



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, Regulatory Lead,
Hazardous Materials and Waste Management Division
Jennifer Opila, Manager, Colorado Radiation Control Program

Through: Gary W. Baughman, Director, Hazardous Materials and Waste Management Division *GWB*

Date: April 29, 2016

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1007-1, Part 19, Licenses and Radiation Safety Requirements for Irradiators, with a request for the rulemaking hearing to occur in July of 2016

The Division is proposing amendments to regulatory Part 19, titled *Radiation Licenses and Radiation Safety Requirements for Irradiators*. Part 19 is a specific rule which applies only to entities using a specific type of irradiator.

The regulatory part is being amended to ensure consistency with the language of federal regulations in 10 CFR Part 36.

The proposed changes to Part 19 involve minor updates for consistency with federal rule. 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/cdphe/radregs> (See "Stakeholder processes")

Although only a few licensees are governed by the rule requirements, in late-February, 2016, approximately 180 stakeholders were notified of the proposed rule amendment and were provided the opportunity to comment over a 45 day period. The stakeholder comment period remained open through April 10, 2016. No comments were received.

At the May 2016 request for rulemaking, the Radiation Program requests that the Board of Health set a rulemaking hearing for July 20 of 2016.

cc: Deborah Nelson, Administrator, State Board of Health

DRAFT

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY**

for Amendments to

6 CCR 1007-1, Part 19, Licenses and Radiation Safety Requirements for Irradiators

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 current Part 19 regulation - is based on SSRCR model regulation Part "Q". Part Q - was last amended in 2005 and is not consistent with language contained in federal rule in 10 CFR Part 36. The proposed Part 19 amendment modifies the rule contents for consistency with federal rule changes.

The Department is proposing minor amendments to Part 19 to maintain consistency with federal rules changes to address past and recent federal rule changes of the NRC.

The specific proposed amendments to Part 19 involve:

- The addition of cross-references to other regulatory parts, including Part 17 (transportation) and Part 22 (well logging) for consistency with federal rule;
- The addition of cross-references to specific licensing requirements contained in Part 3 for consistency with federal rule;
- The incorporation of the updated definitions for "construction" and "commencement of construction" which were recently amended in the Part 1 regulation;
- The addition of a reference to a standard for construction of concrete, which would apply only for construction of new irradiator facilities;
- Several editorial and formatting adjustments and corrections of typographical errors.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutory provisions: 25-1.5-101(1)(I), 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 _____; 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 19, Licenses and Radiation Safety Requirements for Irradiators

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 19 rule is a specific regulation containing licensing, technical, design, construction and radiation safety requirements for entities that hold a specific radioactive materials license to possess and operate one or more panoramic irradiators. Currently, there are 3 such entities specifically licensed by the Colorado radiation program to possess and use panoramic irradiators in Colorado. Due to the minor nature of the proposed changes, no impact is expected as a result of the proposed rule changes.

Entities using radioactive materials or radiation producing (x-ray) machines for purposes other than in a panoramic irradiator would not be impacted by the proposed rule. Licensees using other types of non-panoramic irradiators such as blood irradiators are not impacted by these rule changes and are not governed by this regulation.

There are no known classes of persons who would specifically benefit from the proposed rule.

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.**

There is no quantitative impact of the proposed rule changes since the proposed changes are so minor and are mostly administrative in nature. It is not expected that the proposed changes would have an impact on the operations of current licensees using panoramic irradiators.

The qualitative impact of the proposed changes will be to bring the rule in better alignment with current federal regulations. This is expected to benefit the Department, regulated community, and stakeholders by ensuring that there is consistency in regulatory requirements between state and federal regulations. The added or clarified language throughout the rule is expected to enhance the understanding of the rule requirements and maintain Colorado's requirements consistent 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 expected to be negligible 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.

There are no significant anticipated costs as a result of the proposed rule amendments to Part 19.

The benefits of amending the rule will be to address past comments and federal rule changes from the NRC such that the rule is made consistent with the national framework of regulating licensed entities that use panoramic irradiators. The rule amendments will help ensure that Colorado's status as an agreement state is maintained.

Inaction on the proposed rule will result in continued or potential future conflict with federal 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 interstate 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 and rule language with federal rules. There are believed to be no less costly or less intrusive methods to achieve the purpose of the proposed changes and maintain consistency with federal rule.

