



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: October 7, 2015

Subject: Request for Rulemaking Hearing
Proposed Amendments to 6 CCR 1007-1, Part 3, Licensing of Radioactive
Material with a request 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>

At the October 21, 2015 request for rulemaking, the Radiation Program requests that the Board of Health set a rulemaking hearing for 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(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.

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 process, 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.	<p>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.</p> <p>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.</p>

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-regulati		A commenter provided numerous documents	The information provided did not clearly address any specific

	on		pertaining to specific facilities in Colorado as well as facilities outside Colorado many of which are not regulated by the Department.	changes to the proposed rules. No change to the proposed rules was made as a result of the information submitted.
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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.

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 manufacturers, 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.13~~14.

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 concentrations
136 and in the form of depleted uranium, not more than 6.82 kg (15 pounds) of source material at any
137 one time for research, development, educational, commercial, or operational purposes in the
138 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., gaseous,
140 liquid, powder, etc.) at any one time. Any material processed by the general licensee that
141 alters the chemical or physical form of the material containing source material must be
142 accounted for as a dispersible form. A person authorized to possess, use, and transfer
143 source material under 3.5.1.1 may not receive more than a total of 7 kg (15.4 lb) of
144 uranium and thorium in any one calendar year. Persons possessing source material in
145 excess of these limits as of August 27, 2016, may continue to possess up to 7 kg (15.4
146 lb) of uranium and thorium at any one time for one year beyond this date, or until the
147 Department takes final action on a pending application submitted on or before August 27,
148 2017, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium
149 or thorium in any one calendar year until December 31, 2017, or until the Department
150 takes final action on a pending application submitted on or before August 27, 2017, for a
151 specific license for such material; and

152 3.5.1.2 No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person
153 authorized to possess, use, and transfer source material under 3.5.1.2 may not receive
154 more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A
155 person may not alter the chemical or physical form of the source material possessed
156 under 3.5.1.2 unless it is accounted for under the limits of 3.5.1.1; or

157 3.5.1.3 No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water,
158 at any one time. A person may not remove more than 70 kg (154 lb) of uranium from
159 drinking water during a calendar year under 3.5.1.3; or

160 3.5.1.4 No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of
161 determining the concentration of uranium and thorium contained within the material being
162 analyzed at any one time. A person authorized to possess, use, and transfer source
163 material under 3.5.1.4 may not receive more than a total of 70 kg (154 lb) of source
164 material in any one calendar year.

165 3.5.1.1 A person authorized to use or transfer source material, pursuant to this general license,
166 may not receive more than a total of 68.2 kg (150 pounds) of source material in any one
167 calendar year.

172
173 3.5.1.22 — Any persons who receives, possesses, uses or transfers source material in accordance
174 with pursuant to the general license in 3.5.1; are prohibited from administering source material, or

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 | the radiation therefrom, either externally or internally, to human beings except as may be
176 | authorized in a specific license.

Comment [JJ11]:
Language is added consistent with 10 CFR 40.22(b).

178 | 3.5.2.1 Is prohibited from administering source material, or the radiation therefrom, either
179 | externally or internally, to human beings except as may be authorized by the NRC in a
180 | specific license.

NRC Compatibility = B
NRC RATS = 2013-2

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.

NRC Compatibility = B
NRC RATS = 2013-2

183 | 3.5.2.2 Shall not abandon such source material. Source material may be disposed of as follows:
184 | (1) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form
185 | may be transferred each calendar year, by a person authorized to receive, possess, use,
186 | and transfer source material under this general license to persons receiving the material
187 | for permanent disposal. The recipient of source material transferred under the provisions
188 | of this paragraph is exempt from the requirements to obtain a license under this part to
189 | the extent the source material is permanently disposed. This provision does not apply to
190 | any person who is in possession of source material under a specific license issued under
191 | this chapter; or
192 | (2) In accordance with 4.33.

Comment [JJ13]: The mass limit applies to the mass of the U or Th only and not the material that contains the source material.

193 | 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,
194 | through 3.15.4.4, 3.22, 3.23, 4.40, 4.50, 4.52, and 10.5.1.

196 | 3.5.2.4 Shall respond to written requests from the Department to provide information relating to
197 | the general licensee within 30 calendar days of the date of the request, or other time
198 | specified in the request. If the person cannot provide the requested information within
199 | the allotted time, the person shall, within that same time period, request a longer period
200 | to supply the information by providing the Department a written justification for the
201 | request.

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.

203 | 3.5.2.5 Shall not export such source material except in accordance with a license issued by NRC
204 | pursuant to 10 CFR Part 110.

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.

206 | 3.5.3 Any person who receives, possesses, uses, or transfers source material in accordance with 3.5.1
207 | shall conduct activities so as to minimize contamination of the facility and the environment. When
208 | activities involving such source material are permanently ceased at any site, if evidence of
209 | significant contamination is identified, the general licensee shall notify the Department about such
210 | contamination and may consult with the Department as to the appropriateness of sampling and
211 | restoration activities to ensure that any contamination or residual source material remaining at the
212 | site where source material was used under this general license is not likely to result in exposures
213 | that exceed the limits in 4.61.2.

NRC Compatibility = B
NRC RATS = 2013-2

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

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.

214 | 3.5.24 Any persons who receives, possesses, uses, or transfers source material in accordance with
215 | pursuant to the general license granted issued in 3.5.1 are exempt from the provisions of Parts 4
216 | and 10 to the extent that such receipt, possession, use, and transfer are within the terms of
217 | such general license, except that such person shall comply with the provisions of 4.61.2 and 4.33;
218 | to the extent necessary to meet the provisions of 3.5.2.2 and 3.5.3 provided, however, that this
219 | exemption shall not be deemed to apply to any such person who is also in possession of source
220 | material under a specific license issued pursuant to this part. However, this exemption does not
221 | apply to any person who also holds a specific license issued under Part 3.

NRC Compatibility = C
NRC RATS = 2013-2

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.

223 | 3.5.5 No person may initially transfer or distribute source material to persons generally licensed under
224 | 3.5.1.1 or 3.5.1.2, or equivalent regulations of an Agreement State or NRC, unless authorized by
225 | a specific license issued in accordance with 3.22.6 or equivalent provisions of an Agreement
226 | State or NRC. This prohibition does not apply to analytical laboratories returning processed
227 | samples to the client who initially provided the sample. Initial distribution of source material to
228 | persons generally licensed under 3.5.1 before August 27, 2016, without specific authorization
229 | may continue for 1 year beyond this date. Distribution may also be continued until the
230 | Department takes final action on a pending application for license or license amendment to
231 | specifically authorize distribution submitted on or before August 27, 2017.

NRC Compatibility = B
NRC RATS = 2013-2

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

- 232 3.5.36 A general license is hereby issued authorizing the receipt of title to source material without regard
233 to quantity.
- 234 3.5.36.1 _____ This general license does not authorize any person to receive, possess, use, or
235 transfer source material.
- 236 3.5.47 A general license is hereby issued authorizing the possession of source material involved in
237 mining operations provided such operations meet the regulatory requirements of the Division of
238 Reclamation, Mining and Safety, Colorado Department of Natural Resources, or any successor
239 thereto, and, except as authorized in a specific license, such mining operations shall not refine or
240 process such ore.
- 241 3.5.58 Depleted Uranium in Industrial Products and Devices.
- 242 3.5.58.1 _____ A general license is hereby issued to receive, acquire, possess, use, or transfer,
243 in accordance with the provisions of 3.5.58.2, 3.5.58.3, and 3.5.58.4, and ~~3.5.5.5~~,
244 depleted uranium contained in industrial products or devices for the purpose of providing
245 a concentrated mass in a small volume of the product or device.
- 246 3.5.58.2 _____ The general license in 3.5.58.1 applies only to industrial products or devices
247 which have been manufactured either in accordance with a specific license issued to the
248 manufacturer of the products or devices pursuant to 3.12.13 or in accordance with a
249 specific license issued to the manufacturer by NRC or an Agreement State which
250 authorizes manufacture of the products or devices for distribution to persons generally
251 licensed by NRC or an Agreement State.
- 252 (1) Persons who receive, acquire, possess, or use depleted uranium pursuant to the
253 general license established by 3.5.58.1 shall file Department Form R-52,
254 "Registration Certificate - Use of Depleted Uranium Under General License", with
255 the Department.
- 256 (a) The form shall be submitted within 30 days after the first receipt or
257 acquisition of such depleted uranium.
- 258 (b) The general licensee shall furnish on Department Form R-52 the
259 following information and such other information as may be required by
260 that form:
- 261 (i) Name and address of the general licensee;
- 262 (ii) A statement that the general licensee has developed and will
263 maintain procedures designed to establish physical control over
264 the depleted uranium described in 3.5.58.1 and designed to
265 prevent transfer of such depleted uranium in any form, including
266 metal scrap, to persons not authorized to receive the depleted
267 uranium; and
- 268 (iii) Name and title, address, and telephone number of the individual
269 duly authorized to act for and on behalf of the general licensee in
270 supervising the procedures identified in 3.5.58.32(1)(b)(ii).
- 271 (2) The general licensee possessing or using depleted uranium under the general
272 license established by 3.5.58.1 shall report in writing to the Department any
273 changes in information furnished by him in Department Form R-52, "Registration
274 Certificate - Use of Depleted Uranium Under General License". The report shall
275 be submitted within 30 days after the effective date of such change.
- 276 3.5.85.43 A person who receives, acquires, possesses, or uses depleted uranium pursuant
277 to the general license established by 3.5.58.1:

- 278 (1) Shall not introduce such depleted uranium, in any form, into a chemical, physical,
279 or metallurgical treatment or process, except a treatment or process for repair or
280 restoration of any plating or other covering of the depleted uranium;
- 281 (2) Shall not abandon such depleted uranium;
- 282 (3) Shall transfer or dispose of such depleted uranium only by transfer in accordance
283 with the provisions of 3.22.
- 284 (a) In the case where the transferee receives the depleted uranium pursuant
285 to the general license established by 3.5.58.1, the transferor shall furnish
286 the transferee a copy of this regulation and a copy of Department Form
287 R-52.
- 288 (b) In the case where the transferee receives the depleted uranium pursuant
289 to a general license contained in NRC's or Agreement State's regulation
290 equivalent to 3.5.58.1, the transferor shall furnish the transferee a copy
291 of this regulation and a copy of Department Form R-52 accompanied by
292 a note explaining that use of the product or device is regulated by NRC
293 or Agreement State under requirements substantially the same as those
294 in this regulation;
- 295 (4) Within 30 days of any transfer, shall report in writing to the Department the name
296 and address of the person receiving the depleted uranium pursuant to such
297 transfer, and
- 298 (5) Shall not export such depleted uranium except in accordance with a license
299 issued by NRC pursuant to 10 CFR Part 110 (January 1, 2013~~15~~).

300 3.5.58.54 Any person receiving, acquiring, possessing, using, or transferring depleted uranium
301 pursuant to the general license established by 3.5.58.1 is exempt from the
302 requirements of Parts 4 and 10 with respect to the depleted uranium covered by that
303 general license.

304 **3.6 General Licenses ² - Radioactive Material Other Than Source Material.**

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

306 3.6.1 ~~Certain Devices and Equipment~~ Reserved.

307 ~~3.6.1.1 A general license is hereby issued to transfer, receive, acquire, own, possess, and use~~
308 ~~radioactive material incorporated in the following devices or equipment which have been~~
309 ~~manufactured, tested and labeled by the manufacturer in accordance with a specific~~
310 ~~license issued to the manufacturer by NRC for use pursuant to Section 31.3 of 10 CFR~~
311 ~~Part 31 (January 1, 2013).~~

312 (1) ~~Devices designed for use as static eliminators which contain, as a sealed source~~
313 ~~or sources, radioactive material consisting of a total of not more than 18.5 MBq~~
314 ~~(500 µCi) of polonium-210 per device.~~

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

319 ~~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,~~
320 ~~and 3.23, part 4³, part 10 and part 17.~~

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

322 3.6.2 Reserved.

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

323 3.6.3 Reserved.

324 3.6.4 Certain Measuring, Gauging or Controlling Devices.

325 3.6.4.1 A general license is hereby issued to commercial and industrial firms and to research,
326 educational and medical institutions, individuals in the conduct of their business, and
327 State or local government agencies to receive, acquire, possess, use or transfer, in
328 accordance with the provisions of 3.6.4.2, 3.6.4.3, and 3.6.4.4, radioactive material,
329 excluding special nuclear material, contained in devices designed and manufactured for
330 the purpose of detecting, measuring, gauging or controlling thickness, density, level,
331 interface location, radiation, leakage, or qualitative or quantitative chemical composition,
332 or for producing light or an ionized atmosphere.

