

1 ~~(DRAFT)~~ 1 02/25/2021

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~~ May 19, 2021, effective date July 15, 2021

10 PART 19: LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

11
12 [* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

13 * * *
14 (19.1.5) Published Material Incorporated by Reference.

15 ~~Published material incorporated in Part 19 by reference is available in accord with Part 1, Section~~
16 ~~1.4.~~

17 19.1.5.1. Throughout this Part 19, federal regulations, state regulations, and
18 standards or guidelines of outside organizations have been adopted and
19 incorporated by reference. Unless a prior version of the incorporated
20 material is otherwise specifically indicated, the materials incorporated by
21 reference cited herein include only those versions that were in effect as of
22 the most recent effective date of this Part 19 (July 2021), and not later
23 amendments or editions of the incorporated material.

24 19.1.5.2. Materials incorporated by reference are available for public inspection, and
25 copies (including certified copies) can be obtained at reasonable cost,
26 during normal business hours from the Colorado Department of Public
27 Health and Environment, Hazardous Materials and Waste Management
28 Division, 4300 Cherry Creek Drive South, Denver, Colorado 80246.
29 Additionally, <https://www.colorado.gov/cdphe/radregs> identifies where the
30 incorporated materials are available to the public on the internet at no cost.
31 Due to copyright restrictions certain materials incorporated in this Part are
32 available for public inspection at the state publications depository and
33 distribution center.

34 19.1.5.3. Availability from Source Agencies or Organizations.
35 (1) All federal agency regulations incorporated by reference herein are
36 available at no cost in the online edition of the Code of Federal Regulations
37 (CFR) hosted by the U.S. Government Printing Office, online at
38 www.govinfo.gov.

Commented [JSJ6]:
Editorial note1: All comments (such as this one) shown in the right side margin of this draft document are for information purposes only to assist the reader in understanding the proposed rule change during the review and comment process. These side margin notes are **not** part of the rule and all comments will be deleted prior to publication of the final rule by the Colorado Secretary of State.
Editorial note2: Alignment and formatting corrections and minor typographical adjustments may be made in the rule and may not be specifically identified with a side margin comment.
Editorial note3: Note that this is only a partial rule and only those sections impacted by the proposed changes are included.

Commented [JSJ7]:
Adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule, and the Colorado Register publication dates.
The annual rulemaking schedule (regulatory agenda) for the Department may be found [online](#).

Commented [JSJ8]:
Language in section 19.1.5, is revised and amended for consistency with the Colorado Administrative Procedure Act (24-103(12.5)(a)(2), CRS) regarding documents incorporated by reference, and consistent with other recently amended rules.

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

43
 44 * * *

45 "Underwater irradiator" means an irradiator in which the sources always remain shielded under
 46 water and humans do not have access to the sealed sources or the space subject to irradiation
 47 without entering the pool.

Commented [JSJ9]: Formatted to remove unneeded spaces/gaps in the current rule between the definition "underwater irradiator" and section 19.3.

There are no proposed changes to the regulatory requirements.

50 **SPECIFIC LICENSING REQUIREMENTS**

51 **19.3 Application for a specific license.**

52 * * *

53 **DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS**

54 **19.7 Requirements and performance criteria for sealed sources.**

55 Sealed sources shall:

56 19.7.1 Have a certificate of registration issued by the NRC or an Agreement State, or shall have been
 57 evaluated in accordance with 10 CFR **Part 32.210** or the equivalent state regulation;

58
 59 * * *

60
 61 19.8.7 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area
 62 within the personnel access barrier of an underwater irradiator must be posted as required by
 63 **Part 4, Section 4.28**.

64 19.8.7.1 Radiation postings for panoramic irradiators must comply with the posting
 65 requirements of **Part 4, Section 4.28**, except that signs may be removed,
 66 covered, or otherwise made inoperative when the sources are fully shielded.

Commented [JSJ10]: Formatted to delete unneeded spaces/gaps in the current rule between 19.8.7.1 and 19.8.8.

There are no proposed changes to the regulatory requirements.

68 19.8.8 If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must
 69 not be possible to operate the irradiator unless the shielding is in its proper location.

70
 71 * * *

72 19.12.4 Each control for a panoramic irradiator must be clearly marked as to its function.

Commented [JSJ11]: Formatted to delete unneeded spaces/gaps in the current rule between 19.12.4 and 19.13.

There are no proposed changes to the regulatory requirements.

76 **19.13 Irradiator pools.**

77 * * *

78 19.17.1.6 Source Rack

79 (1) For panoramic irradiators, the licensee shall test the movement of the source
80 racks for proper operation prior to source loading, and testing must include
81 source rack lowering due to simulated loss of power.

82 (2) For all irradiators with product conveyor systems, the licensee shall observe and
83 test the operation of the conveyor system to assure that the requirements in
84 19.14 are met for protection of the source rack and the mechanism that moves
85 the rack.

86 (3) Testing must include tests of any limit switches and interlocks used to protect the
87 source rack and mechanism that moves the rack from moving product carriers.

89 19.17.1.7 Access Control.

90 (1) For panoramic irradiators, the licensee shall test the completed access control
91 system to assure that it functions as designed and that all alarms, controls, and
92 interlocks work properly.

93 * * *

95 19.18.7 Individuals who must be prepared to respond to alarms required by 19.8.2, 19.8.9, 19.10.1,
96 19.11.1, 19.11.2, and 19.22.2 shall be trained and tested on how to respond.

97 19.18.7.1 Each individual shall be retested at least once a year.

98 19.18.7.2 Tests may be oral.