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

The proposed rule amendments are needed to achieve consistency with federal rules, some of which are needed for compatibility as an agreement state. There are no alternate rules or alternatives to rulemaking that will achieve the same goals and requirements. This rule does not overlap with other radiation related regulatory requirements and is the only applicable radioactive materials regulation specific to panoramic irradiators in Colorado.

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 federal rules and requirements some of which may be 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. Such oversight could result in additional short term and potential long term expenditures by the state to address program inadequacies.

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STAKEHOLDER COMMENTS
for Amendments to

6 CCR 1007-1, Part 19, Licenses and Radiation Safety Requirements for Irradiators

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

On February 24, 2016, approximately 182 stakeholders were notified of the opportunity to comment on the proposed draft rule over an approximate 45 day period. The entities notified represented:

- 5 radioactive materials licensees specifically licensed for higher activity irradiators including panoramic irradiators;
- Approximately 177 "other stakeholders" who have specifically signed up to receive notification of proposed radiation regulation changes and who represent a wide variety of interests. These stakeholder entities may include: x-ray registrants, radioactive materials licensees; heavy industry; private citizens; private companies; professional organizations; and special interest groups. Only those entities expressing interest in "all" or "industrial uses" or "research uses" of regulations were notified due to the subject matter of the proposed rule.

Due to the minor nature of the proposed changes, no stakeholder meetings were held.

During the comment period, the radiation program directly contacted (by phone) each of the 5 licensees having higher activity irradiators (including panoramic irradiator licensees) to ensure they were aware of the proposed rulemaking as well as giving them an opportunity to ask any specific questions. No stakeholders expressed concerns over the proposed changes.

The Colorado Radiation Advisory Committee reviewed and discussed the proposed regulation during the January 28, 2016 regular meeting. The committee did not express any specific concerns or issues regarding the proposed rule.

Due to the minor nature of the proposed rule and that some items are not required for compatibility the U.S. Nuclear Regulatory Commission (NRC) determined it would review the rule once it becomes final.

This rulemaking does not include a local government mandate. The burden of regulatory conformity to this rule applies to all applicable regulated entities. EO5 does not apply.

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 as 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 continues to be made available to stakeholders through posting on the Department website.

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.

There are no major factual and policy issues identified as a result of the proposed changes.

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 editorial and technical in nature and are specific to the requirements for entities using panoramic irradiators. Due to the purpose and structure of the rule, there is minimal opportunity for specific accommodations for HEEJ since the activities performed are regulated in the same manner. The rule (with or without the proposed changes) addresses matters related to radiation safety regarding the construction and use of panoramic irradiators. The rule requirements are such that they apply regardless of the facility or location.

1 **DRAFT 1 05/05/16**

2 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

3 **Hazardous Materials and Waste Management Division**

4 **RADIATION CONTROL - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR**
5 **IRRADIATORS**

6 **6 CCR 1007-1 Part 19**

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

8 _____

9 **Adopted by the Board of Health on July 20, 2016.**

10 **PART 19: LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS**

11 **19.1 Purpose and Scope.**

12 19.1.1 Authority.

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

15 19.1.2 Basis and Purpose.

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

18 19.1.3 Scope.

19 Part 19 contains requirements for the issuance of a license authorizing the use of sealed sources
20 containing radioactive materials in irradiators used to irradiate objects or materials using gamma
21 radiation. Part 19 also contains radiation safety requirements for operating irradiators.

22 19.1.4 Applicability.

23 19.1.4.1 The regulations in this part apply to panoramic irradiators that have either dry or
24 wet storage of the radioactive sealed sources and to underwater irradiators in
25 which both the source and the product being irradiated are under water.
26 Irradiators whose dose rates exceed 5 gray (500 rad) per hour at 1 meter from
27 the radioactive sealed sources in air or in water, as applicable for the irradiator
28 type, are covered by this part.

29 19.1.4.2 The regulations in this part do not apply to self-contained dry-source-storage
30 irradiators (those in which both the source and the area subject to irradiation are
31 contained within a device and are not accessible by personnel), medical
32 radiology or teletherapy, radiography (the irradiation of materials for
33 nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

34 19.1.4.3 The requirements of this part are in addition to the requirements of Parts 1, 3, 4,
35 10, 12, 13, 17 and 4722.