333 3.6.4.2 The general license in 3.6.4.1 applies only to radioactive material contained in devices
334 which have been:

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

338 (a) The Department pursuant to 3.12.4 or

339 (b) By NRC or an Agreement State ⁴

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

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

344 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers
345 radioactive material in a device pursuant to the general license in 3.6.4.1:

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

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

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

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

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

363 (a) In accordance with the instructions provided by the labels; or

364 (b) By a person holding an applicable specific license from the Department,
365 NRC or an Agreement State to perform such activities;

- 366 (4) Shall maintain records showing compliance with the requirements of 3.6.4.3(2)
367 and 3.6.4.3(3).
- 368 (a) The records shall show the results of tests.
- 369 (b) The records also shall show the dates of performance of, and the names
370 of persons performing, testing, installation, servicing, and removal from
371 installation concerning the radioactive material, its shielding or
372 containment.
- 373 (c) Records of tests for leakage of radioactive material required by 3.6.4.3(2)
374 shall be maintained for 3 years after the next required leak test is
375 performed or until the sealed source is transferred or disposed of.
- 376 (d) Records of tests of the "on-off" mechanism and indicator required by
377 3.6.4.3(2) shall be maintained for 3 years after the next required test of
378 the "on-off" mechanism and indicator is performed or until the sealed
379 source is transferred or disposed of.
- 380 (e) Records which are required by 3.6.4.3(3) shall be maintained for a period
381 of 3 years from the date of the recorded event or until the device is
382 transferred or disposed of;
- 383 (5) Upon the occurrence of a failure of or damage to, or any indication of a possible
384 failure of or damage to, the shielding of the radioactive material or the "on-off"
385 mechanism or indicator, or upon the detection of 185 Bq (0.005 μ Ci) or more
386 removable radioactive material, shall immediately suspend operation of the
387 device and shall:
- 388 (a) Not operate the device until it has been repaired by the manufacturer or
389 other person holding an applicable specific license from the Department,
390 NRC or an Agreement State to repair such devices;
- 391 (b) Ensure that, if dispositioned, the device and any radioactive material
392 from the device is disposed of by transfer to a person authorized by an
393 applicable specific license to receive the radioactive material contained
394 in the device;
- 395 (c) Within 30 days, furnish to the Department a report containing a brief
396 description of the event and the remedial action taken; and
- 397 (d) In the case of detection of 185 Bq (0.005 microcurie) or more removable
398 radioactive material or failure of or damage to a source likely to result in
399 contamination of the premises or the environs, furnish to the Director of
400 the Hazardous Materials And Waste Management Division, within 30
401 days, a plan for ensuring that the premises and environs are acceptable
402 for unrestricted use.
- 403 (i) Under these circumstances, the criteria set out in 4.61.2,
404 "Radiological Criteria For Unrestricted Use," may be applicable,
405 as determined by the division on a case by case basis;
- 406 (6) Shall not abandon the device containing radioactive material;
- 407 (7) Shall not export the device except in accordance with 10 CFR Part 110 (January
408 1, 20~~15~~³¹⁵) and shall obtain written approval from NRC before transferring the
409 device to any other specific licensee not specifically identified in 3.6.4.3(8);
- 410 (8) Except as provided in 3.6.4.3(9), shall transfer or dispose of the device
411 containing radioactive material:

- 412 (a) Only by transfer to a specific licensee of the Department, NRC or an
- 413 Agreement State whose specific license authorizes receipt of the device;
- 414 and
- 415 (b) Within 30 days after transfer or export, shall furnish to the Department a
- 416 report containing:
 - 417 (i) Identification of the device by manufacturer's (or initial
 - 418 transferor's) name, model number and serial number;
 - 419 (ii) The name, address and license number of the person receiving
 - 420 the device;
 - 421 (iii) The date of the transfer;
 - 422 (iv) The identity of the radionuclide(s) present and activity present,
 - 423 by assay or calculation;
- 424 (c) ~~Comply with 10 CFR 31.5(c)(8)(iii), as applicable~~ Shall obtain written
- 425 Department approval before transferring the device to any other specific
- 426 licensee not specifically identified in 3.6.4.3(8). However, a holder of a
- 427 specific license may transfer a device for possession and use under its
- 428 own specific license without prior approval, if, the holder:-
 - 429 (i) Verifies that the specific license authorizes the possession and
 - 430 use, or applies for and obtains an amendment to the license
 - 431 authorizing the possession and use;
 - 432 (ii) Removes, alters, covers, or clearly and unambiguously
 - 433 augments the existing label (otherwise required by 3.6.4.3(1) of
 - 434 this part) so that the device is labeled in compliance with Part 4,
 - 435 Section 4.30; however the manufacturer, model number, and
 - 436 serial number must be retained;
 - 437 (iii) Obtains the manufacturer's or initial transferor's information
 - 438 concerning maintenance that would be applicable under the
 - 439 specific license (such as leak testing procedures); and
 - 440 (iv) Reports the transfer under 3.6.4.3(8)(b).
- 441 (9) Shall transfer the device to another general licensee only:
 - 442 (a) Where the device remains in use at a particular location.

443 In such case the transferor shall give the transferee a copy of this

444 regulation and any safety documents identified in the label on the device

445 and within 30 days of the transfer, report to the Department the

446 manufacturer's (or initial transferor's) name and model number and serial

447 number of device transferred, the identity of the radionuclide(s) present

448 and assayed or calculated activity present, the transferee's name and

449 mailing address for the location of use, and the name title, and phone

450 number of the responsible individual identified by the transferee in

451 accordance with 3.6.4.3(12) to have knowledge of and authority to take

452 actions to ensure compliance with the appropriate regulations and

453 requirements; or
 - 454 (b) Where the device is held in storage by an intermediate person in the
 - 455 original shipping container at its intended location of use prior to initial
 - 456 use by a general licensee; and

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

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

- 503 (v) Certification by the responsible representative of the general
504 licensee that the information concerning the device(s) has been
505 verified through a physical inventory and checking of label
506 information; and
- 507 (vi) Certification by the responsible representative of the general
508 licensee that they are aware of the requirements of the general
509 license.
- 510 (c) A general licensee holding devices meeting the criteria of 3.6.4.3(13) is
511 subject to the bankruptcy notification requirement in 3.15.5.
- 512 (d) Persons generally licensed by an Agreement State with respect to
513 devices meeting the criteria in paragraph 3.6.4.3(13) are not subject to
514 U.S. Nuclear Regulatory Commission registration requirements if the
515 devices are used in areas subject to NRC jurisdiction for a period less
516 than 180 days in any calendar year. The Commission will not request
517 registration information from such licensees.
- 518 (14) Shall report changes to the mailing address for the location of use (including
519 change in name of general licensee) to the director of the hazardous materials
520 and waste management division within 30 days of the effective date of the
521 change.
- 522 (a) For a portable device, a report of address change is only required for a
523 change in the device's primary place of storage.
- 524 (15) May not hold a device that is not in use for longer than 2 years.
- 525 (a) If a device with shutters is not being used, the shutter must be locked in
526 the closed position.
- 527 (b) The testing required by 3.6.4.3(2) need not be performed during the
528 period of storage only.
- 529 (c) However, when a device is put back into service or transferred to another
530 person, and has not been tested within the required test interval, the
531 device must be tested for leakage before use or transfer and the shutter
532 tested before use.
- 533 (d) A device kept in standby for future use is excluded from the two-year
534 time limit if the general licensee performs quarterly physical inventories
535 of the device while the device is in standby.
- 536 3.6.4.4 The general license in 3.6.4.1 does not authorize the manufacture of devices containing
537 radioactive material.
- 538 3.6.4.5 The general license provided in 3.6.4.1 is subject to the provisions of 1.4 through 1.9,
539 3.15, 3.22, 3.23 and Part 17.
- 540 3.6.5 Luminous Safety Devices for Aircraft.
- 541 3.6.5.1 A general license is hereby issued to receive, acquire, possess, and use tritium or
542 promethium-147 contained in luminous safety devices for use in aircraft, provided:
- 543 (1) Each device contains not more than 370 GBq (10 Ci) of tritium or 11.1 GBq (300
544 mCi) of promethium-147; and
- 545 (2) Each device has been manufactured, assembled or imported in accordance with
546 a specific license issued by NRC or each device has been manufactured or

- 547 assembled in accordance with the specifications contained in a specific license
548 issued by the Department or any Agreement State to the manufacturer or
549 assembler of such device pursuant to licensing requirements equivalent to those
550 in Section 32.53 of 10 CFR Part 32 (January 1, 20~~13~~15).
- 551 3.6.5.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to
552 the general license in 3.6.5.1 are exempt from the requirements of Parts 4 and 10 except
553 that they shall comply with the provisions of 4.51 and 4.52.
- 554 3.6.5.3 This general license does not authorize the manufacture, assembly, or repair of luminous
555 safety devices containing tritium or promethium-147.
- 556 3.6.5.4 This general license does not authorize the ownership, receipt, acquisition, possession or
557 use of promethium-147 contained in instrument dials.
- 558 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
559 Part 17.
- 560 3.6.6 Ownership of Radioactive Material.
- 561 3.6.6.1 A general license is hereby issued to own radioactive material without regard to quantity.
- 562 3.6.6.2 Notwithstanding any other provisions of this part, this general license does not authorize
563 the manufacture, production, transfer, receipt, possession or use of radioactive material.
- 564 3.6.7 Calibration and Reference Sources.
- 565 3.6.7.1 A general license is hereby issued to those persons listed below to own, receive, acquire,
566 possess, use, and transfer, in accordance with the provisions of 3.6.7.4 and 3.6.7.5,
567 americium-241 in the form of calibration or reference sources:
- 568 (1) Any person who holds a specific license issued by the Department which
569 authorizes him to receive, possess, use, and transfer radioactive material; and
- 570 (2) Any person who holds a specific license issued by NRC which authorizes him to
571 receive, possess, use, and transfer special nuclear material.
- 572 3.6.7.2 A general license is hereby issued to receive, possess, use, and transfer plutonium in the
573 form of calibration or reference sources in accordance with the provisions of 3.6.7.4 and
574 3.6.7.5 to any person who holds a specific license issued by the Department which
575 authorizes him to receive, possess, use, and transfer radioactive material.
- 576 3.6.7.3 A general license is hereby issued to own, receive, possess, use, and transfer radium
577 226 in the form of calibration or reference sources in accordance with the provisions of
578 3.6.7.4 and 3.6.7.5 to any person who holds a specific license issued by the Department
579 which authorizes him to receive, possess, use, and transfer radioactive material.
- 580 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
581 sources which have been manufactured in accordance with the specifications contained
582 in a specific license issued to the manufacturer or importer of the sources by NRC
583 pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70
584 (January 1, 20~~13~~15) or which have been manufactured in accordance with the
585 specifications contained in a specific license issued to the manufacturer by the
586 Department or any Agreement State pursuant to licensing requirements equivalent to
587 those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70
588 (January 1, 20~~13~~15).
- 589 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
590 provisions of 1.4 through 1.9, 3.15, 3.22, 3.23 and 3.24, and Parts 4 and 10. In addition,

591 persons who own, receive, acquire, possess, use, or transfer one or more calibration or
592 reference sources pursuant to these general licenses, shall:

- 593 (1) Not possess at any one time, at any one location of storage or use, more than
594 185 kBq (5 μ Ci) of americium-241, 185 kBq (5 μ Ci) of plutonium, or 185 kBq
595 (5 μ Ci) of radium-226 in such sources;
- 596 (2) Not receive, possess, use, or transfer such source unless the source, or the
597 storage container, bears a label which includes one of the following statements,
598 as appropriate, or a substantially similar statement which contains the
599 information called for in one of the following statements, as appropriate:
- 600 (a) The receipt, possession, use and transfer of this source, Model ____,
601 Serial No.___ are subject to a general license and the regulations of the
602 U.S. Nuclear Regulatory Commission or an Agreement State. Do not
603 remove this label.

604 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
605 (AMERICIUM-241) (PLUTONIUM) (RADIUM-226). ⁵ DO NOT TOUCH
606 RADIOACTIVE PORTION OF THIS SOURCE.

607

608 _____
609 Name of manufacturer or importer

609 ⁵ Showing only the name of the appropriate material.

- 610 (3) Not transfer, abandon, or dispose of such source except by transfer to a person
611 authorized by a license from the Department, NRC or an Agreement State to
612 receive the source;
- 613 (4) Store such source, except when the source is being used, in a closed container
614 adequately designed and constructed to contain americium-241, plutonium, or
615 radium-226 which might otherwise escape during storage; and
- 616 (5) Not use such source for any purpose other than the calibration of radiation
617 detectors or the standardization of other sources.

618 3.6.7.6 These general licenses do not authorize the manufacture of calibration or reference
619 sources containing americium-241, plutonium or radium-226.

620 3.6.8 Reserved.

621 3.6.9 General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing.

622

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

625 3.6.9.1 A general license is hereby issued to any physician, veterinarian, clinical laboratory or
626 hospital to receive, acquire, possess, transfer or use, for any of the following stated tests,
627 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
628 following radioactive materials in prepackaged units for use in *in vitro* clinical or
629 laboratory tests not involving internal or external administration of radioactive material, or
630 the radiation therefrom, to human beings or animals:

- 631 (1) Carbon-14, in units not exceeding 370 kBq (10 μ Ci) each;
- 632 (2) Cobalt-57, in units not exceeding 370 kBq (10 μ Ci) each;
- 633 (3) Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 μ Ci) each;

- 634 (4) Iodine-125, in units not exceeding 370 kBq (10 µCi) each;
- 635 (5) Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85
636 kBq (0.05 µCi) of iodine-129 and 185 Bq (0.005 µCi) of americium-241 each;
- 637 (6) Iodine-131, in units not exceeding 370 kBq (10 µCi) each;
- 638 (7) Iron-59, in units not exceeding 740 kBq (20 µCi) each; or
- 639 (8) Selenium-75, in units not exceeding 370 kBq (10 µCi) each.
- 640 3.6.9.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant
641 to the general license established by 3.6.9.1 until the person has filed Department Form
642 R-27, "Certificate - *In Vitro* Testing with Radioactive Material Under General License",
643 with the Department and received from the Department a validated copy of Department
644 Form R-27 with certification number assigned. The physician, veterinarian, clinical
645 laboratory or hospital shall furnish on Department Form R-27 the following information
646 and such other information as may be required by that form:
- 647 (1) Name and address of the physician, veterinarian, clinical laboratory or hospital;
- 648 (2) The location of use; and
- 649 (3) A statement that the physician, veterinarian, clinical laboratory or hospital has
650 appropriate radiation measuring instruments to carry out *in vitro* clinical or
651 laboratory tests with radioactive material as authorized under the general license
652 in 3.6.9.1 and that such tests will be performed only by personnel competent in
653 the use of such instruments and in the handling of the radioactive material.
- 654 3.6.9.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the
655 general license established by 3.6.9.1 shall comply with the following requirements.
- 656 (1) The general licensee shall not possess at any one time, pursuant to the general
657 license in 3.6.9.1, at any one location of storage or use, a total amount of iodine
658 125, iodine 131, selenium 75, iron 59, and/or cobalt 57 in excess of 7.4 MBq (200
659 µCi).
- 660 (2) The general licensee shall store the radioactive material, until used, in the
661 original shipping container or in a container providing equivalent radiation
662 protection.
- 663 (3) The general licensee shall use the radioactive material only for the uses
664 authorized by 3.6.9.1.
- 665 (4) The general licensee shall not transfer the radioactive material to a person who is
666 not authorized to receive it pursuant to a license issued by the Department, NRC
667 or any Agreement State nor transfer the radioactive material in any manner other
668 than in the unopened, labeled shipping container as received from the supplier.
- 669 (5) The general licensee shall dispose of the Mock Iodine 125 reference or
670 calibration sources described in 3.6.9.1(5) as required by 4.33.
- 671 3.6.9.4 The general licensee shall not receive, acquire, possess, or use radioactive material
672 pursuant to 3.6.9.1:
- 673 (1) Except as prepackaged units which are labeled in accordance with the provisions
674 of an applicable specific license issued pursuant to 3.12.8 or in accordance with
675 the provisions of a specific license issued by NRC or any Agreement State which
676 authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14,