100 **19.19 Operating and emergency procedures.**

101 * * *

104 **19.20 Personnel monitoring.**

105 ~~(19.20.1) Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an~~
106 ~~accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while~~
107 ~~operating a panoramic irradiator or while in the area around the pool of an underwater~~
108 ~~irradiator. Irradiator operators shall wear a personnel dosimeter while operating a~~
109 ~~panoramic irradiator or while in the area around the pool of an underwater irradiator.~~

110 19.20.1.1 ~~The personnel dosimeter processor must be accredited for high energy photons~~
111 ~~in the normal and accident dose ranges (see Part 4, Section 4.17.3). The personnel~~
112 ~~dosimeter must be capable of detecting high energy photons in the normal and~~
113 ~~accident dose ranges.~~

Commented [JSJ12]:
Formatted to delete unneeded spaces/gaps in the current rule between 19.17.1.6(3) and 19.17.1.7.

There are no proposed changes to the regulatory requirements.

Commented [JSJ13]:
Formatted to delete unneeded spaces/gaps between 19.18.7.2 and 19.19 in the current rule.

There are no proposed changes to the regulatory requirements.

Commented [JSJ14]:
The provisions of 19.20 are revised for consistency with 2020 amendments to U.S. Nuclear Regulatory Commission (NRC) regulations in [10 CFR Part 36.55](#).

The NRC amended this federal rule to authorize/allow the use of modern individual monitoring devices at panoramic irradiator facilities. In the past, NRC has required the use of personnel dosimetry that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. Some new dosimetry devices do not require the type of processing envisioned in the text of the prior rule and may instead be read directly by internet-enabled computers, smartphones, and tablets by the licensee. The design of these newer devices (rather than the qualifications of the processor) allow for collection of accurate dose information. The proposed rule is rephrased to allow the use of individual monitoring devices that do not require NVLAP processing.

NRC [RATS 2020-1](#)
NRC Compatibility "H&S"

114 19.20.1.2 Each personnel dosimeter must be assigned to and worn by only one individual.

115 19.20.1.3 Film badges must be ~~processed~~ replaced at least monthly and all other
116 personnel dosimeters that require replacement must be ~~processed~~ replaced at
117 least quarterly.

118 19.20.1.4 ~~After replacement, each personnel dosimeter must be promptly processed. All~~
119 ~~personnel dosimeters must be evaluated at least quarterly or promptly after~~
120 ~~replacement, whichever is more frequent.~~

121 * * *

122 19.21.2 If the radiation levels specified in 19.9 are exceeded, the facility must be modified to comply with
123 the requirements in 19.9.

124 } **Commented [JSJ15]:**
125 Formatted to delete unneeded spaces/gaps in the current rule between 19.21.2 and 19.21.3.

126 19.21.3 Portable radiation survey meters must be calibrated at least annually to an accuracy of 20
127 percent for the gamma energy of the sources in use.
128 There are no proposed changes to the regulatory requirements.

128 * * *

129 19.25.2 At a panoramic irradiator at which static irradiations (no movement of the product) are occurring,
130 an individual who has received the training required in 19.18.7 on how to respond to alarms must
131 be onsite.

132 } **Commented [JSJ16]:**
133 Formatted to delete unneeded spaces/gaps in the current rule between 19.25.2 and 19.25.3.
134 There are no proposed changes to the regulatory requirements.

135 19.25.3 At an underwater irradiator, an irradiator operator must be present at the facility whenever the
136 product is moved into or out of the pool.

137 * * *

138 19.27.2.1 Authorization will not be granted unless the licensee can demonstrate that a fire
139 in the radiation room could be controlled without damage to the sealed sources or safety
140 systems and without radiation overexposures of personnel.

141 } **Commented [JSJ17]:**
142 Formatted to delete unneeded spaces/gaps in the current rule between 19.27.2.1 and 19.28.
143 There are no proposed changes to the regulatory requirements.
144

145 **RECORDS AND REPORTS**

146 **19.28 Records and retention periods.**

147 19.28.1 The licensee shall maintain the following records at the irradiator for the periods specified:

148 19.28.1.1 A copy of the license, license conditions, documents incorporated into a license
149 by reference, and amendments thereto until superseded by new documents or until the
150 Department terminates the license for documents not superseded;

151 19.28.1.2 Records of each individual's training, tests, and safety reviews provided to meet
152 the requirements of 19.18.1, 19.18.2, 19.18.3, 19.18.4, 19.18.6, and 19.18.7 until 3 years
153 after the individual terminates work;

154 19.28.1.3 Records of the annual evaluations of the safety performance of irradiator
155 operators required by 19.18.5 for 3 years after the evaluation;

156 19.28.1.4 A copy of the current operating and emergency procedures required by 19.19
157 until superseded or the Department terminates the license. Records of the radiation
158 safety officer's review and approval of changes in procedures as required by 19.19.3.3
159 retained for 3 years from the date of the change;

160 ~~19.28.1.5~~ Evaluations of personnel dosimeters (~~film badge, optically stimulated~~
161 ~~luminescence and thermoluminescence dosimeter~~) required by 19.20 in accordance with
162 Part 4, Section 4.46 until the Department terminates the license;

* * *

164 19.28.1.13 Records related to decommissioning of the irradiator as required by Part 3,
165 Section 3.16.5.

Commented [JSJ18]:
Reference to specific types of dosimeters is removed for consistency with the proposed change in Section 19.20. The proposed change will also make the language consistent with [10 CFR Part 36.81\(e\)](#).

166 }
167

Commented [JSJ19]:
Formatted to delete unneeded spaces/gaps in the current rule between 19.28.1.13 and 19.29.
There are no proposed changes to the regulatory requirements.

168 **19.29 Reports.**

* * *

170 [NO FURTHER CHANGES TO THE RULE AFTER THIS POINT]

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172