COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: James H. Grice, Radiation Program Manager, Hazardous Materials and Waste Management Division
James S. Jarvis, Regulatory Lead, Hazardous Materials and Waste Management Division
Katherine Liberman, X-Ray Unit Leader, Hazardous Materials and Waste Management Division

Through: Jennifer T. Opila, Division Director JTO

Date: June 16, 2021

Subject: **Rulemaking Hearing** concerning proposed amendments to 6 CCR 1007-1 Part 8, Radiation safety requirements for radiation generating devices (RGDs) not used in the healing arts, Part 5, Radiation safety requirements for industrial radiographic operations, and Part 2, Registration of radiation machines, facilities and services.

The radiation program is proposing changes to the Part 8, Part 5, and Part 2 regulations to conform to the 2016 Part H model regulation of the Conference of Radiation Control Program Directors (CRCPD), Inc., and minor 2020 federal rule changes of the U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 34. In accordance with state statute, Colorado is required to adopt rules which are compatible and consistent with the applicable model rules and federal regulation. In addition to these more externally driven changes, minor technical changes to the rules are also proposed for consistency with other recent radiation regulation changes and based on stakeholder feedback and consideration.

The proposed changes to the Part 8 rule will specify requirements that are specific to different types of non-healing arts x-ray systems rather than limiting the rule to mostly analytical x-ray systems as found in current rule. The rule will clarify what types of use fall within Part 8 and which do not. Included are new sections to address the requirements based on design along with some specific types of use, including open beam systems, open beam hand-held systems, closed beam systems, and systems used for human security screening or cargo where there is likelihood for human exposure. The proposed rule provides some additional control requirements specific to the safety concerns for these x-ray devices.

The proposed Part 5 rule changes will remove references to processing of dosimeters used for occupational monitoring (similar to other recently proposed rule changes) which will allow for use of instant read dosimeters. Additionally, the proposed change will remove the requirements for cabinet x-ray systems and instead defer to Part 8 for requirements.

The proposed Part 2 rule changes will add a tie-in to the Part 8 training requirements.

New text appears as red bold text and deleted text shown as strikethrough text. The Part 8 proposed changes impact numerous rule sections and therefore the entire rule is included. The Part 5 proposed are limited in scope and impact only a few areas of the rule, therefore, only those impacted sections are included in the proposed draft. Consistent with Board practice, changes since the request for rulemaking in April are highlighted in yellow.

The Radiation Program requests that the Board of Health adopt the changes as proposed.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1007-1,
Part 8, Radiation safety requirements for RGDs not used in the healing arts
Part 5, Radiation safety requirements for industrial radiographic operations
Part 2, Registration of radiation machines, facilities, and services

Basis and Purpose.

The current Part 8 rule is focused on the regulation of non-healing arts radiation generating devices (RGDs) (x-ray machines) used in a variety of non-medical settings. Excluding open-beam systems used for commercial industrial radiography purposes, all other RGDs/uses are regulated under Part 8. The examples and wording in the current rule have mostly been limited to and focused on analytical equipment for x-ray diffraction or fluorescence analysis. The use of these industrial type x-ray devices has expanded over the years but the requirements in the current rule have not specifically addressed them. In keeping with statutory requirements to base the radiation regulations on the model rules of CRCPD and the need to more clearly address RGDs beyond the analytical instrument focus of the current rule, the rule is being updated.

The types of industries currently regulated under Part 8 are very diverse and include x-ray devices used in manufacturing, elemental analysis, food processing, antiquities evaluation, research, security and safety, forensics, and higher education, among other uses. The proposed Part 8 changes are based on the CRCPD model Part H rule which was amended in 2016 to address the many non-healing arts RGDs used in industry. The rule is structured to address general requirements applicable to all RGDs, but also includes provisions that are specific to the relative radiation hazard based on the configuration of the device (closed-beam, open-beam, etc.) or the specific application.

The following information highlights the more significant changes to the Part 8 by section. Except where otherwise indicated, or are needed for continuity between regulatory parts, the proposed changes are based on the 2016 Part H model rule of CRCPD.

Section 8.1.3 (Scope)
The scope section is modified, to include the operating constraints of Part H. Devices outside of the specified range would either be outside of regulatory view or would be regulated under another rule. The section also includes new language on specific devices or equipment that is excluded from regulation under Part 8, with modifications made for consistency with statute. The section also includes explanatory language to help guide the user on the types of devices or uses regulated outside of Part 8.

Section 8.1.5 (Intent)
Although not all encompassing, this informational "intent" section is added to again aide the user in understanding the scope and breadth of devices regulated under the rule.