- 677 hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to
678 persons generally licensed under 3.6.9 or its equivalent; and
- 679 (2) Unless one of the following statements, as appropriate, or a substantially similar
680 statement which contains the information called for in one of the following
681 statements, appears on a label affixed to each prepackaged unit or appears in a
682 leaflet or brochure which accompanies the package:
- 683 (a) This radioactive material shall be received, acquired, possessed, and
684 used only by physicians, veterinarians, clinical laboratories or hospitals
685 and only for *in vitro* clinical or laboratory tests not involving internal or
686 external administration of the material, or the radiation therefrom, to
687 human beings or animals. Its receipt, acquisition, possession, use, and
688 transfer are subject to the regulations and a general license of the U.S.
689 Nuclear Regulatory Commission or an Agreement State.
- 690 _____
- 691 Name of manufacturer
- 692 3.6.9.5 The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive
693 material under the general license of 3.6.9.1 shall report in writing to the Department, any
694 changes in the information furnished by him in the "Certificate - *In Vitro* Testing with
695 Radioactive Material Under General License", Department Form R-27. The report shall
696 be furnished within 30 days after the effective date of such change.
- 697 3.6.9.6 Any person using radioactive material pursuant to the general license of 3.6.9.1 is
698 exempt from the requirements of Part 4 and 10 with respect to radioactive material
699 covered by that general license, except that such persons using the Mock Iodine-125
700 described in 3.6.9.1(5) shall comply with the provisions of 4.33, 4.51 and 4.52.
- 701 3.6.10 Ice Detection Devices.
- 702 3.6.10.1 A general license is hereby issued to receive, acquire, possess, use, and transfer
703 strontium-90 contained in ice detection devices, provided each device contains not more
704 than 1.85 MBq (50 μ Ci) of strontium-90 and each device has been manufactured or
705 imported in accordance with a specific license issued by NRC or each device has been
706 manufactured in accordance with the specifications contained in a specific license issued
707 by the Department or an Agreement State to the manufacturer of such device pursuant to
708 licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 (January
709 1, 2015).
- 710 3.6.10.2 Persons who own, receive, acquire, possess, use, or transfer strontium-90
711 contained in ice detection devices pursuant to the general license in 3.6.10.1:
- 712 (1) Shall, upon occurrence of visually observable damage, such as a bend or crack
713 or discoloration from overheating to the device, discontinue use of the device
714 until it has been inspected, tested for leakage and repaired by a person holding a
715 specific license from NRC or an Agreement State to manufacture or service such
716 devices; or shall dispose of the device pursuant to the provisions of 4.33;
- 717 (2) Shall assure that all labels affixed to the device at the time of receipt, and which
718 bear a statement which prohibits removal of the labels, are maintained thereon;
719 and
- 720 (3) Are exempt from the requirements of Parts 4 and 10 except that such persons
721 shall comply with the provisions of 4.33, 4.51, and 4.52.
- 722 3.6.10.3 This general license does not authorize the manufacture, assembly, disassembly
723 or repair of strontium-90 in ice detection devices.

724 3.6.10.4 This general license is subject to the provisions of 1.4 through 1.9, 3.15, 3.22,
725 3.23 and Part 17.

726 **ADDITIONAL EXEMPTIONS**

727 **3.7 Reserved Carriers**

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

733 **SPECIFIC LICENSES**

734 **3.8 Filing An Application for A Specific License.**

735 3.8.1 Applications for specific licenses shall be filed on a form prescribed by the Department.

736 3.8.2 The Department may at any time after the filing of the original application, and before the
737 expiration of the license, require further statements in order to enable the Department to
738 determine whether the application should be granted or denied or whether a license should be
739 modified or revoked.

740 3.8.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act
741 for and on the applicant's or licensee's behalf.

742 3.8.4 An application for a license may include a request for a license authorizing one or more activities.

743 3.8.5 In the application, the applicant may incorporate by reference information contained in previous
744 applications, statements, or reports filed with the Department provided such references are clear
745 and specific.

746 3.8.6 Applications and documents submitted to the Department may be made available for public
747 inspection except that the Department may withhold any document or part thereof from public
748 inspection pursuant to 24-72-204, CRS.

749 3.8.7 Pre-licensing Construction

750 3.8.7.1 An application for a license, or to amend or renew an existing license, for (1) source
751 material milling, (2) commercial waste storage, treatment or disposal by incineration, (3)
752 transfer for disposal of wastes from treatment or incineration, (4) commercial waste
753 disposal by land burial or by underground injection, or the (5) conduct of any other activity
754 within the licensing authority of the Department which the Department determines will
755 significantly affect the radiological quality of the human environment, shall be filed with
756 the Department at least nine (9) months prior to the anticipated commencement of
757 construction of the plant or facility in which the activity will be conducted or in accordance
758 with the requirements of Part 18 if applicable, and shall be accompanied by the
759 environmental ~~reportassessment~~ required by 3.8.8, unless an exemption from the
760 requirement of furnishing such ~~a reportassessment~~ has been obtained from the
761 Department.

762 3.8.7.2 No construction shall be commenced until the license has been issued.

763 ~~3.8.7.3 For the purpose of 3.8.7 the terms "construction" and "commencement of construction",~~
764 ~~are defined in Part 1. 1.2. means any clearing of land, excavation or other substantial~~
765 ~~action related to a proposed activity for specific licensing that would adversely affect the~~
766 ~~natural environment of a site; this term does not include changes desirable for the~~
767 ~~temporary use of the land for public recreational uses, limited borings to determine site~~
768 ~~characteristics as necessary for environmental assessment of other pre-construction~~

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

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).

769 | ~~monitoring to establish background information related to the suitability of a site, or to the~~
770 | ~~protection of environmental values.~~

771 | 3.8.8 Environmental ~~Impact~~ Assessment

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.

772 | 3.8.8.1 In the case of an application for a license, or to amend or renew an existing license, for
773 | (1) source material milling, (2) commercial waste storage, treatment or disposal by
774 | incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste
775 | disposal by land burial or by underground injection, or for (5) the conduct of any other
776 | activity which will affect the quality of the human environment by reason of exposure to
777 | radiation, before "commencement of construction", as defined in 3.8.7.3, of the plant or
778 | facility in or at which the activity will be conducted, or in case of a renewal of such a
779 | license, the applicant shall submit all information required under these regulations and
780 | such other material as the Department may deem necessary.

781 | (1) Such information shall include the environmental ~~report~~assessment and other
782 | information required by 3.8.8.2 to be submitted to assist the Department in the
783 | evaluation of the short-term and long-range environmental impact of the project
784 | and activity so that the Department may weigh environmental, economic,
785 | technical, and other benefits against environmental costs, while considering
786 | 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).

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

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

798 | 3.8.8.2 An environmental ~~report~~assessment shall be required of the applicant and shall contain
799 | all information deemed necessary by the Department as required by the Act.

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

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

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

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

814 | 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
815 | radioactive material in the form of a sealed source or in a device that contains the sealed source
816 | ~~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

- 817 3.8.9.1 Identify the source or device by manufacturer and model number as registered with the
818 NRC under 10 CFR 32.210 or with an Agreement State, or for a source or a device
819 containing radium-226 or accelerator produced radioactive material with an Agreement
820 State under provisions comparable to 10 CFR 32.210; or
- 821 3.8.9.2 Contain the information ~~contained~~identified in ~~10 CFR 32.210(e)~~3.12.14.3; or
- 822 3.8.9.3 For sources or devices ~~containing naturally occurring or accelerator produced radioactive~~
823 ~~material~~ manufactured ~~before prior to November 30, 2007~~ October 23, 2012 that are not
824 registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which
825 the applicant is unable to provide all categories of information specified in ~~10 CFR~~
826 ~~32.210(e)~~3.12.14.3, the ~~applicant~~application must ~~provide~~include:
- 827 (1) All available information identified in ~~10 CFR 32.210(e)~~3.12.14.3 concerning the
828 source, and, if applicable, the device; and
- 829 (2) Sufficient additional information to demonstrate that there is reasonable
830 assurance that the radiation safety properties of the source or device are
831 adequate to protect health and minimize danger to life and property. Such
832 information must include a description of the source or device, a description of
833 radiation safety features, the intended use and associated operating experience,
834 and the results of a recent leak test.
- 835 3.8.9.4 For sealed sources and devices allowed to be distributed without registration of safety
836 information in accordance with 3.12.14.7(1), the applicant may supply only the
837 manufacturer, model number, and radionuclide and quantity.
- 838 3.8.9.5 If it is not feasible to identify each sealed source and device individually, the applicant
839 may propose constraints on the number and type of sealed sources and devices to be
840 used and the conditions under which they will be used, in lieu of identifying each sealed
841 source and device.
- 842 3.8.10 An application from a medical facility, educational institution, or Federal facility to produce
843 Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees
844 in its consortium authorized for medical use under Part 7 of these regulations or equivalent
845 Agreement State requirements shall include:
- 846 3.8.10.1 A request for authorization for the production of PET radionuclides or evidence of
847 an existing license issued under this Part or Agreement State requirements for a PET
848 radionuclide production facility within its consortium from which it receives PET
849 radionuclides.
- 850 3.8.10.2 Evidence that the applicant is qualified to produce radioactive drugs for medical
851 use by meeting one of the criteria in 3.12.10.1(2).
- 852 3.8.10.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if
853 the applicant is a pharmacy, and documentation that each individual meets the
854 requirements of an authorized nuclear pharmacist as specified in 3.12.10.2(2).
- 855 3.8.10.4 Information identified in 3.12.10.1(3) on the PET drugs to be noncommercially
856 transferred to members of its consortium.

857 3.9 General Requirements for the Issuance of Specific Licenses.

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

Comment [JJ26]: Language added for clarity.

- 859 3.9.1 The applicant is qualified by reason of training and experience to use the material in question for
860 the purpose requested in accordance with these regulations in such a manner as to minimize
861 danger to public health and safety or property;

862 3.9.2 The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger
 863 to public health and safety or property and the applicant's facilities are permanently located in
 864 Colorado;

865 3.9.3 The issuance of the license will not be inimical to the health and safety of the public;

866 3.9.4 The applicant satisfies any applicable special requirements in 3.10, 3.11, or 3.12 parts 3, 5, 7, 16,
 867 19, and 22; and

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

868 3.9.5 The applicant has established Department-approved financial assurance warranties in
 869 accordance with the following requirements.

870 3.9.5.1 A signed executed original copy of each warranty required by this part shall be furnished
 871 to and approved by the Department prior to the issuance of a new license, or any
 872 amendment or renewal of an existing license.

873 DECOMMISSIONING WARRANTY

874 3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a
 875 dollar amount determined by the agency as necessary to protect public health and safety,
 876 to ensure corrective action during operation, to ensure decontamination and
 877 decommissioning of a facility and disposal of radioactive materials in the event of
 878 abandonment, default or inability of the licensee to meet the requirements of the Act,
 879 these regulations, or the license.

880 3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

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

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

885 (a) Greater than 10^3 times the applicable quantity of Schedule 3B in
 886 unsealed form. For a combination of isotopes if R divided by 10^3 is
 887 greater than 1 (unity rule), where R is defined here as the sum of the
 888 ratios of the quantity of each isotope to the applicable value in Schedule
 889 3B.

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

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

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

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

900 (5) Radioactive waste disposal licensees;

901 (6) Source material milling licensees;

902 (7) Ore refineries; and

- 903 (8) Other persons with, or applicants for, a specific license as determined by the
904 agency.
- 905 3.9.5.4 Acceptable Financial Assurance Methods.
- 906 (1) Financial assurance warranties shall contain provisions which are acceptable to
907 the Department for:
- 908 (a) Defining the amount and term of the warranty;
- 909 (b) Providing written notification to the Department by the warrantor at least
910 ninety (90) days prior to cancellation, termination, or revocation of the
911 warranty; and
- 912 (c) Converting the warranty into cash upon forfeiture of the warranty, and
- 913 (2) Financial assurance warranties shall be in the form of a cash deposit,
914 prepayment of a trust, escrow account, government fund, certificate of deposit, or
915 deposit of government securities.
- 916 (a) Prepayment is the deposit prior to the start of operation into an account
917 segregated from licensee assets and outside the licensee's
918 administrative control of cash or liquid assets such that the amount of
919 funds would be sufficient to pay decommissioning costs; or
- 920 (3) Financial assurance warranties which involve a guarantee method to ensure that
921 costs will be paid should the licensee default shall be in a form as described
922 below:
- 923 (a) A bond issued by a fidelity or surety company consistent with the
924 provisions of Section 25-11-110(6)(b)(l), CRS;
- 925 (b) An irrevocable "letter of credit" or "line of credit" issued by a recognized
926 financial institution whose financial condition and commitment are
927 established to the satisfaction of the Department;
- 928 (c) For a decommissioning warranty, a guarantee of funds by the applicant,
929 licensee, or parent company which satisfies the requirements listed
930 below. However, this self-guarantee shall not apply to uranium or thorium
931 milling licensees.
- 932 (i) The Department may accept a parent company guarantee of
933 funds for decommissioning costs based upon a financial test of
934 the parent company and a written guarantee as contained in
935 Appendix 3F.
- 936 (ii) The Department may accept an applicant or licensee guarantee
937 of funds for decommissioning costs based upon a financial test
938 of the applicant or licensee and a written guarantee as contained
939 in Appendix 3G.
- 940 (iii) A guarantee by the applicant, licensee, or parent company may
941 not be used in combination with other financial methods to
942 satisfy the requirements of this section.
- 943 (iv) A guarantee by the applicant or licensee may not be used in any
944 situation where the applicant or licensee has a parent company
945 holding majority control of the voting stock of the company; or

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

992 that may be incurred in successfully revoking, foreclosing, or realizing the
993 decommissioning warranties established by the licensee in accordance with Part
994 3.