36 19.1.4.4 Nothing in this part relieves the licensee from complying with other applicable
37 Federal, State and local regulations governing the siting, zoning, land use, and
38 building code requirements for industrial facilities.
39

Comment [jsj1]:
EDITORIAL NOTE 1: ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DOCUMENT ARE FOR INFORMATION PURPOSES ONLY. THESE COMMENTS ARE NOT PART OF THE RULE AND WILL BE DELETED PRIOR TO FINAL SUBMISSION PRIOR TO THE COLORADO SECRETARY OF STATE.

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 THE U.S. NUCLEAR REGULATORY COMMISSION (NRC) REGULATIONS AND THE SSRCR REGULATIONS. HOWEVER, DUE TO DIFFERING LANGUAGE, IT MAY NOT ALWAYS BE POSSIBLE TO HAVE CONSISTENCY BETWEEN BOTH NRC RULES AND THE SSRCR'S. DIFFERENCES ARE IDENTIFIED WHEREVER POSSIBLE.

THE SSRCRS MAY BE FOUND ONLINE AT:
<http://www.crcpd.org/ssrcrs/default.aspx>

THE PART 19 RULE IS BASED ON SSRCR PART "Q" DATED MAY 2005 EXCEPT WHERE NRC REGULATIONS HAVE BEEN UPDATED SINCE PART Q WAS LAST AMENDED. COMPATIBILITY WITH FEDERAL (NRC) REGULATIONS IS REQUIRED TO MAINTAIN AGREEMENT STATE STATUS. INFORMATION ON NRC COMPATIBILITY CATEGORIES MAY BE FOUND AT:

<https://scp.nrc.gov/procedures/sa200.pdf>

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

EDITORIAL NOTE 4: THROUGHOUT THE RULE MULTIPLE PROVISIONS HAVE BEEN REALIGNED FOR FORMATTING PURPOSES.

Comment [jsj2]: This reflects the date of anticipated adoption by the Colorado Board of Health. The effective date is typically 60 days beyond this date.

Comment [jsj3]: Cross-reference to additional regulatory parts is added, consistent with 10 CFR Part 36.1(a).

References to Part 17 (transportation) and Part 22 (physical security) are added.

NRC RATS 2013-1
NRC Compatibility = D

[* * * = Indicates omission of unaffected rules/sections]
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SPECIFIC LICENSING REQUIREMENTS

19.3 Application for a Sspecific Llicense.

19.3.1 A person shall file an application for a specific license authorizing the use of sealed sources in an irradiator pursuant to 3.8.

19.4 Specific Llicenses for Irradiators.

19.4.1 The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

19.4.2 The applicant shall satisfy the general requirements specified in 3.9, 3.9.1, 3.9.2, 3.9.4, and 3.9.7 of the regulations and the requirements contained in this part.

19.4.3 The applicant must describe the training provided to irradiator operators including:

- 19.4.3.1 Classroom training;
- 19.4.3.2 On-the-job or simulator training;
- 19.4.3.3 Safety reviews;
- 19.4.3.4 Means employed by the applicant to test each operator’s understanding of the Department’s regulations and licensing requirements and the irradiator operating and emergency procedures; and
- 19.4.3.5 Minimum training and experience of personnel who may provide training.

19.4.4 The application must include an outline of the written operating and emergency procedures listed in 19.19 that describes the radiation safety aspects of the procedures.

19.4.5 The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities.

19.4.5.1 In particular, the application must specify who, within the management structure, has authority to stop unsafe operations.

19.4.5.2 The application must also describe the training and experience required for the position of radiation safety officer.

19.4.6 The application must include:

- 19.4.6.1 A description of the access control systems required by 19.8;
- 19.4.6.2 A description of the radiation monitors required by 19.11;
- 19.4.6.3 A description of the method of detecting leaking sources required by 19.22 including the sensitivity of the method; and
- 19.4.6.4 A diagram of the facility that shows the locations of all required interlocks and radiation monitors.

Comment [jsj4]: Cross-references are expanded for consistency with the expanded cross-references contained in 10 CFR 36.13(a) (to 30.33(a)(1-4) and 30.33(b) which were amended in 2011.

This provision is expanded for consistency with federal rules and differs from SSRCR Part Q. Part Q has not been updated since 2005 and is not current with all federal rules.

