported, or initially transferred in accordance
 2310 with a specific license issued by NRC¹⁸ pursuant to section 32.26 of 10 CFR Part 32
 2311 (January 1, 2015); or pursuant to 3.12.3, which license authorizes the initial transfer
 2312 of the detectors to persons who are exempt from regulatory requirements. This
 2313 exemption also covers gas and aerosol detectors manufactured or distributed
 2314 before November 30, 2007, in accordance with a specific license issued by NRC or
 2315 an Agreement State under comparable provisions to 10 CFR Part 32.26 authorizing
 2316 distribution to persons exempt from regulatory requirements.

Comment [JJ76]:
 Language in 3C.13 (and subparagraphs) is added for consistency with federal rule in 10 CFR 30.20. The provision expands the class of products exempted from licensing; clarifies that applicants under 10 CFR 32.26 should also apply for a registration certificate; updates the parts of the regulations from which persons are exempt to include 10 CFR part 19.

 NRC Compatibility = B
 NRC RATS = 2012-4
 NRC Cross-reference = 10 CFR 30.20

2317 ¹⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
 2318 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 2319 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 2320 20555.

2321 **3C.13.2** Any person who desires to manufacture, process, or produce gas and aerosol
 2322 detectors containing byproduct material, or to initially transfer such products for
 2323 use under 3C.13.1, should apply for a license under paragraph 32.26 of 10 CFR
 2324 Part 32 and for a certificate of registration in accordance with 32.210 of 10 CFR
 2325 Part 32.

2326 **3C.4213.23** Gas and aerosol detectors previously manufactured and distributed to general
 2327 licensees in accordance with a specific license issued by a state shall be considered
 2328 exempt under 3C.4213.1, provided that the device is labeled in accordance with the
 2329 specific license authorizing distribution of the generally licensed device, and provided
 2330 further that they meet the requirements of 3.12.34.

2331 **3C.4314** Radioactive drug capsules containing carbon-14 urea for "in vivo" diagnostic use for
 2332 humans.

2333 **3C.4314.1** Except as provided in paragraphs 3C.4314.2 and 3C.4314.3, any person is
 2334 exempt from the regulations in this part provided that such person receives, possesses,
 2335 uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi) carbon-14 urea
 2336 (allowing for nominal variation that may occur during the manufacturing process) each,
 2337 for "in vivo" diagnostic use for humans.

2338 **3C.4314.2** Any person who desires to use the capsules for research involving human
 2339 subjects shall apply for and receive a specific license pursuant to Part 7.

2340 **3C.4314.3** Nothing in this section relieves persons from complying with applicable FDA,
 2341 federal, and state requirements governing receipt, administration, and use of drugs.

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3C.15 Certain industrial devices

3C.15.1 Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in the Act and from the regulations in parts 3, 4, 5, 7, 10, 16, and 19 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by NRC under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

3C.15.2 Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under 3C.15.1, should apply for an NRC license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

Comment [JJ77]:
This provision is added consistent with the language of 10 CFR 30.22 which became effective in federal rule in October 2012.

NRC Compatibility = B
NRC RATS = 2012-4
NRC Cross-reference = 10 CFR 30.22

2365 **PART 3, SCHEDULE 3D: LIMITS FOR BROAD LICENSES (3.11)**

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Comment [JJ78]:

Page break inserted for formatting purposes to ensure Schedule 3D begins at the top of the page.

There are no changes to the content of Schedule 3D.

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**PART 3, SCHEDULE 3E: QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING
CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A
RELEASE (3.9.11)**

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Comment [JJ79]:

Page break inserted for formatting purposes to ensure Schedule 3E begins at the top of the page.

There are no changes to the content of Schedule 3E.

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PART 3, APPENDIX 3F: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

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Comment [JJ80]:
Page break inserted for formatting purposes to ensure Appendix 3F begins at the top of the page.
There are no changes to the content of Appendix 3F.

2379 **PART 3, APPENDIX 3G: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-**
2380 **GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR**
2381 **DECOMMISSIONING**

2382 * * *

2383 _____

2384 **EDITOR'S NOTES**

2385 6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule
2386 history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link
2387 that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the
2388 desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

2389 **History**

2390 *[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]*
2391

Comment [JJ81]:
Page break inserted for formatting purposes to ensure Appendix 3G begins at the top of the page.
There are no changes to the content of Appendix 3G.