995 3.9.5.6 The licensee shall provide in writing to the Department, no later than June 30th of each
996 calendar year, an annual report demonstrating proof of the value of existing financial
997 warranties and any licensee-proposed changes to the financial assurance warranties,
998 including updated decommissioning funding plans, cost estimates, or the type of
999 warranty. The annual report shall describe any changes in operations, estimated costs, or
1000 any other circumstances that may affect the amount of the required financial assurance
1001 warranties, including any increased or decreased costs attributable to inflation.

1002 3.9.5.7 Each licensee's financial assurance warranties shall be subject to review annually by the
1003 Department to assure the continued adequacy of each warranty. Public notice of the
1004 submittal of the licensee's annual report shall be posted on the Department's web site
1005 and published by the licensee in the local paper of general circulation. Any person may
1006 submit written comments to the Department concerning the adequacy of any financial
1007 assurance warranties. The act of submitting such comments does not provide a right to
1008 administrative appeal concerning the financial assurance warranties.

1009 3.9.5.8 The Department will determine if the licensee must adjust the amount of the warranty to
1010 account for increases or decreases in cost estimates resulting from:

1011 (1) inflation or deflation;

1012 (2) eChanges in engineering plans;

1013 (3) aActivities performed;

1014 (4) Spills, leakage or migration of radioactive material producing additional contamination
1015 in onsite subsurface material that must be remediated to meet applicable remediation
1016 criteria;

1017 (5) Waste inventory increasing above the amount previously estimated;

1018 (6) Waste disposal costs increasing above the amount previously estimated;

1019 (7) Facility modifications;

1020 (8) Changes in authorized quantities of radioactive material possession limits; or

1021 (9) Actual remediation costs that exceed the previous cost estimate;

1022 (10) Onsite disposal; and

1023 (11) eChanges in any other conditions affecting disposal, decontamination, and
1024 decommissioning costs.

1025 3.9.5.9 Regardless of whether reclamation (disposal, decontamination and decommissioning) is
1026 phased through the life of the licensed operations or takes place at the end of
1027 operations, an appropriate portion of surety liability must be retained until final
1028 compliance with the reclamation plan is determined by the Department.

1029 3.9.5.10 The appropriate portion of surety liability retained until final compliance with the
1030 reclamation plan is determined will be at least sufficient at all times to cover the costs of
1031 decommissioning and reclamation of the areas that are expected to be disturbed before
1032 the next license renewal. The term of the surety mechanism must be open ended,
1033 unless it can be demonstrated that another arrangement would provide an equivalent
1034 level of assurance. This assurance would be provided with a surety instrument which is
1035 written for a specified time (e.g., 5 years) and which must be automatically renewed

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

1036 unless the surety notifies the beneficiary (the NRC or the Department) and the principal
1037 (the licensee) with reasonable time (e.g., 90 days) before the renewal date of their
1038 intention not to renew. In such a situation the surety requirement still exists and the
1039 licensee would be required to submit an acceptable replacement surety within a brief
1040 time to allow at least 60 days for the regulatory agency to collect.

1041 3.9.5.11 Proof of forfeiture must not be necessary to collect the surety. In the event the licensee
1042 can not provide an acceptable replacement surety within the required time, the surety
1043 shall be automatically collected before its expiration. The surety instrument must
1044 provide for collection of the full face amount immediately on demand without reduction
1045 for any reason, except for trustee fees and expenses provided for in a trust agreement,
1046 and that the surety will not refuse to make full payment. The conditions described
1047 previously would have to be clearly stated on any surety instrument which is not open
1048 ended, and must be agreed to by all parties. Financial surety arrangements generally
1049 acceptable to the Department are:

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

1050 (1) Trust funds;

1051 (2) Surety bonds;

1052 (3) Irrevocable letters of credit; and

1053 (4) Combinations of the financial surety arrangements or other types of arrangements as
1054 may be approved by the Department. If a trust is not used, then a standby trust must
1055 be set up to receive funds in the event the NRC or Department exercises its right to
1056 collect the surety. The surety arrangement and the surety or trustee, as applicable,
1057 must be acceptable to the Department. Self insurance, or any arrangement which
1058 essentially constitutes self insurance (e.g., a contract with a State or Federal
1059 agency), will not satisfy the surety requirement because this provides no additional
1060 assurance other than that which already exists through license requirements.

1061 3.9.5.12(1) With the approval of the Department, a licensee may reduce the amount of a
1062 decommissioning warranty as decommissioning activities are completed in accordance
1063 with an approved decommissioning plan and/or to reflect current site conditions and
1064 license authorizations.

1065 3.9.5.13(2) The licensee shall have sixty days after the date of written notification by the
1066 Department of a required adjustment to establish a warranty fulfilling all new
1067 requirements unless granted an extension by the Department. If the licensee disputes the
1068 amount of the required financial assurance warranties, the licensee may request a
1069 hearing to be conducted in accordance with section 24-4-105, CRS.

1070 3.9.5.14(3) If the licensee requests a hearing, no new ~~classified material, as that term is~~
1071 ~~defined in 1.2.2, ore or other radioactive material~~ may be brought on site for processing
1072 or disposal and no ~~classified-new radioactive~~ material may be processed until the
1073 licensee's dispute over the financial assurance warranty is resolved, unless the licensee
1074 posts a bond in a form approved by the Department equal to the amount in dispute.

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)

1075 ~~3.9.5.9~~ ~~Regardless of whether the disposal, decontamination and decommissioning work is~~
1076 ~~phased through the life of the licensed operations or takes place at the end of the~~
1077 ~~operation, an appropriate and adequate decommissioning warranty shall be maintained~~
1078 ~~in good standing by the licensee until termination of the license or as otherwise~~
1079 ~~authorized by the Department.~~

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.

1080 LONG-TERM CARE WARRANTY

Comment [JJ34]: Header added for clarity.

1081 3.9.5.105 In addition to the decommissioning warranty required by 3.9.5.2, the Department
1082 may require any licensee to provide a long-term care warranty if the licensed facility will
1083 remain a disposal site for radioactive materials subsequent to the termination of the
1084 license, or the license will be terminated using criteria in 4.61.3 or 4.61.4.

- 1085 | (1) Except as provided in 3.9.5.159(2), the following specific licensees are required
1086 | to provide long-term care warranties:
- 1087 | (a) Radioactive waste disposal licensees;
- 1088 | (b) Commercial radioactive waste handling and/or packaging licensees;
- 1089 | (c) Source material milling licensees; and
- 1090 | (d) Formerly U.S. Atomic Energy Commission or U.S. Nuclear Regulatory
1091 | Commission-licensed facilities;
- 1092 | (2) A long-term care warranty is not required for a licensee identified in 3.9.5.159(1)
1093 | if the disposition of radioactive materials by the licensee is made in such a
1094 | manner as the Department determines does not require long-term monitoring
1095 | and maintenance of the site.
- 1096 | (3) The long-term care warranty shall be in a form as described in 3.9.5.4.
- 1097 | (4) The amount of funds to be provided by such long-term care warranties shall be
1098 | based on Department-approved cost estimates and ~~shall~~**must** be enough that
1099 | with an assumed ~~six~~**one** percent annual real interest rate, the annual interest
1100 | earnings will be sufficient to cover the annual costs of site surveillance, including
1101 | reasonable administrative costs incurred, in perpetuity, subsequent to the
1102 | termination of the license.
- 1103 | (a) For each source material mill licensee, the long-term care warranty must
1104 | have a minimum value equivalent to \$250,000 in 1978 dollars.
- 1105 | (i) The value of the long-term care warranty shall be adjusted
1106 | annually to recognize inflation.
- 1107 | (ii) The inflation rate to be used for this adjustment is that indicated
1108 | by the change in the consumer price index published by the U.S.
1109 | Department of Labor, Bureau of Labor Statistics.
- 1110 | (iii) The Department may use other indicators of the inflation rate if
1111 | reasonable; provided, however, that the license shall not
1112 | terminate unless the amount of the long-term care warranty is
1113 | acceptable to the licensing agency and site caretaker.
- 1114 | (b) Cost estimates for facilities and sites requiring long-term care
1115 | subsequent to license termination are to be based on the final disposition
1116 | of wastes such that ongoing active maintenance is not necessary to
1117 | preserve isolation.
- 1118 | (i) It is expected that, as a minimum, annual site inspections shall
1119 | be conducted to confirm the integrity of the stabilized waste
1120 | systems and to determine the need, if any, for maintenance
1121 | and/or monitoring.
- 1122 | (ii) Cost estimates shall be adjusted if more frequent site inspections
1123 | are required based on an evaluation of a particular site.
- 1124 | (c) For sites decommissioned in accordance with the provisions of 4.61.3 or
1125 | 4.61.4, cost estimates for long-term care subsequent to license
1126 | termination must be sufficient to enable the Department, a responsible
1127 | government agency, or an independent third party to:

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.

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

- 1128 (i) Perform periodic site inspections no less frequently than each
1129 five years;
- 1130 (ii) Assure the continuation of institutional controls; and
- 1131 (iii) Assume responsibilities and carry out any necessary control and
1132 maintenance of the site. Cost estimates shall be adjusted if more
1133 frequent site inspections are required based on an evaluation of
1134 a particular site and the institutional controls established for that
1135 site.
- 1136 (5) Whenever the Department determines that a licensee's disposal,
1137 decommissioning and decontamination requirements have been satisfied,
1138 provisions shall be made for transferring custody of the site and the long-term
1139 care warranty funds for that license in accordance with the act.
- 1140 (a) If the value of the long-term care warranty funds exceeds the amount
1141 required by the government agency overseeing the long-term care of the
1142 site, then all such excess amounts shall be returned to the licensee.

1143 3.9.6 Decommissioning Funding Plan Required.

1144 3.9.6.1 Each applicant for and holder of a license authorizing the possession and use unsealed
1145 radioactive materials with half-life greater than 120 days and in quantities greater than 10^5
1146 times the applicable quantity of Schedule 3B, shall establish a Department-approved
1147 decommissioning funding plan to assure the availability of funds for decommissioning
1148 activities conducted over the life of the licensed facility. 370 Bq (0.01 μ Ci) shall be used
1149 as the Schedule 3B value for any alpha emitting radionuclide not listed in Schedule 3B, or
1150 mixtures of alpha emitters of unknown composition. A decommissioning funding plan is
1151 also required for licensees authorized a combination of isotopes if R divided by 10^5 is
1152 greater than 1 (unity rule), where R is defined in 3.9.5.3(2)(a).

1153 3.9.6.2 Each holder of, or applicant for, any specific license authorizing the possession and use
1154 of sealed sources or plated foils of half-life greater than 120 days and in quantities
1155 greater than 10^{12} times the applicable quantity in Schedule 3B shall establish a
1156 Department-approved decommissioning funding plan to assure the availability of funds
1157 for decommissioning activities conducted over the life of the licensed facility. 370 Bq
1158 (0.01 μ Ci) shall be used as the Schedule 3B value for any alpha emitting radionuclide not
1159 listed in Schedule 3B, or mixtures of alpha emitters of unknown composition. The
1160 decommissioning funding plan is also required for licensees authorized for a combination
1161 of isotopes if R divided by 10^{12} is greater than 1 (unity rule), where R is defined as in
1162 3.9.5.3(2)(a).

1163 3.9.6.3 Waste collectors and waste processors, as defined in Part 4, Appendix D, shall establish
1164 an agency-approved decommissioning funding plan to assure the availability of funds for
1165 decommissioning activities conducted over the life of the licensed facility.

1166 (1) The decommissioning funding plan must include the cost of disposal of the
1167 maximum radioactivity (becquerel or curie) of radioactive material permitted by
1168 the license, and the cost of disposal of the maximum quantity, by volume, of
1169 radioactive material that could be present at the licensee's facility at any time, in
1170 addition to the cost to remediate the licensee's site to meet the license
1171 termination criteria of Part 4.

1172 3.9.6.4 Each decommissioning funding plan must be submitted for review and approval by the
1173 Department and must contain:

1174 (1) A detailed cost estimate for decommissioning, in an amount reflecting:

- 1175 (a) The cost of an independent contractor to perform all decommissioning
1176 activities;
- 1177 (b) The cost of meeting the 4.61.2 criteria for unrestricted use, provided that,
1178 if the applicant or licensee can demonstrate its ability to meet the
1179 provisions of 4.61.3 for restricted use, the cost estimate may be based
1180 on meeting the 4.61.3 restricted use criteria;
- 1181 (c) The volume of onsite subsurface material containing residual
1182 radioactivity that will require remediation to meet the criteria for license
1183 termination; and
- 1184 (d) An adequate contingency factor.
- 1185 (i) Identification of and justification for using the key assumptions
1186 contained in the detailed cost estimate;
- 1187 (ii) A description of the method of assuring funds for
1188 decommissioning as required in this section, including means for
1189 adjusting cost estimates and associated funding levels
1190 periodically over the life of the facility.
- 1191 (iii) A certification by the licensee that financial assurance for
1192 decommissioning has been provided in the amount of the cost
1193 estimate for decommissioning; and
- 1194 (iv) A signed original, or if permitted, a copy, of the financial
1195 instrument obtained to satisfy the requirements of this section
1196 (unless a previously submitted and accepted financial instrument
1197 continues to cover the cost estimate for decommissioning).

1198 3.9.6.5 At the time of license renewal and at intervals not to exceed three years, the
1199 decommissioning funding plan must be resubmitted with adjustments as necessary to
1200 account for changes in costs and the extent of contamination. If the amount of financial
1201 assurance will be adjusted downward, this can not be done until the updated
1202 decommissioning funding plan is approved. The decommissioning funding plan must
1203 update the information submitted with the original or prior approved plan, and must
1204 specifically consider the effect of the following events on decommissioning costs:

- 1205 (1) Spills of radioactive material producing additional residual radioactivity in onsite
1206 subsurface material;
- 1207 (2) Waste inventory increasing above the amount previously estimated;
- 1208 (3) Waste disposal costs increasing above the amount previously estimated;
- 1209 (4) Facility modifications;
- 1210 (5) Changes in authorized possession limits;
- 1211 (6) Actual remediation costs that exceed the previous cost estimate;
- 1212 (7) Onsite disposal; and
- 1213 (8) Use of a settling pond.

1214 3.9.6.6 The decommissioning funding plan must also include a certification by the licensee that
1215 funding for decommissioning activities has been provided for in the amount of the cost
1216 estimate for decommissioning.