NRC RATS 2011-2
 NRC Compatibility (36.13(a)) = H&S

NRC Compatibility (30.33(a)(2), (3)) = H&S, while 30.33(a)(1), (a)(4), and (b) are compatibility “D” and are not required for compatibility.

77 19.4.7 If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant
78 shall establish procedures for leak testing and submit a description of these procedures to the
79 Department. The description shall include the:

80 19.4.7.1 Instruments to be used;

81 19.4.7.2 Methods of performing the analysis; and

82 19.4.7.3 Pertinent experience of the individual who analyzes the samples.

83 19.4.8 If licensee personnel are to load or unload sources, the applicant shall describe the qualifications
84 and training of the personnel and the procedures to be used. If the applicant intends to contract
85 for source loading or unloading at its facility, the loading or unloading must be done by an
86 organization specifically authorized by the ~~U.S. Nuclear Regulatory Commission~~NRC or an
87 Agreement State to load or unload irradiator sources.

88 19.4.9 The applicant shall describe the inspection and maintenance checks, including the frequency of
89 the checks required by 19.23.

90 **19.5 Start Commencement of Construction.**

91 19.5.1 ~~The applicant may not begin~~Commencement of construction of a new irradiator ~~may not occur~~
92 prior to the submission to the Department of both the application for a license for the irradiator
93 and the fee required by Part 12 of these regulations.

94 19.5.1.1 ~~As used in this section, the term "construction" includes the construction of any~~
95 ~~portion of the permanent irradiator structure on the site but does not include: engineering~~
96 ~~and design work, purchase of a site, site surveys or soil testing, site preparation, site~~
97 ~~excavation, construction of warehouse or auxiliary structures, and other similar tasks.~~

98 19.5.1.21 Any activities undertaken prior to the issuance of a license are entirely at the risk
99 of the applicant and have no bearing on the issuance of a license with respect to
100 the requirements of the Act, and rules, regulations, and orders issued under the
101 Act.

102 19.5.1.2 Commencement of construction as defined in Part 1 may include non-
103 construction activities if the activity has a reasonable nexus to radiological
104 safety.

105 **19.6 Applications for Exemptions.**

106 19.6.1 Any application for a license or for amendment of a license authorizing use of a teletherapy-type
107 unit for irradiation of materials or objects may include proposed alternatives for the requirements
108 of this part. The Department will approve the proposed alternatives if the applicant provides
109 adequate rationale for the proposed alternatives and demonstrates that they are likely to provide
110 an adequate level of safety for workers and the public.

111 **DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS**

112 **19.7 Requirements and Performance Criteria for Sealed Sources.**

113 Sealed sources shall:

114 19.7.1 Have a certificate of registration issued by the ~~U.S. Nuclear Regulatory Commission~~NRC or an
115 Agreement State, or shall have been evaluated in accordance with 10 CFR 32.210 or the
116 equivalent state regulation;

117
118 * * *

Comment [jsj5]: Section 19.5 is modified consistent with 10 CFR 36.15.

Original subsection 19.5.1.1 is deleted and replaced by new provision 19.5.1.2

Part 1 is currently being/has been amended to incorporate/expand the definitions for "construction" and "commencement of construction", consistent with the definitions in federal rule. These definitions were incorporated into an amendment to Part 1 (which became effective in February 2016) as these terms are used across multiple regulatory parts.

This provision is expanded for consistency with federal rules and differs from SSRCR Part Q. Part Q has not been updated since 2005 and is not current with all federal rules or more recent rule changes.

NRC RATS 2011-2
NRC Compatibility (36.2*)= D
(*definitions for "construction" and "commencement of construction").
NRC Compatibility (36.15) = D

119 | **19.8 Access Control.**

120 | * * *

121 | **19.9 Shielding.**

122 | 19.9.1 The radiation dose rate in areas that are normally occupied during operation of a panoramic
123 | irradiator may not exceed 0.02 millisievert (2 millirem) per hour at any location 30 centimeters or
124 | more from the wall of the room when the sources are exposed.

125 | 19.9.91.1 The dose rate must be averaged over an area not to exceed 100 square
126 | centimeters having no linear dimension greater than 20 centimeters.

127 | 19.9.91.2 Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirem) per
128 | hour must be locked, roped off, or posted.

