

DRAFT B 12/09/2020

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

6 CCR 1007-1 Part 19

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

Adopted by the Board of Health on July 20, 2016 May 19, 2021, effective date July 15, 2021

PART 19: LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

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* * * DENOTES UNAFFECTED SECTIONS/PROVISIONS IN THE DRAFT RULE]

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19.1.5 Published Material Incorporated by Reference.

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

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

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

19.1.5.3. Availability from Source Agencies or Organizations.

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

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Editorial note 1: 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 note 2: 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 note 3: Note that this is only a partial rule and only those sections impacted by the proposed changes are included.

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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](#).

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Language in section 19.1.5, is revised and amended for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS) regarding documents incorporated by reference, and consistent with other recently amended rules.

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

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

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SPECIFIC LICENSING REQUIREMENTS

19.3 Application for a specific license.

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DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

19.7 Requirements and performance criteria for sealed sources.

Sealed sources shall:

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

* * *

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

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

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

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

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19.13 Irradiator pools.

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19.17.1.6 Source Rack.

- (1) For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading, and testing must include source rack lowering due to simulated loss of power.
- (2) For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 19.14 are met for protection of the source rack and the mechanism that moves the rack.
- (3) Testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

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19.17.1.7 Access Control.

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

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

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

19.18.7.2 Tests may be oral.

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19.19 Operating and emergency procedures.

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19.20 Personnel monitoring.

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

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

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

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

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

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

19.21.3 Portable radiation survey meters must be calibrated at least annually to an accuracy of 20 percent for the gamma energy of the sources in use.

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

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

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

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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"

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RECORDS AND REPORTS

19.28 Records and retention periods.

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

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

19.28.1.2 Records of each individual's training, tests, and safety reviews provided to meet 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 after the individual terminates work;

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

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

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

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

19.29 Reports.

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[NO FURTHER CHANGES TO THE RULE AFTER THIS POINT]

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Commented [JSJ13]:
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\(e\)](#).

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