- 1217 (1) For an applicant, this certification may state that the appropriate assurance will
1218 be obtained after the application has been approved and the license issued, but
1219 prior to the receipt or possession of radioactive material.
- 1220 (2) A signed original of the financial instrument shall be submitted to the Department.

1221 3.9.7 In the case of an application for a license for (1) source material milling, (2) commercial waste
1222 storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration,
1223 (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of
1224 any other activity which the Department determines will significantly affect the quality of the
1225 human environment, the Department, before commencement of construction, on the basis of
1226 information filed and evaluations made, has concluded, after weighing the environmental,
1227 economic, technical and other benefits against environmental costs and considering available
1228 alternatives, that the action called for is the issuance of the proposed license with any appropriate
1229 conditions to protect environmental values.

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 SSRRCR Part C (2010) which pre-dates the revision to 40.32(e).

NRC Compatibility = H&S

1230 3.9.7.1 ~~Such determination shall be made before c~~Commencement of construction prior to this
1231 conclusion is grounds for denial of a license to possess and use source and byproduct
1232 material of in the plant or facility, ~~in which the activity will be conducted and based on~~
1233 ~~information filed and evaluation made pursuant to 3.8.8.~~

1234 3.9.8 Commencement of construction prior to the issuance of a license, or of an amendment or renewal
1235 thereof, or of an exemption under the requirements of 3.8.7, may be grounds for denial of such
1236 license, amendment or renewal. ~~and~~

1237 3.9.9 Reserved.

1238 3.9.10 License Hearings.

1239 3.9.10.1 There shall be an opportunity for public hearings to be held in the following
1240 circumstances in accordance with the procedures in 24-4-104 and -105, CRS. and this
1241 paragraph:

1242 (1) Prior to the licensing or leasing of state-owned property for the concentration,
1243 storage or permanent disposal of radioactive materials.

1244 (2) For each proposed license, five-year license renewal, or license amendment
1245 pertaining to a uranium recovery facility's receipt of ~~classified~~ material as
1246 specified in Part 18 of these regulations.

1247 3.9.11 Contingency Plans

1248 3.9.11.1 Each application to possess radioactive materials in unsealed form, on foils or
1249 plated sources, or sealed in glass in excess of the quantities in Schedule 3E - "Quantities
1250 of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for
1251 Responding to a Release", must contain either:

1252 (1) An evaluation, as described in 3.9.11.2, showing that the projected dose to a
1253 person offsite due to a release of radioactive materials would not exceed 0.01 Sv
1254 (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or

1255 (2) A contingency plan for responding to a release of radioactive material.

1256 3.9.11.2 In evaluating the total effective dose equivalent to an individual pursuant to
1257 3.9.11.1(1):

1258 (1) The radioactive material is physically separated so that only a portion could be
1259 involved in an accident;

- 1260 (2) All or part of the radioactive material is not subject to release during an accident
1261 because of the way it is stored or packaged;
- 1262 (3) The release fraction in the respirable size range is predicted to be lower than the
1263 release fraction shown in Schedule 3E due to the chemical or physical form of
1264 the material;
- 1265 (4) The solubility of the radioactive material would reduce the dose received;
- 1266 (5) Facility design or engineered safety features in the facility would cause the
1267 release fraction to be lower than shown in Schedule 3E.
- 1268 (6) Operating restrictions or procedures would prevent a release fraction as large as
1269 that shown in Schedule 3E.
- 1270 3.9.11.3 A contingency plan for responding to a release of radioactive material submitted
1271 under 3.9.11.1(2) must include the following information, in separate sections having
1272 each page numbered and labeled with a revision date and revision number:
- 1273 (1) Facility description - a brief description of the licensee's facility and surroundings.
- 1274 (2) Types of accidents - a n identification of each type of accident involving
1275 radioactive material for which actions by licensee staff or offsite response
1276 organizations will be needed to protect members of the public.
- 1277 (3) Classification of accidents - a method for classifying and declaring each alert or
1278 site area emergency, as defined in Part 1.
- 1279 (4) Detection of accidents - identification of the means of detecting each type of
1280 accident in a timely manner.
- 1281 (5) Mitigation of consequences - a brief description of the means and equipment for
1282 mitigating the consequences of each type of accident, including those provided to
1283 protect workers onsite, and a description of the program for maintaining the
1284 equipment.
- 1285 (6) Assessment of releases - a brief description of the methods and equipment to
1286 assess releases of radioactive materials.
- 1287 (7) Responsibilities - a brief description of the responsibilities of licensee personnel
1288 should an accident occur, including identification of personnel responsible for
1289 promptly notifying offsite response organizations and the Department; also
1290 responsibilities for developing, maintaining, and updating the plan.
- 1291 (8) Notification and coordination.
- 1292 (a) A commitment to and a brief description of the means to promptly notify
1293 offsite response organizations and request offsite assistance, including
1294 medical assistance for the treatment of contaminated injured onsite
1295 workers when appropriate.
- 1296 (b) A control point must be established.
- 1297 (c) The notification and coordination must be planned so that unavailability
1298 of some personnel, parts of the facility, and some equipment will not
1299 prevent the notification and coordination.
- 1300 (d) The licensee shall also commit to notify the Department immediately
1301 after notification of the appropriate offsite response organizations and not
1302 later than one hour after the licensee declares an emergency.

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- (9) Information to be communicated - a brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.
- 1306
- (10) Training.
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- (a) A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel.
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- (b) The training shall familiarize personnel with site-specific emergency procedures.
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- (c) Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
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- (11) Safe shutdown - a brief description of the means of restoring the facility to a safe condition after an accident.
- 1320
- (12) Exercises.
- 1321
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- (a) Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies.
- 1324
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- (b) Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers.
- 1326
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- (c) The licensee shall invite offsite response organizations to participate in the biennial exercises.
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- (d) Participation of offsite response organizations in biennial exercises although recommended is not required.
- 1330
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- (e) Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants.
- 1333
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- (f) The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan.
- 1335
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- (g) Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response.
- 1338
- (h) Deficiencies found by the critiques must be corrected.
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- (13) Hazardous chemicals - a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-To-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.
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- 3.9.11.4 The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Department.

1346 (1) The licensee shall provide any comments received within 60 days to the
1347 Department with the emergency plan.

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1349 **3.10 Additional Requirements for Issuance of Specific Licenses for Use of Unsealed**

1350 **Radioactive Material.**

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1352 3.10.1 In addition to the requirements set forth in 3.9, applicants for licenses authorizing the possession
1353 and use of unsealed radioactive materials shall include in the application a description of the
1354 facility and procedures for operation which

1355 3.10.1.1 Minimize to the extent practicable, contamination of the facility and environment;

1356 3.10.1.2 Facilitate eventual decommissioning; and

1357 3.10.1.3 Minimize, to the extent practicable, the generation of radioactive waste.

1358 3.10.2 Licensees shall, to the extent practical, conduct operations to minimize the introduction of
1359 residual radioactivity into the site, including the subsurface, in accordance with the existing
1360 radiation protection requirements in Part 4, Section 4.5 and radiological criteria for license
1361 termination in Part 4, Section 4.61 of the regulations.

1362 **3.11 Special Requirements for Specific Licenses of Broad Scope.**

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1364 [* * * = Indicates omission of unaffected rule sections]

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

1365

1366 **3.12 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or**
1367 **Distribute Commodities, Products, or Devices which Contain Radioactive Material.**

1368 3.12.1 A licensee authorized to introduce radioactive material into a product or material owned by or in
1369 the possession of the licensee or another to be transferred to persons exempt under 3.3.1.1 shall
1370 meet the requirements of 10 CFR 32.11 and any other applicable NRC requirement.

1371 3.12.2 No person may introduce byproduct material into a product or material knowing or having reason
1372 to believe that it will be transferred to persons exempted pursuant to 3.3.2, under 10 CFR 30.14
1373 or equivalent regulations of an Agreement State, except in accordance with a license issued
1374 under 10 CFR 32.⁸

1375 ⁸ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
1376 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
1377 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
1378 20555.

1379 3.12.2.3 Each person licensed under 3.12.2 shall maintain records identifying, by name
1380 and address, each person to whom radioactive material is transferred for use under
1381 3.3.2, and stating the kinds and quantities of radioactive material transferred. An annual
1382 summary report stating the total quantity of each radionuclide transferred under the
1383 specific license shall be filed with the Department. Each report shall cover the year
1384 ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive
1385 material have been made pursuant to 3.12.2 during the reporting period, the report shall
1386 so indicate.

1387 3.12.3 RESERVED.

1388 3.12.4 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under
1389 3.6.4.

1390 3.12.4.1 An application for a specific license to manufacture, or initially transfer/distribute
 1391 devices containing radioactive material, excluding special nuclear material, to persons
 1392 generally licensed under 3.6.4 or equivalent regulations of NRC or an Agreement State
 1393 will be approved if:

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

- 1394 (1) The applicant satisfies the general requirements of 3.9;
- 1395 (2) The applicant submits sufficient information relating to the design, manufacture,
 1396 prototype testing, quality control, labels, proposed uses, installation, servicing,
 1397 leak testing, operating and safety instructions, and potential hazards of the
 1398 device to provide reasonable assurance that:
- 1399 (a) The device can be safely operated by persons not having training in
 1400 radiological protection;
- 1401 (b) Under ordinary conditions of handling, storage, and use of the device,
 1402 the radioactive material contained in the device will not be released or
 1403 inadvertently removed from the device, and it is unlikely that any person
 1404 will receive in any period of 1 calendar quarter a dose in excess of 10
 1405 percent of the limits specified in 4.6.1; and
- 1406 (c) Under accident conditions such as fire and explosion associated with
 1407 handling, storage, and use of the device, it is unlikely that any person
 1408 would receive an external radiation dose or dose commitment in excess
 1409 of the following organ doses:
- 1410 (i) Whole body; head and trunk; active blood-forming organs;
 1411 gonads; or lens of eye: 150 mSv (15 rem)
- 1412 (ii) Hands and forearms; feet and ankles; localized areas of skin
 1413 averaged over areas no larger than 1 square centimeter: 2 Sv
 1414 (200 rem)
- 1415 (iii) Other organs: 500 mSv (50 rem); and
- 1416 (3) Each device bears a durable, legible, clearly visible label or labels approved by
 1417 the Department, which contain in a clearly identified and separate statement:
- 1418 (a) Instructions and precautions necessary to assure safe installation,
 1419 operation, and servicing of the device; documents such as operating and
 1420 service manuals may be identified in the label and used to provide this
 1421 information;
- 1422 (b) The requirement, or lack of requirement, for leak testing, or for testing
 1423 any "on-off" mechanism and indicator, including the maximum time
 1424 interval for such testing, and the identification of radioactive material by
 1425 isotope, quantity of radioactivity, and date of determination of the
 1426 quantity; and
- 1427 (c) The information called for in one of the following statements, as
 1428 appropriate, in the same or substantially similar form:
- 1429 (i) The receipt, possession, use, and transfer of this device, Model
 1430 ____, Serial No. ____⁹, are subject to a general license or the
 1431 equivalent and the regulations of the U.S. Nuclear Regulatory
 1432 Commission or an Agreement State. This label shall be
 1433 maintained on the device in a legible condition. Removal of this
 1434 label is prohibited.

1435 CAUTION - RADIOACTIVE MATERIAL

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Name of manufacturer or distributor

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

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

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CAUTION - RADIOACTIVE MATERIAL

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Name of manufacturer or distributor

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

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

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

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

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

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

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- (1) Primary containment or source capsule;
- (2) Protection of primary containment;
- (3) Method of sealing containment;
- (4) Containment construction materials;
- (5) Form of contained radioactive material;
- (6) Maximum temperature withstood during prototype tests;
- (7) Maximum pressure withstood during prototype tests;
- (8) Maximum quantity of contained radioactive material;
- (9) Radiotoxicity of contained radioactive material; and
- (10) Operating experience with identical devices or similarly designed and constructed devices.

1476 | 3.12.4.4 ~~_____~~ In the event the applicant desires that the general licensee under 3.6.4, or under
1477 | equivalent regulations of NRC or an Agreement State, be authorized to install the device,
1478 | collect the sample to be analyzed by a specific licensee for leakage of radioactive
1479 | material, service the device, test the "on-off" mechanism and indicator, or remove the
1480 | device from installation, the applicant shall include in the application written instructions
1481 | to be followed by the general licensee, estimated calendar quarter doses associated with
1482 | such activity or activities, and bases for such estimates.

1483 | (1) The submitted information shall demonstrate that performance of such activity or
1484 | activities by an individual untrained in radiological protection, in addition to other
1485 | handling, storage, and use of devices under the general license, is unlikely to
1486 | cause that individual to receive a calendar quarter dose in excess of 10 percent
1487 | of the limits specified in 4.6.1.

1488 | 3.12.4.5 ~~_____~~ Each person licensed under 3.12.4 to distribute devices to generally licensed
1489 | persons shall:

1490 | (1) Before a device is transferred, furnish information specified in this paragraph to
1491 | each person to whom a device is to be transferred, or in the case of a transfer
1492 | through an intermediate person, to the intended user prior to initial transfer to the
1493 | intermediate person, including:

1494 | (a) A copy of the general license contained in 3.6.4 and a copy of the
1495 | general license contained in the NRC or Agreement State regulation
1496 | equivalent to 3.6.4;

1497 | (b) A copy of sections 3.6 and 4.40 through 4.52;

1498 | (c) A list of the services that can only be performed by a specific licensee;

1499 | (d) Information on acceptable disposal options including estimated costs of
1500 | disposal;

1501 | (e) An indication that federal policy is to issue high civil penalties for
1502 | improper disposal; and

1503 | (f) The name or title, address, and phone number of the contact at the
1504 | transferee's NRC or Agreement State location.

1505 | (2) Report to the Department all transfers of such devices to persons for use under
1506 | the general license in 3.6.4 and all receipts of such devices.

1507 | (a) Such a report to the Department shall include:

1508 | (i) The identity of each general licensee by name and mailing
1509 | address for the location of use; if there is no mailing address for
1510 | the location of use, an alternate address for the general licensee
1511 | shall be submitted along with information on the actual location
1512 | of use;

1513 | (ii) The name, title, and phone number of the person identified by
1514 | the general licensee as having knowledge of and authority to
1515 | take required actions to ensure compliance with the appropriate
1516 | regulations and requirements;

1517 | (iii) The date of transfer;

1518 | (iv) The type, model number, and serial number of the device
1519 | transferred; and

- 1520 (v) The quantity and type of radioactive material contained in the
- 1521 device.