129 | 19.9.2 The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not
130 | exceed 0.02 millisievert (2 millirem) per hour when the sources are in the fully shielded position.

131 | 19.9.3 The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator
132 | when the source is shielded may not exceed 0.02 millisievert (2 millirem) per hour and at 5
133 | centimeters from the shield may not exceed 0.2 millisievert (20 millirem) per hour.

134 | **19.10 Fire Protection.**

135 | * * *

136 | **19.11 Radiation Monitors.**

137 | * * *

138 | **19.12 Control of Source Movement.**

139 | 19.12.1 The mechanism that moves the sources of a panoramic irradiator must require a key to actuate.

140 | 19.12.1.1 Actuation of the mechanism must cause an audible signal to indicate that the
141 | sources are leaving the shielded position.

142 | 19.12.1.2 Only one key may be in used at any time, and only one operators or facility
143 | management may possess it.

144 | 19.12.1.3 The key must be attached to a portable radiation survey meter by a chain or
145 | cable.

146 | 19.12.1.4 The lock for source control must be designed so that the key may not be
147 | removed if the sources are in an unshielded position.

148 | 19.12.1.5 The door to the radiation room must require the same key.

149 | 19.12.2 The console of a panoramic irradiator must have a source position indicator that indicates when
150 | the sources are in the fully shielded position, when they are in transit, and when the sources are
151 | exposed.

152 | 19.12.3 The control console of a panoramic irradiator must have a control that promptly returns the
153 | sources to the shielded position.

154 | 19.12.4 Each control for a panoramic irradiator must be clearly marked as to its function.
155 |
156 |
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158 | **19.13 Irradiator Pools.**

Comment [jsj6]: Numbering for subsections 19.9.1.1 and 19.9.1.2 are corrected for consistency with standard rule numbering and are realigned for formatting purposes.

Comment [jsj7]: Minor wording changes are made consistent with 10 CFR 36.31(a) and SSR CR Part Q.
NRC Compatibility = H&S

159 * * *

160 | 19.14 Source Rrack Pprotection. * * *
 161

162 | 19.15 Power Ffailures. * * *
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164 | 19.16 Design Rrequirements. * * *
 165

166 | 19.16.1.10 Seismic.

167 (1) For panoramic irradiators to be built in seismic areas, the licensee shall design
 168 the reinforced concrete radiation shields to retain their integrity in the event of an
 169 earthquake by designing to the seismic requirements of an appropriate source
 170 such as **American Concrete Institute Standard ACI 318-89m "Building Code**
 171 **Requirements for Reinforced Concrete," Chapter 21, "Special Provisions**
 172 **for Seismic Design,"** ~~current national standards~~ or local building codes.

Comment [jsj8]: Provision updated to reflect the reference to American Concrete Institute document, consistent with 10 CFR 36.39(j) and SSR CR Part Q.
 NRC Compatibility = H&S

173 | 19.16.1.11 Wiring.

174 (1) For panoramic irradiators, the licensee shall verify that electrical wiring and
 175 electrical equipment in the radiation room are selected to minimize failures due to
 176 prolonged exposure to radiation.

177 | 19.17 Construction Mmonitoring and Aacceptance Ttesting.
 178 * * *

179 | **OPERATION OF IRRADIATORS**

180 | 19.18 Training.

181 | 19.18.1 Before an individual is permitted to operate an irradiator without a supervisor present, the
 182 individual must be instructed in:

183 | 19.18.1.1 The fundamentals of radiation protection applied to irradiators (including the
 184 differences between external radiation and radioactive contamination, units of
 185 radiation dose, Department dose limits, why large radiation doses must be
 186 avoided, how shielding and access controls prevent large doses, how an
 187 irradiator is designed to prevent contamination, the proper use of survey meters
 188 and personnel dosimeters, other radiation safety features of an irradiator, and the
 189 basic function of the irradiator);

190 | 19.18.1.2 The requirements of Parts 4, 10 and 19 that are relevant to the irradiator;

191 | 19.18.1.3 The operation of the irradiator;

192 | 19.18.1.4 Those operating and emergency procedures listed in 19.19 that the individual is
 193 responsible for performing; and

194 | 19.18.1.5 Case histories of accidents or problems involving irradiators.