- 1522 (b) If one or more intermediate persons will temporarily possess the device
- 1523 at the intended place of use before its possession by the user, the report
- 1524 must include the same information for both the intended user and each
- 1525 intermediate person, and clearly designate the intermediate person(s).

- 1526 (c) For devices received from a 3.6.4 general licensee, the report must
- 1527 include the identity of the general licensee by name and address, the
- 1528 type, model number, and serial number of the device received, the date
- 1529 of receipt, and, in the case of devices not initially transferred by the
- 1530 reporting licensee, the name of the manufacturer or initial transferor.

- 1531 (d) If the licensee makes changes to a device possessed by a 3.6.4 general
- 1532 licensee, such that the label must be changed to update required
- 1533 information, the report must identify the general licensee, the device, and
- 1534 the changes to information on the device label.

- 1535 (e) The report must cover each calendar quarter, must be filed within 30
- 1536 days of the end of the calendar quarter, and must clearly indicate the
- 1537 period covered by the report.

- 1538 (f) The report must clearly identify the specific licensee submitting the report
- 1539 and include the license number of the specific licensee.

- 1540 (g) If no transfers have been made to or from persons generally licensed
- 1541 under 3.6.4 during the reporting period, the report must so indicate.

- 1542 (3) Furnish clear and legible reports to other agencies, containing all of the data
- 1543 required by Form 653, "Transfers of Industrial Devices Report", including:
 - 1544 (a) Report the information specified in 3.12.4.5(2) to NRC for all transfers of
 - 1545 such devices to persons for use under NRC general license in Section
 - 1546 31.5 of 10 CFR Part 31 (January 1, 2013~~15~~).
 - 1547 (b) Report the information specified in 3.12.4.5 (2) to the responsible State
 - 1548 agency for all transfers of devices manufactured and distributed pursuant
 - 1549 to 3.12.4 for use under a general license in that State's regulations
 - 1550 equivalent to 3.6.4.

- 1551 (4) Maintain all information concerning transfers and receipts of devices that
- 1552 supports the reports required by this section for a period of 3 years following the
- 1553 date of the recorded event.

- 1554 3.12.5 Special Requirements for the Manufacture, Assembly, ~~or~~ Repair or Initial Transfer of Luminous
- 1555 Safety Devices for Use in Aircraft.
 - 1556 3.12.5.1 An application for a specific license to manufacture, assemble, ~~or~~ repair or
 - 1557 initially transfer luminous safety devices containing tritium or promethium-147 for use in
 - 1558 aircraft, for distribution to persons generally licensed under 3.6.5 will be approved if:
 - 1559 (1) The applicant satisfies the general requirements specified in 3.9; and
 - 1560 (2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and
 - 1561 32.56, ~~and 32.101~~ of 10 CFR Part 32 (January 1, 2013~~15~~), or their equivalent.
 - 1562 (3) The device has been registered in the Sealed Source and Device Registry.

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

1563 3.12.6 Special Requirements for License to Manufacture or initially transfer Calibration Sources
1564 Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally
1565 Licensed Under 3.6.7.

1566 3.12.6.1 An application for a specific license to manufacture calibration and reference sources
1567 containing americium-241, plutonium or radium-226 to persons generally licensed
1568 under 3.6.7 will be approved if:

1569 (1) The applicant satisfies the general requirement of 3.9; and

1570 (2) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59, and
1571 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 (January 1,
1572 2013) or their equivalent.

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

1573 3.12.7 Reserved.

1574 3.12.8 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory
1575 Testing Under General License.

1576 * * *

1577 3.12.9 Licensing the Manufacture or initial transfer and Distribution of Ice Detection Devices.

1578 3.12.9.1 An application for a specific license to manufacture and distribute ice detection
1579 devices to persons generally licensed under 3.6.10 will be approved if:

1580 (1) The applicant satisfies the general requirements of 3.9; and

1581 (2) The criteria of Sections 32.61, and 32.62, and 32.103 of 10 CFR Part 32
1582 (January 1, 2013) are met.

1583 (3) The device has been registered in the Sealed Source and Device Registry.

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

1584 3.12.10 Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs for
1585 Medical Use.

1586 * * *

1587 3.12.11 Reserved.

1588 3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical
1589 Use.

1590 3.12.12.1 An application for a specific license to manufacture and distribute sources and
1591 devices containing radioactive material to persons licensed pursuant to Part 7 for use as
1592 a calibration, transmission, or reference source or for the uses listed in 7.19, 7.40, 7.42,
1593 7.48 and 7.62 will be approved if:

1594 (1) The applicant satisfies the general requirements in 3.9 of this part;

1595 (2) The applicant submits sufficient information regarding each type of source or
1596 device pertinent to an evaluation of its radiation safety, including:

1597 (a) The radioactive material contained, its chemical and physical form, and
1598 amount,

1599 (b) Details of design and construction of the source or device,

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

- 1600 (c) Procedures for, and results of, prototype tests to demonstrate that the
- 1601 source or device will maintain its integrity under stresses likely to be
- 1602 encountered in normal use and accidents,

- 1603 (d) For devices containing radioactive material, the radiation profile of a
- 1604 prototype device,

- 1605 (e) Details of quality control procedures to assure that production sources
- 1606 and devices meet the standards of the design and prototype tests,

- 1607 (f) Procedures and standards for calibrating sources and devices,

- 1608 (g) Legend and methods for labeling sources and devices as to their
- 1609 radioactive content, and

- 1610 (h) Instructions for handling and storing the source or device from the
- 1611 radiation safety standpoint; these instructions are to be included on a
- 1612 durable label attached to the source or device or attached to a
- 1613 permanent storage container for the source or device; provided, that
- 1614 instructions which are too lengthy for such label may be summarized on
- 1615 the label and printed in detail on a brochure which is referenced on the
- 1616 label;

- 1617 (3) The label affixed to the source or device, or to the permanent storage container
- 1618 for the source or device, contains information on the radionuclide, quantity, and
- 1619 date of assay, and a statement that the source or device is licensed by the
- 1620 Department for distribution to persons licensed pursuant to 7.40 and 7.42 or
- 1621 under equivalent licenses of NRC or an Agreement State, provided that such
- 1622 labeling for sources which do not require long term storage may be on a leaflet or
- 1623 brochure which accompanies the source;

1624 ~~(4) The source or device has been registered in the Sealed Source and Device~~

1625 ~~Registry.~~

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

1626 3.12.12.2 In the event the applicant desires that the source or device be required to be

1627 tested for leakage of radioactive material at intervals longer than 6 months, the applicant

1628 shall include in the application sufficient information to demonstrate that such longer

1629 interval is justified by performance characteristics of the source or device or similar

1630 sources or devices and by design features that have a significant bearing on the

1631 probability or consequences of leakage of radioactive material from the source; and

1632 3.12.12.3 In determining the acceptable interval for test of leakage of radioactive material,

1633 the Department will consider information that includes, but is not limited to:

- 1634 (1) Primary containment or source capsule,
- 1635 (2) Protection of primary containment,
- 1636 (3) Method of sealing containment,
- 1637 (4) Containment construction materials,
- 1638 (5) Form of contained radioactive material,
- 1639 (6) Maximum temperature withstood during prototype tests,
- 1640 (7) Maximum pressure withstood during prototype tests,
- 1641 (8) Maximum quantity of contained radioactive material,

- 1642 (9) Radiotoxicity of contained radioactive material, and
- 1643 (10) Operating experience with identical sources or devices or similarly designed and
- 1644 constructed sources or devices.

1645 3.12.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted
1646 Uranium for Mass-Volume Applications.

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1650 3.12.14 Registration of Product Information.

1651 **3.12.14.1** Any manufacturer or initial distributor of a sealed source, or ~~of a~~ device containing a
1652 sealed source, ~~whose product is intended for use under a specific license~~ may submit a
1653 request to the Department for evaluation of radiation safety information about ~~its~~**the**
1654 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

1655 3.12.14.2 The request for review must be ~~made in duplicate and~~ sent to the Radiation Program
1656 Manager~~Director~~, Hazardous Materials and Waste Management Division, Colorado
1657 Department of Public Health and Environment, 4300 Cherry Creek Drive South,
1658 Denver, Colorado 80246-1530.

1659 3.12.14.3 The request for review of a sealed source or device must include sufficient information
1660 about the design, manufacture, prototype testing, quality control program, labeling,
1661 proposed uses and leak testing and, for a device, the request must also include
1662 sufficient information about installation, service and maintenance, operating and safety
1663 instructions, and its potential hazards, to provide reasonable assurance that the
1664 radiation safety properties of the source or device are adequate to protect health and
1665 minimize danger to life and property.

1666 3.12.14.4 The Department normally evaluates a sealed source or device using radiation safety
1667 criteria in accepted industry standards.

1668 (1) If these standards and criteria do not readily apply to a particular case, the
1669 Department formulates reasonable standards and criteria with the help of the
1670 manufacturer or distributor.

1671 **(2)** The Department shall use criteria and standards sufficient to ensure that the
1672 radiation safety properties of the device or sealed source are adequate to protect
1673 health and minimize danger to life and property. Subpart A of 10 CFR Part 32
1674 includes specific criteria that apply to certain exempt products and 3.12.4, 3.12.5,
1675 3.12.6, 3.12.8, and 3.12.9 of this part includes specific criteria applicable to
1676 certain generally licensed devices. Sections 3.12.10 and 3.12.12 include specific
1677 provisions that apply to certain specifically licensed items.

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

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

Compatibility = B
NRC RATS 2012-4

1678 **3.12.14.5** After completion of the evaluation, the Department issues a certificate of
1679 registration to the person making the request. The certificate of registration
1680 acknowledges the availability of the submitted information for inclusion in an application
1681 for specific license proposing use of the product or concerning use under an exemption
1682 from licensing or general license as applicable for the category of certificate.

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

NRC RATS 2012-4
Compatibility = B

1683 3.12.14.6 The person submitting the request for evaluation and registration of safety
1684 information about the product shall manufacture and distribute the product in accordance
1685 with:

- 1686 (1) The statements and representations, including quality control program, contained
- 1687 in the request; and
- 1688 (2) The provisions of the certificate of registration.

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

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

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

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

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

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

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

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

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

3.12.15 Inactivation of certificates of registration of sealed sources and devices

3.12.15.1 A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Department shall request inactivation of the registration certificate. Such a request must be made to the Department and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

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

3.12.15.3 A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such

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

1735 | sources or devices for use. Servicing of devices must be in accordance with any
1736 | conditions in the certificate, including in the case of an inactive certificate.

1737 **3.13 Third-Party Method.**

1738 * * *

1739 **3.14 Issuance of a Specific License.**

1740 * * *

1741 **3.15 Specific Terms and Conditions of License.**

1742 3.15.1 Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or
1743 hereafter in effect, and to all rules, regulations, and orders of the Department.

1744 3.15.2 Inalienability of Licenses. _____

1745 3.15.2.1 No license issued or granted under this part and no right to possess or utilize
1746 radioactive material granted by any license issued pursuant to this part shall be
1747 transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily,
1748 directly or indirectly, through transfer of control of any license to any person unless the
1749 Department shall, after securing full information, find that the transfer is in accordance
1750 with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations,
1751 and orders of the Department, and shall give its consent in writing.

1752 3.15.2.2 An application for transfer of license must include:

- 1753 (1) The identity, technical and financial qualifications of the proposed transferee;
- 1754 (2) Financial assurance for decommissioning information required by 3.9.6;
- 1755 (3) A description of the acquisition or proposed transfer including dates;
- 1756 (4) An updated organizational chart including the proposed transferee's
1757 management structure for the licensed activities;
- 1758 (5) Documentation of registration with the Colorado Secretary of State for the
1759 proposed transferee;
- 1760 (6) A statement from the proposed transferee's management that they will conduct
1761 business in accord with all of the commitments previously submitted by the
1762 current licensee;
- 1763 (7) A statement from the proposed transferee's management accepting liability for all
1764 licensed materials that are and have been possessed under the license; and
- 1765 (8) A copy of the appropriate radioactive materials license application signed by the
1766 RSO and the proposed transferee's management.

1767 3.15.3 Each person licensed by the Department pursuant to this part shall confine use and possession
1768 of the material licensed to the locations and purposes authorized in the license. Except as
1769 otherwise provided in the license, a license issued pursuant to Part 3 shall carry with it the right to
1770 receive, possess, and use source or byproduct material. Preparation for shipment and transport
1771 of source or radioactive material shall be in accordance with the provisions of Part 17.

1772 3.15.4 Notice and Disposition of Records Prior to License Termination.

1773

Comment [JJ52]:
Language added consistent with 40.41(c).
NRC Compatibility = C

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* * *

1775 **3.16 Expiration, Decommissioning and Termination of Licenses.**

1776 3.16.1 Definition of "principal activity".

1777 3.16.1.1 As used in this regulation, "principal activity" means an activity authorized by the
 1778 license which is essential to achieving the purpose(s) for which the license was issued
 1779 or amended.

1780 3.16.1.2 Not included as principal activities are:

1781 (1) Radioactive material storage while no licensed material is accessed for use or
 1782 disposal; and

1783 (2) Any activity incidental to decontamination or decommissioning.

1784 3.16.2 Expiration.

1785 3.16.2.1 Except as provided in 3.17.2, each specific license shall expire at the end of the
 1786 specified day in the month and year stated therein.

1787 3.16.2.2 Each specific license revoked by the Department expires at the end of the day on
 1788 the date of final determination to revoke the license, or on the expiration date stated in
 1789 the determination, or as otherwise provided by order.

1790 3.16.2.3 With respect to possession of radioactive material and residual radioactive
 1791 contamination, each specific license continues in effect beyond the expiration date until
 1792 the Department notifies the licensee in writing that the license is terminated, even if:

1793 (1) The licensee decides not to renew the license;

1794 (2) No application for license renewal is submitted;

1795 (3) An application for renewal is denied; or

1796 (4) The Department modifies or suspends a license.

1797 3.16.2.4 No less than 30 days before the expiration date specified in the license, the
 1798 licensee shall either:

1799 (1) Submit an application for license renewal under 3.17; or

1800 (2) Notify the Department, in writing, that the licensee has decided not to renew the
 1801 license.

1802 3.16.2.5 If a licensee does not submit an application for license renewal under 3.17, the
 1803 licensee shall, on or before the expiration date specified in the license:

1804 (1) Terminate use of radioactive material;

1805 (2) Transfer radioactive materials to an authorized recipient and/or properly dispose
 1806 of radioactive material;

1807 (3) Reduce residual radioactive contamination to levels which are as low as
 1808 reasonably achievable (ALARA); and

1809 (4) Submit a completed Department Form R-23, *Request for Termination of a*
 1810 *Radioactive Materials License*, or equivalent information requesting license
 1811 termination, including survey results, leak tests, disposal records, and/or other

- 1812 documentation which demonstrates acceptable conditions for license termination
1813 as specified in 3.16.6.
- 1814 3.16.2.6 Each licensee who possesses radioactive material, including residual radioactive
1815 contamination attributable to licensed activities, following the expiration date specified in
1816 the license shall:
- 1817 (1) Limit actions involving radioactive material to those related to decontamination
1818 and other activities related to preparation for release for unrestricted use; and
- 1819 (2) Continue to control entry to restricted areas until they are suitable for release for
1820 unrestricted use or the Department notifies the licensee in writing that the license
1821 is terminated.
- 1822 3.16.2.7 Each licensee or person responsible for a facility or site which includes a non-
1823 exempt source of radiation or which may be contaminated by residual radioactivity shall,
1824 no less than 30 days before vacating or relinquishing possession or control of the facility
1825 or site, notify the agency, in writing, of the intent to vacate.
- 1826 3.16.3 Timely Decommissioning.
- 1827 3.16.3.1 Each licensee or person in possession of a non-exempt source of radiation who
1828 decides to terminate all activities involving that source of radiation shall notify the
1829 hazardous materials and waste management division immediately, in writing.
- 1830 3.16.3.2 The licensee shall notify the Hazardous Materials And Waste Management
1831 Division in writing within 60 days of the occurrence of any of the following:
- 1832 (1) The licensee has decided to permanently cease principal activities, as defined in
1833 this part, at the entire site or in any separate building or outdoor area that
1834 contains residual radioactivity such that the building or outdoor area is unsuitable
1835 for unrestricted use in accordance with 4.61; or
- 1836 (2) No principal activities under the license have been conducted for a period of 24
1837 months; or
- 1838 (3) No principal activities have been conducted for a period of 24 months in any
1839 separate building or outdoor area that contains residual radioactivity such that
1840 the building or outdoor area is unsuitable for unrestricted use in accordance with
1841 these regulations.
- 1842 3.16.3.3 Concurrent with the notification of the Hazardous Materials And Waste
1843 Management Division required in 3.16.3.1 and 3.16.3.2, the licensee shall either:
- 1844 (1) Begin decommissioning activities; or,
- 1845 (2) Within 12 months of notification, submit a decommissioning plan if required by
1846 3.16.4, and begin decommissioning upon approval of that plan.
- 1847 3.16.3.4 Licensees shall complete decommissioning of the site or separate building or
1848 outdoor area as soon as practicable but no later than 24 months following the initiation of
1849 decommissioning, unless an alternate schedule addressing the factors in 3.16.4 is
1850 requested and approved by the Department.
- 1851 3.16.3.5 When decommissioning involves the entire site, the licensee shall request
1852 license termination upon completion of decommissioning activities.
- 1853 3.16.3.6 The Department may approve alternate schedules for the submission of plans
1854 and for the completion of decommissioning as required pursuant to 3.16.3.3 and 3.16.3.4
1855 if the Department determines that the alternate schedule:

- 1856 (1) Is necessary to effectively conduct decommissioning;
- 1857 (2) Presents no undue risks to public health and safety; and
- 1858 (3) Is otherwise in the public interest.
- 1859
- 1860 3.16.4 Decommissioning Plan.
- 1861 3.16.4.1 A licensee must submit a decommissioning plan:
- 1862 (1) If the licensee intends to terminate the license using radiological criteria specified
1863 in 4.61.3 or 4.61.4 (the exemption of 4.61.1.1 applies);
- 1864 (2) If required otherwise by these regulations;
- 1865 (3) If required by license condition; or
- 1866 (4) If the procedures and activities necessary to carry out decommissioning of the
1867 site or separate building or outdoor area have not been previously approved by
1868 the Department and these procedures could increase potential health and safety
1869 impacts to workers or to the public, such as in any of the following cases:
- 1870 (a) Procedures would involve techniques not applied routinely during
1871 cleanup or maintenance operations;
- 1872 (b) Workers would be entering areas not normally occupied where surface
1873 contamination and radiation levels are significantly higher than routinely
1874 encountered during operation;
- 1875 (c) Procedures could result in significantly greater airborne concentrations of
1876 radioactive materials than are present during operation; or
- 1877 (d) Procedures could result in significantly greater releases of radioactive
1878 material to the environment than those associated with operation.
- 1879 3.16.4.2 Procedures such as those listed in 3.16.4.1 of this section with potential health
1880 and safety impacts may not be carried out prior to Department approval of the
1881 decommissioning plan.
- 1882 3.16.4.3 The decommissioning plan for the site or separate building or outdoor area must
1883 include:
- 1884 (1) A description of the conditions of the site, separate buildings, and/or outdoor
1885 areas sufficient to evaluate the acceptability of the plan;
- 1886 (2) A description of planned decommissioning activities and a schedule for
1887 completion;
- 1888 (3) A description of methods used to ensure protection of workers and the
1889 environment against radiation hazards during decommissioning;
- 1890 (4) A description of the planned final radiation survey;
- 1891 (5) A current detailed cost estimate for decommissioning, comparison of that
1892 estimate with present funds set aside for decommissioning, and a plan for
1893 assuring the availability of adequate funds for completion of decommissioning;
1894 and

- 1895
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- (6) A description of the intended final condition of the site, separate buildings, and/or outdoor areas upon completion of decommissioning activities.
- 1897
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- (7) Decommissioning plans proposing the use of radiological criteria specified in 4.61.3 or 4.61.4, must also include:
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- (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.
- 1904
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- (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;
- 1908
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- (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;
- 1912
1913
- (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;
- 1914
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1916
- (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;
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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
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- (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.
- 1930
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- 3.16.4.4 For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the decommissioning schedule which addresses the following:
- 1933
1934
- (1) Whether it is technically feasible to complete decommissioning within a 24-month period;
- 1935
1936
- (2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning with a 24-month period;
- 1937
1938
- (3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
- 1939
1940
- (4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

1941 (5) Other site-specific factors which the Department may consider appropriate on a
 1942 case-by-case basis, such as the regulatory requirements of other government
 1943 agencies, lawsuits, ground-water treatment activities, monitored natural ground-
 1944 water restoration, actions that could result in more environmental harm than
 1945 deferred cleanup, and other factors beyond the control of the licensee.

1946 3.16.4.5 Upon the receipt of a decommissioning plan or proposal by the licensee for
 1947 release of a site pursuant to 4.61.3 or 4.61.4, or whenever the Department deems such
 1948 notice to be in the public interest, the Department shall:

1949 (1) Notify and solicit comments from:

1950 (a) Local and state governments in the vicinity of the site and any Indian
 1951 nation or other indigenous people that have treaty or statutory rights that
 1952 could be affected by the decommissioning; and

1953 (b) The environmental protection agency for cases where the licensee
 1954 proposes to release a site pursuant to 4.61.4.

1955 (2) Publish a notice in a forum, such as local newspapers, letters to state or local
 1956 organizations, or other appropriate forum, that is readily accessible to individuals
 1957 in the vicinity of the site, and solicit comments from affected parties.

1958 3.16.4.6 The proposed decommissioning plan will be approved by the Department if the
 1959 information therein demonstrates that the decommissioning will be in accordance with the
 1960 requirements of 3.9.5.105, 3.16, and 4.61 (the exemption of 4.61.1.1 applies), completed
 1961 as soon as practicable, and that the health and safety of workers and the public will be
 1962 adequately protected.

1963 3.16.5 Decommissioning Record Keeping.

1964 * * *

1965 3.16.6 Demonstrating Acceptable Conditions for License Termination.

1966 * * *

1967 3.16.6.4 The licensee's report required by 3.16.6.3 shall specify, as appropriate:

1968 * * *

1969 3.16.7 License Termination.

1970 3.16.7.1 Specific licenses, including expired licenses, will be terminated by written notice
 1971 to the licensee when the Department determines that:

1972 (1) Radioactive materials have been properly disposed and records of disposal
 1973 required by 4.48 to be maintained and retained have been forwarded to the
 1974 Department as required by 3.15.4;

1975 (2) Reasonable effort has been made to eliminate residual radioactive
 1976 contamination, if present;

1977 (3) The licensee has demonstrated, by radiation survey results and/or other
 1978 appropriate methods, that the license termination will be in compliance with these
 1979 regulations;

1980 (34) The licensee has established a Department approved long term care warranty, if
 1981 required;

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

1982 (45) Department approved institutional controls have been implemented to limit public
1983 doses, if required; and

1984 (56) All records required by 3.16.5 have been transferred to the Department.

1985 3.16.8 Additional Cleanup.

1986 3.16.8.1 Except for facilities exempted under 4.61.1.1, after a site has been
1987 decommissioned and the license terminated in accordance with 3.16 and 4.61, the
1988 Department may reinstate the terminated license or issue a new license and require
1989 additional cleanup only if, based on new or previously unknown information, it determines
1990 that the criteria of 4.61 were not met and residual radioactivity remaining at the site could
1991 result in significant threat to public health and safety.

1992 3.17 Renewal of Licenses.

1993 * * *

1994 3.18 Amendment of Licenses at Request of Licensee.

1995 * * *

1996 3.19 Agency Action on Applications to Renew and Amend.

1997 * * *

1998 3.20 Reserved.

1999 3.21 Reserved.

2000 TRANSFER OF MATERIALS

2001 3.22 Transfer of Material.

2002 * * *

2003 REQUIREMENTS FOR LICENSE TO INITIALLY TRANSFER SOURCE MATERIAL FOR USE UNDER
2004 THE SMALL QUANTITIES OF SOURCE MATERIAL GENERAL LICENSE

2005
2006 3.22.6 An application for a specific license to initially transfer source material for use under 3.5.1, or
2007 equivalent regulations of the NRC or an Agreement State, will be approved if:

2008
2009 3.22.6.1 The applicant satisfies the general requirements specified in 3.9; and

2010
2011 3.22.6.2 The applicant submits adequate information on, and the Department approves the
2012 methods to be used for quality control, labeling, and providing safety instructions to
2013 recipients.

2014
2015 3.22.7 License Conditions for Initial Transfer of Source Material

2016
2017 Conditions of licenses to initially transfer source material for use under the 'small quantities of
2018 source material' general license: Quality control, labeling, safety instructions, and records and
2019 reports.

2020
2021 3.22.7.1 Each person licensed under 3.22.6 shall label the immediate container of each quantity
2022 of source material with the type of source material and quantity of material and the words,
2023 "radioactive material."

2024
2025 3.22.7.2 Each person licensed under 3.22.6 shall ensure that the quantities and concentrations of
2026 source material are as labeled and indicated in any transfer records.

2027

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

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

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

NRC Compatibility = B
NRC RATS = 2013-2

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

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

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

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

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

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

(a) The name, address, and license number of the person who transferred the source material;

(b) For each general licensee under 3.5.1 or equivalent NRC or Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(c) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

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

(a) The name, address, and license number of the person who transferred the source material; and

(b) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

(c) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State or under NRC jurisdiction, as appropriate.

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

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

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

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

2081 **MODIFICATION AND REVOCATION OF LICENSES**

2082 **3.23 Modification and Revocation of Licenses.**

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2086 **3.24 Reciprocal Recognition of Licenses.**

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2089 **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.

2094 **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.

2098 **PART 3, SCHEDULE 3C: UNIMPORTANT QUANTITIES OF SOURCE MATERIAL AND EXEMPT**
 2099 **ITEMS (3.2.3-AND 3.3.3)**

2100 **3C Any person is exempt from the requirements for a license set forth in section 62 of the**
 2101 **Atomic Energy Act and from the regulations in this part 3, and parts 4 and 10, to the**
 2102 **extent that such person receives, possesses, uses, or transfers ~~an item listed below~~:**

2103 3C.1 Any quantities of thorium contained in:

2104 3C.1.1 Incandescent gas mantles;

2105 3C.1.2 Vacuum tubes;

2106 3C.1.3 Welding rods;

2107 3C.1.4 Electric lamps for illuminating purposes provided that each lamp does not contain more
 2108 than 50 milligrams of thorium;

2109 3C.1.5 Germicidal lamps, sunlamps, and lamps for outdoors or industrial lighting provided that
 2110 each lamp does not contain more than 2 grams of thorium;

2111 3C.1.6 Rare earth metals and compounds, mixtures, and products containing not more than 0.25
 2112 percent by weight thorium, uranium, or any combination of these; or

2113 3C.1.7 Personnel neutron dosimeters provided that each dosimeter does not contain more than
 2114 50 milligrams of thorium.

2115 3C.2 Source material contained in the following products:

2116 3C.2.1 Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze
 2117 contains not more than 20 percent by weight source material;

2118 3C.2.2 Glassware containing not more than 2 percent by weight source material or, for
 2119 glassware manufactured before August 27, 2013, 10 percent by weight source material,
 2120 but not including commercially manufactured glass brick, pane glass, ceramic tile or other
 2121 glass or ceramic used in construction;

2122 3C.2.3 Glass enamel or glass enamel frit containing not more than 10 percent by weight source
 2123 material imported or ordered for importation into the United States, or initially distributed
 2124 by manufacturers in the United States, before July 25, 1983; or

2125 3C.2.4 Piezoelectric ceramic containing not more than 2 percent by weight source material.

2126 3C.3 Photographic film, negatives, and prints containing uranium or thorium.

2127 3C.4 Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium
 2128 alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and
 2129 that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical
 2130 treatment or processing of any such product or part.