195 | 19.18.2 Before an individual is permitted to operate an irradiator without a supervisor present, the
 196 individual shall pass a written test on the instruction received consisting primarily of questions
 197 based on the licensee's operating and emergency procedures that the individual is responsible
 198 for performing and other operations necessary to safely operate the irradiator without supervision.

199 19.18.3 Before an individual is permitted to operate an irradiator without a supervisor present, the
200 individual must have received on-the-job training or simulator training in the use of the irradiator
201 as described in the license application.

202 19.18.3.1 The individual shall also demonstrate the ability to perform those portions of the
203 operating **and emergency** procedures that he or she is to perform.

Comment [jsj9]: The phrase "and emergency" is added, consistent with 10 CFR 36.51(c) and SSR CR Part Q. This wording was previously omitted from Part 19.

204 19.18.4 The licensee shall conduct safety reviews for irradiator operators at least annually.

* * *

The requirement clarifies that the individual must demonstrate the capability to perform both operating and emergency procedures that they would be expected to perform. If not currently required, licensees using panoramic irradiators would be required to incorporate this requirement into the irradiator operator evaluation/demonstration process.

NRC Compatibility = H&S

207 **19.19 Operating and Emergency Procedures.**

* * *

210 **19.20 Personnel Monitoring.**

211 19.20.1 Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an
212 accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while
213 operating a panoramic irradiator or while in the area around the pool of an underwater irradiator.

Comment [jsj10]: Minor grammar and language corrections are made to 19.20.1, consistent with 10 CFR 36.55 and SSR CR Part Q.21.

Section 19.20.1 is reformatted for alignment.

NRC Compatibility = H&S

214 19.20.1.1 The personnel dosimeter processor must be accredited for high-energy photons
215 in the normal and accident dose ranges (see 4.17.3).

216 19.20.1.2 Each personnel dosimeter must be assigned to and worn by only one individual.

217 19.20.1.3 Film badges must be ~~replaced~~**processed** at least monthly and ~~each~~-other
218 personnel dosimeters ~~s~~ must be ~~replaced~~**processed** at least quarterly.

219 19.20.1.4 After replacement, each personnel dosimeter must be promptly processed.

220 19.20.2 Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter,
221 which may be a pocket dosimeter.

222 19.20.2.1 For groups of visitors, only two people who enter the radiation room are required
223 to wear dosimeters.

224 19.20.2.2 If pocket dosimeters are used to meet the requirements of this paragraph, a
225 check of their response to radiation must be done at least annually.

226 19.20.2.3 Acceptable dosimeters must read within ~~+ or -~~ **+20** percent of the true radiation
227 dose.

Comment [jsj11]:
NOTE: The equivalent provision in 10 CFR 36.55(b) and SSR CR Part Q requires a 30 % tolerance. The 20% value is retained as it is more conservative.

[NOTE: Common industry practice and other regulatory requirements e.g., 10 CFR 34.47 (pertaining to industrial radiography) typically require a 20 % tolerance.]

NRC Compatibility = H&S

228 **19.21 Radiation Surveys.**

* * *

230 19.21.5 Before releasing resins for unrestricted use, they must be monitored before release in an area
231 with a background level less than 0.5 microsievert (0.05 millirem) per hour.

232 19.21.5.1 The ~~resins may be released only if the survey does not detect~~ **radiation** levels
233 above background **radiation** levels.

Comment [jsj12]: In 19.21.5.1, "radiation" is added for clarity, consistent with 10 CFR 36.57(d) and SSR CR Part Q.

NRC Compatibility = H&S

234 19.21.5.2 The survey meter used must be capable of detecting radiation levels of 0.5
235 microsievert (0.05 millirem) per hour.

236 **19.22 Detection of Leaking Sources.**

- 237 19.22.1 Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6
 238 months using a leak test kit or method approved by the ~~U.S. Nuclear Regulatory~~
 239 ~~Commission~~**NRC** or an Agreement State.
- 240 19.22.1.1 In the absence of a certificate from a transferor that a test has been made within
 241 the 6 months before the transfer, the sealed source may not be used until tested.
- 242 19.22.1.2 The test must be capable of detecting the presence of 200 becquerel (0.005
 243 microcurie) of radioactive material and must be performed by a person approved
 244 by the ~~U.S. Nuclear Regulatory Commission~~**NRC** or an Agreement State to
 245 perform the test.
- 246 19.22.2 For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for
 247 leaks or has a certificate from a transferor that a leak test has been done within the 6 months
 248 before the transfer.
- 249 19.22.2.1 Water from the pool must be checked for contamination each day the irradiator
 250 operates. This check may be done either by using a radiation monitor on a pool
 251 water circulating system or by analysis of a sample of pool water.
- 252 19.22.2.2 If a check for contamination is done by analysis of a sample of pool water, the
 253 results must be available within 24 hours.
- 254 19.22.2.3 If the licensee uses a radiation monitor on a pool water circulating system, the
 255 detection of above normal radiation levels must activate an alarm.
- 256 (1) The alarm set-point must be set as low as practical, but high enough to avoid
 257 false alarms.
- 258 (2) The licensee may reset the alarm set point to a higher level if necessary to
 259 operate the pool water purification system to clean up contamination in the pool if
 260 specifically provided for in written emergency procedures.
- 261 19.22.3 If a leaking source is detected, the licensee shall arrange to remove the leaking source from
 262 service and have it decontaminated, repaired, or disposed of by an ~~U.S. Nuclear Regulatory~~
 263 ~~Commission~~**NRC** or Agreement State licensee that is authorized to perform these functions.
- 264 19.22.3.1 The licensee shall promptly check its personnel, equipment, facilities, and
 265 irradiated product for radioactive contamination.
- 266 19.22.3.2 No product may be shipped until the product has been checked and found free of
 267 contamination.
- 268 19.22.3.3 If a product has been shipped that may have been inadvertently contaminated,
 269 the licensee shall arrange to locate and survey that product for contamination.
- 270 19.22.3.4 If any personnel are found to be contaminated, decontamination must be
 271 performed promptly.
- 272 19.22.3.5 If contaminated equipment, facilities, or products are found, the licensee shall
 273 arrange to have them decontaminated or disposed of by a ~~U.S. Nuclear~~
 274 ~~Regulatory Commission~~**NRC** or Agreement State licensee that is authorized to
 275 perform these functions.
- 276 19.22.3.6 If a pool is contaminated, the licensee shall arrange to clean the pool until the
 277 water contamination levels do not exceed the appropriate concentration in Part 4,
 278 Appendix 4B, Table 4B2, Column 2 (See 4.52 and 4.53 for notification and
 279 reporting requirements).
- 280 **19.23 Inspection and Maintenance.**

281 * * *

282 **19.24 Pool Wwater Ppurity.**

283 19.24.1 Pool water purification systems must be run sufficiently to maintain the conductivity of the pool
284 water below 20 microsiemens per centimeter under normal circumstances.

285 19.24.1.1 If pool water conductivity rises above 20 microsiemens per centimeter, the
286 licensee shall take prompt actions to lower the pool water conductivity and shall
287 take corrective actions to prevent future recurrences.

288 19.24.2 The licensee shall measure the pool water conductivity frequently enough, but no less than
289 weekly, to assure that the conductivity remains below 20 microsiemens per centimeter.
290 Conductivity instruments must be calibrated at least annually.

291 **19.25 Attendance Dduring Ooperations.**

292 19.25.1 Both an irradiator operator and at least one other individual, who is trained on how to respond
293 and prepared to promptly render or summon assistance if the access control alarm sounds, shall
294 be present onsite:

295 19.25.1.1 Whenever the irradiator is operated using an automatic product conveyor
296 system; and

297 19.25.1.2 Whenever the product is moved into or out of the radiation room when the
298 irradiator is operated in a batch mode.

299 19.25.2 At a panoramic irradiator at which static irradiations (no movement of the product) are occurring,
300 an individual who has received the training required in 19.18.7 on how to respond to alarms must
301 be onsite.

302 19.25.3 At an underwater irradiator, an irradiator operator must be present at the facility whenever the
303 product is moved into or out of the pool.

304 19.25.3.1 An individual who moves the product into or out of the pool of an underwater
305 irradiator need not be qualified as an irradiator operator; however, each such
306 individual shall have received the training required in 19.18.6 and 19.18.7. **Static**
307 **irradiations may be performed without a person present at the facility.**

Comment [jsj13]: Language relating to static irradiations is added consistent with 10 CFR 36.65(c) and SSR CR Part Q.26.c.
NRC Compatibility = H&S

308 **19.26 Entering and LLeaving the Irradiation RRoom.**

309 * * *

311 **19.27 Irradiation of Eexplosive or Fflammable Mmaterials.**

312 19.27.1 Irradiation of explosive material is prohibited unless the licensee has received prior written
313 authorization from the Department.