2131 3C.5 Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or
 2132 stored or handled in connection with installation or removal of such counterweights, provided that:

2133 ~~3C.5.1 The counterweights are manufactured in accordance with a specific license issued by~~
 2134 ~~NRC, authorizing distribution by the licensee pursuant to 10 CFR Part 40 (January 1,~~
 2135 ~~2010);~~

2136 3C.5.21 Each counterweight has been impressed with the following legend clearly legible through
 2137 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

2138 14 The requirement specified in 3C.5.12 need not be met by counterweights manufactured prior to December 31, 1969; provided,
2139 that such counterweights ~~were manufactured under a specific license issued by the Atomic Energy Commission and were are~~
2140 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

2141 3C.5.32 Each counterweight is durably and legibly labeled or marked with the identification of the
2142 manufacturer and the statement: "Unauthorized Alterations Prohibited" ¹⁵ ; and

2143 15 The requirement specified in 3C.5.23 need not be met by counterweights manufactured prior to December 31, 1969; provided,
2144 that such counterweights ~~were manufactured under a specific license issued by the Atomic Energy Commission and were are~~
2145 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

2146 3C.5.43 This exemption shall not be deemed to authorize the chemical, physical, or metallurgical
2147 treatment or processing of any such counterweights other than repair or restoration of
2148 any plating or other covering.

2149 3C.6 Natural or depleted uranium used as shielding constituting part of any shipping container,
2150 provided that:

2151 3C.6.1 The shipping container is conspicuously and legibly impressed with the legend "Caution -
2152 Radioactive Shielding - Uranium"; and

2153 3C.6.2 The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall
2154 thickness of 1/8 inch (3.2 mm).

2155 3C.7 Thorium ~~or uranium~~ contained in ~~or on~~ finished optical lenses ~~and mirrors~~, provided that each
2156 lens ~~or mirror~~ does not contain more than 10 percent by weight thorium or uranium or, for lenses
2157 manufactured before August 27, 2013, 30 percent by weight of thorium; and that ~~the~~this
2158 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

2159 3C.7.1 The shaping, grinding, or polishing of such lens or manufacturing processes other than
2160 the assembly of such lens ~~or mirror~~ into optical systems and devices without any
2161 alteration of the lens ~~or mirror~~; or

2162 3C.7.2 The receipt, possession, use, or transfer of uranium or thorium contained in contact
2163 lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

2164 3C.8 ~~Uranium contained in detector heads for use in fire detection units, provided that each detector~~
2165 ~~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

2166 3C.9 Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

2167 3C.9.1 The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria
2168 (thorium dioxide); and

2169 3C.9.2 The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

2170 3C.10 No person may initially transfer for sale or distribution a product containing source material to
2171 persons exempt under 3C.1 through 3C.10, or equivalent regulations of the NRC or an
2172 Agreement State, unless authorized by a license issued by NRC under 10 CFR Part 40.52 to
2173 initially transfer such products for sale or distribution.

2174 3C.10.1 Persons authorized to manufacture, process, or produce these materials or products
2175 containing source material by an Agreement State, and persons who import finished
2176 products or parts, for sale or distribution are exempt from the requirements of parts 4,
2177 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

2178 3C.1140 Except for persons who apply radioactive material to, or persons who incorporate
2179 radioactive material into, the following products, any person is exempt from these regulations to
2180 the extent that the person receives, possesses, uses, transfers, owns, or acquires the following
2181 products ¹⁶ :

2182 16 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or

2183 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
 2184 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
 2185 20555.

2186 3C.~~40~~11.1 Timepieces or hands or dials containing not more than the following specified
 2187 quantities of radioactive material and not exceeding the following specified radiation dose
 2188 rate:

2189 3C.~~1140~~1.1 925 MBq (25 mCi) of tritium per timepiece.

2190 3C.~~1140~~1.2 185 MBq (5 mCi) of tritium per hand.

2191 3C.~~40~~11.1.3 555 MBq (15 mCi) of tritium per dial (bezels when used shall be
 2192 considered as part of the dial).

2193 3C.~~40-11~~1.4 3.7 MBq (100 µCi) of promethium-147 per watch or 7.4 MBq (200 µCi) of
 2194 promethium-147 per any other timepiece.

2195 3C.~~40-11~~1.5 0.74 MBq (20 µCi) of promethium-147 per watch hand or 1.48 MBq (40
 2196 µCi) of promethium-147 per other timepiece hand.

2197 3C.~~40-11~~1.6 2.22 MBq (60 µCi) of promethium-147 per watch dial or 4.44 MBq (120
 2198 µCi) of promethium-147 per other timepiece dial (bezels when used shall be
 2199 considered as part of the dial).

2200 3C.~~40-11~~1.7 The radiation dose rate from hands and dials containing promethium-147
 2201 will not exceed, when measured through 50 milligrams per square centimeter of
 2202 absorber:

(1) For wristwatches, 1 µGy (0.1 mrad) per hour at 10 centimeters from any surface.

(2) For pocket watches, 1 µGy (0.1 mrad) per hour at 1 centimeter from any surface.

(3) For any other timepiece, 2 µGy (0.2 mrad) per hour at 10 centimeters from any surface.

2209 3C.~~40-11~~1.8 37 kBq (1 µCi) of radium-226 per timepiece in timepieces acquired prior
 2210 to the effective date of this regulation;

2211 3C.~~40-11~~2 Static elimination devices and Ion generating tubes

3C.11.2.1 Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device.

3C.11.2.2 Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 uCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3C.11.2.3 Such devices authorized before October 23, 2012 for use under the general license then provided in 3.6 and equivalent regulations of the NRC and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications 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.

 NRC Compatibility = B
 NRC RATS = 2012-4

2224 3C.11.3 Precision balances containing not more than 37 MBq (1 mCi) of tritium per balance or not
 2225 more than 18.5 MBq (0.5 mCi) of tritium per balance part manufactured before December
 2226 17, 2007;

2227 3C.11.40.34 Marine compasses containing not more than 27.8 GBq (750 mCi) of tritium gas
 2228 and other marine navigational instruments manufactured before December 17, 2007
 2229 containing not more than 9.25 GBq (250 mCi) of tritium gas;

2230 3C.11.40.45 Ionization chamber smoke detectors containing not more than 1 microcurie (μCi)
 2231 of americium-241 per detector in the form of a foil and designed to protect life and
 2232 property from fires.

2233 3C.11.40.56 Electron tubes, provided that:

2234 3C.11.40.56.1 Each tube does not contain more than one of the following specified
 2235 quantities of radioactive material:

- 2236 a.(1) 0.55 GBq (150 mCi) of tritium per microwave receiver protector tube or
 2237 370 MBq (10 mCi) of tritium per any other electron tube;
- 2238 (2) 37 kBq (1 μCi) of cobalt-60;
- 2239 (3) 185 kBq (5 μCi) of nickel-63;
- 2240 (4) 1.11 MBq (30 μCi) of krypton-85;
- 2241 (5) 185 kBq (5 μCi) of cesium-137;
- 2242 (6) 1.11 MBq (30 μCi) of promethium-147; and further

2243 3C.11.40.56.2 The radiation dose rate from each electron tube containing radioactive
 2244 material will not exceed 10 μGy (1 mrad) per hour at 1 centimeter from any
 2245 surface when measured through 7 milligrams per square centimeter of absorber;
 2246 ¹⁷

2247 ¹⁷ For purposes of 3C.40.11.56, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving
 2248 tubes, microwave tubes, indicator tubes, pick up tubes, radiation detection tubes, and any other completely sealed tube that is
 2249 designed to conduct or control electrical currents.

2250 3C.40.11.67 Ionizing radiation measuring instruments containing, for purposes of internal
 2251 calibration or standardization, one or more sources of radioactive material, provided that:

2252 3C.40.11.67.1 Each source contains no more than one exempt quantity set forth in
 2253 Schedule 3B of this part; and

2254 3C.40.11.67.2 Each instrument contains no more than 10 exempt quantities. For
 2255 purposes of this requirement, an instrument's source(s) may contain either one or
 2256 different types of radionuclides and an individual exempt quantity may be
 2257 composed of fractional parts of one or more of the exempt quantities in Schedule
 2258 3B of this part, provided that the sum of such fractions shall not exceed unity.

2259 3C.40.11.67.3 For americium-241, 1.85 kBq (0.05 μCi) is considered an exempt
 2260 quantity under 3C.40.611.7;

2261 3C.44.12 Self-luminous products containing radioactive material containing tritium, krypton-85, or
 2262 promethium-147.

2263 3C.44.12.1 Except for persons who manufacture, process, or produce self-luminous products
 2264 containing tritium, krypton-85, or promethium-147, any person is exempt from these
 2265 regulations to the extent that such person receives, possesses, uses, transfers, owns, or
 2266 acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured,

2267 processed, produced, imported, or transferred in accordance with a specific license
2268 issued by NRC pursuant to section 32.22 of 10 CFR Part 32 (January 1, 20+315), which
2269 license authorizes the transfer of the product to persons who are exempt from regulatory
2270 requirements.

2271 3C.12.2 Any person who desires to manufacture, process, or produce, or initially transfer for sale
2272 or distribution self-luminous products containing tritium, krypton-85, or promethium-147
2273 for use under 3C.12.1, should apply for a license under 32.22 of 10 CFR Part 32 and for
2274 a certificate of registration in accordance with 32.210 of 10 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)

2275 3C.412.23 The exemption in this section does not apply to tritium, krypton-85, or
2276 promethium-147 used in products for frivolous purposes or in toys or adornments.

2277 3C.4213 Gas and aerosol detectors containing radioactive material.
2278 3C.4213.1 Except for persons who manufacture, process, or produce, or initially transfer for
2279 sale or distribution gas and aerosol detectors containing radioactive material, any person
2280 is exempt from the requirements for a license set forth in the Act and from these
2281 regulations in 3, 4, 5, 7, 10, 16, and 19 to the extent that such person receives,
2282 possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol
2283 detectors designed to protect health, lifesafety, or property from fires and airborne
2284 hazards provided that detectors containing radioactive material shall have been and
2285 manufactured, processed, produced, imported, or initially transferred in accordance with
2286 a specific license issued by NRC pursuant to section 32.26 of 10 CFR Part 32 (January
2287 1, 201543); or pursuant to 3.12.3, which license authorizes the initial transfer of the
2288 detectors to persons who are exempt from regulatory requirements. This exemption also
2289 covers gas and aerosol detectors manufactured or distributed before November 30,
2290 2007, in accordance with a specific license issued by NRC or an Agreement State under
2291 comparable provisions to 10 CFR Part 32.26 authorizing distribution to persons exempt
2292 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

2293 18 Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or
2294 other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are
2295 exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.
2296 20555.

2297 3C.13.2 Any person who desires to manufacture, process, or produce gas and aerosol detectors
2298 containing byproduct material, or to initially transfer such products for use under
2299 3C.13.1, should apply for a license under paragraph 32.26 of 10 CFR Part 32 and for a
2300 certificate of registration in accordance with 32.210 of 10 CFR Part 32.

2301 3C.4213.23 Gas and aerosol detectors previously manufactured and distributed to general
2302 licensees in accordance with a specific license issued by a state shall be considered
2303 exempt under 3C.4213.1, provided that the device is labeled in accordance with the
2304 specific license authorizing distribution of the generally licensed device, and provided
2305 further that they meet the requirements of 3.12.34.

2306 3C.4314 Radioactive drug capsules containing carbon-14 urea for "in vivo" diagnostic use for
2307 humans.

2308 3C.4314.1 Except as provided in paragraphs 3C.4314.2 and 3C.4314.3, any person is
2309 exempt from the regulations in this part provided that such person receives, possesses,
2310 uses, transfers, owns, or acquires capsules containing 37 kBq (1 µCi) carbon-14 urea
2311 (allowing for nominal variation that may occur during the manufacturing process) each,
2312 for "in vivo" diagnostic use for humans.

2313 3C.4314.2 Any person who desires to use the capsules for research involving human
2314 subjects shall apply for and receive a specific license pursuant to Part 7.

2315 3C.4314.3 Nothing in this section relieves persons from complying with applicable FDA,
2316 federal, and state requirements governing receipt, administration, and use of drugs.

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

2317 3C.15 Certain industrial devices

2318 3C.15.1 Except for persons who manufacture, process, produce, or initially transfer for sale or
2319 distribution industrial devices containing byproduct material designed and manufactured
2320 for the purpose of detecting, measuring, gauging or controlling thickness, density, level,
2321 interface location, radiation, leakage, or qualitative or quantitative chemical composition,
2322 or for producing an ionized atmosphere, any person is exempt from the requirements for
2323 a license set forth in the Act and from the regulations in parts 3, 4, 5, 7, 10, 16, and 19 to
2324 the extent that such person receives, possesses, uses, transfers, owns, or acquires
2325 byproduct material, in these certain detecting, measuring, gauging, or controlling devices
2326 and certain devices for producing an ionized atmosphere, and manufactured, processed,
2327 produced, or initially transferred in accordance with a specific license issued by NRC
2328 under 10 CFR 32.30, which license authorizes the initial transfer of the device for use
2329 under this section. This exemption does not cover sources not incorporated into a
2330 device, such as calibration and reference sources.

2331 3C.15.2 Any person who desires to manufacture, process, produce, or initially transfer for sale or
2332 distribution industrial devices containing byproduct material for use under 3C.15.1, should
2333 apply for an NRC license under 10 CFR 32.30 and for a certificate of registration in
2334 accordance with 10 CFR 32.210.

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2339 **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.

2343 **PART 3, SCHEDULE 3E: QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING**
2344 **CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A**
2345 **RELEASE (3.9.11)**

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2347

* * *

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.

2348 **PART 3, APPENDIX 3F: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT**
2349 **COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR**
2350 **DECOMMISSIONING**

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2352

* * *

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.

2353 **PART 3, APPENDIX 3G: CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-**
2354 **GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR**
2355 **DECOMMISSIONING**

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.

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2358 **EDITOR'S NOTES**

2359 6 CCR 1007-1 has been divided into smaller sections for ease of use. Versions prior to 4/1/07 and rule
2360 history are located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the History link
2361 that appears above the text in 6 CCR 1007-1. To view versions effective on or after 4/1/07, Select the
2362 desired part of the rule, for example 6 CCR 1007-1 Part 1 or 6 CCR 1007-1 Parts 8 - 10.

2363 **History**

2364 *[For history of this section, see Editor's Notes in the first section, 6 CCR 1007-1]*
2365