314 19.27.1.1 Authorization will not be granted unless the licensee can demonstrate that
315 detonation of the explosive would not rupture the sealed sources, injure
316 personnel, damage safety systems, or cause radiation overexposures of
317 personnel.

318 19.27.2 Irradiation of more than small quantities of flammable material (flash point below 140°CF) is
319 prohibited in panoramic irradiators unless the licensee has received prior written authorization
320 from the Department.

Comment [jsj14]: Correction of temperature units, consistent with 10 CFR 36 and SSR CR Part Q.28.

321 19.27.2.1 Authorization will not be granted unless the licensee can demonstrate that a fire
 322 in the radiation room could be controlled without damage to the sealed sources
 323 or safety systems and without radiation overexposures of personnel.

324 **RECORDS AND REPORTS**

325 **19.28 Records and Retention Periods.**

326 19.28.1 The licensee shall maintain the following records at the irradiator for the periods specified:

327 19.28.1.1 A copy of the license, license conditions, documents incorporated into a license
 328 by reference, and amendments thereto until superseded by new documents or
 329 until the Department terminates the license for documents not superseded;

330 19.28.1.2 Records of each individual's training, tests, and safety reviews provided to meet
 331 the requirements of 19.18.1, 19.18.2, 19.18.3, 19.18.4, 19.18.6, and 19.18.7 until
 332 3 years after the individual terminates work;

333 19.28.1.3 Records of the annual evaluations of the safety performance of irradiator
 334 operators required by 19.18.5 for 3 years after the evaluation;

335 19.28.1.4 A copy of the current operating and emergency procedures required by 19.19
 336 until superseded or the Department terminates the license. Records of the
 337 radiation safety officer's review and approval of changes in procedures as
 338 required by 19.19.3.3 retained for 3 years from the date of the change;

339 19.28.1.5 Evaluations of personnel dosimeters (film badge, optically stimulated
 340 luminescence and thermoluminescence dosimeter) required by 19.20 in
 341 accordance with 4.46 **until the Department terminates the license**;
 342 * * *

343 19.28.1.13 Records related to decommissioning of the irradiator as required by 3.16.6-85.

344 **19.29 Reports.**

345 19.29.1 In addition to the reporting requirements in other parts of the regulations, the licensee shall report
 346 the following events **if not reported under other parts of Department regulations**:

347 19.29.1.1 Source stuck in an unshielded position;

348 19.29.1.2 Any fire or explosion in a radiation room;

349 19.29.1.3 Damage to the source racks;

350 19.29.1.4 Failure of the cable or drive mechanism used to move the source racks;

351 19.29.1.5 Inoperability of the access control system;

352 19.29.1.6 Detection of radiation source by the product exit monitor;

353 19.29.1.7 Detection of radioactive contamination attributable to licensed radioactive
 354 material;

355 19.29.1.8 Structural damage to the pool liner or walls;

356 19.29.1.9 Abnormal water loss or leakage from the source storage pool; or

357 19.29.1.10 Pool water conductivity exceeding 100 microsiemen per centimeter.

Comment [jsj15]: Language modified consistent with 10 CFR 36.81(e) and SSRCR Part Q.

 However, the original language in parenthesis and "in accordance with 4.46" which is not found in 10 CFR 36 (or SSRCR Part Q), is retained for clarity.

 NRC Compatibility (36.81)= D

Comment [jsj16]: Cross-reference correction, consistent with 10 CFR 36.81.

 NRC Compatibility = D

Comment [jsj17]: Clarifying language added, consistent with 10 CFR 36.83(a) and SSRCR Part Q.30.

 NRC Compatibility = C

358 19.29.2 The report must include a telephone report within 24 hours as described in ~~4.52.24.53.1.1~~, and a
359 written report within 30 days as described in 4.53.1.2.

Comment [jsj18]: Cross reference is corrected for consistency with 36.83(b) and SSRCR Part Q.
NRC Compatibility = C

360

361 **EDITOR'S NOTES**

362 6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are
363 located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the
364 rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of
365 the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.

366 **History**

367