Section 8.1.6 (Published material…)
Consistent with other recently amended rules, the standard incorporation by reference language is updated.

Section 8.2 (Definitions)
The definitions section has been amended significantly to address the broader content of the proposed rule. Some current definitions have been retained, or were modified slightly, while others are new definitions. Except as specifically noted in the draft rule, the definitions are derived from the current Part 8, federal rule, national or technical standards, or for consistency and compatibility with other regulatory parts.

Sections 8.3 and 8.4 (Administrative requirements)
These provisions have been modified and restructured, but largely retain existing requirements with a few exceptions. Some provisions have been modified to rephrase existing requirements, such as those found in Part 2. Some new training requirements are tied in through reference to Part 8 and are in addition to those found in Part 2. Included is a requirement for records retention, consistent with other regulations. The revised provisions regarding labeling and warning lights are typically mandated at the manufacturing level through federal regulations of FDA. References to "analytical systems" are removed from these sections and elsewhere in the rule, consistent with the intent to address different types and uses of RGDs.

These sections provide a new requirement for testing of the applicable safety devices associated with the RGD at 6 month frequencies. A record of this testing is required under the proposed rule. Additionally, this section provides clarifying training requirements for operators of RGDs.

Section 8.5 (Radiation levels and dosimetry)
This section is updated defer to other sections (typically 8.4) where existing requirements have been relocated. The provision pertaining to personnel monitoring has been modified to allow for exemptions (from dosimetry) when specifically authorized by the Department. The provision clarifies that individuals working near the beam of an open-beam RGD are to utilize extremity dosimetry rather than just those instances where safety devices are not present or deactivated (as stated in the current rule).

Section 8.6 (Additional requirements for closed-beam RGDs)
This new section addresses RGDs that are considered closed-beam systems. Such systems would include cabinet type x-ray systems, and other systems that are required to have interlocked doors, panels or similar safety devices to protect or limit individuals from entering the primary beam. The section provides radiation emission limits. The section also includes specific provisions that require the operators of bag/package type security screening units to be present at the control panel in the event an exposure must be terminated promptly.

Section 8.7 (Additional requirements for open beam RGDs)
This new section addresses RGDs that are open-beam systems that are not otherwise addressed in other sections of the proposed rule. Since open beam systems generally present a greater exposure hazard, the rule proposes that the registrant justify such use and outline the safety devices evaluated and/or in use at the facility. The

proposed rule requires x-ray status indicators, labeling, control of unused beam ports and shutters, and requirements for controlling access to areas of use. The section also provides some specific training topics to be addressed for use of open beam systems.

Section 8.8 (Additional requirements for hand-held open beam RGDs)
This new section provides requirements for devices that are open beam and hand-held during use. A common device for performing x-ray fluorescence in the field is an example of a device falling within the requirements of 8.8. This section of the proposed rule provides conditions for use and training of these devices.

Section 8.9 (Shielded room RGDs)
The section provides requirements for RGDs that cannot meet the occupational dose limits of Part 4 and cannot be otherwise shielded in a cabinet or similar enclosure to reduce exposure. Such devices must be contained in an enclosed, shielded room. The proposed section specifies posting and area control, entrance interlocks, and other safety device and warning system requirements.

Section 8.10 (Reserved)
This section is held in reserve for future use.

Section 8.11 (RGDs used in human body security screening or vehicle screening for public protection)
This section provides requirements for RGDs used for human body security screening. Such devices are typically used in jail or prison facilities to periodically screen incarcerated individuals for contraband items which may present a safety hazard for staff and other inmates. As is required through the current registration process, the proposed rule includes requirements to justify the use of the system. The proposed section also provides limits for quality and optimization requirements when using such systems, and provides dose limits for these RGDs to limit exposure to the individuals being scanned, based on the frequency of use. The proposed language also provides similar dose limit controls for systems used for large cargo/vehicle screening x-ray systems where exposure to humans is anticipated.

Current requirements in Part 5 require the use of individual monitoring devices (personnel dosimetry) that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. This wording effectively prohibits the use of dosimetry technologies that do not require processing by an accredited NVLAP facility.

The proposed Part 5 amendment revise the language, consistent with federal rule, to allow the use of modern personnel dosimetry industrial radiography operations. The types and quantities of radioactive materials used in this industry is of higher risk and has a greater potential for personnel exposure. The modern dosimetry systems permitted under the proposed rule changes typically require electronic communication with the manufacturers systems and thereby providing a level of quality control. This newer technology will allow this industry to obtain a prompt readout following routine activities or during events involving potential high exposures rather than wait for dosimetry processing.

Dosimetry devices that continue to require offsite processing will continue to require processing that is NVLAP accredited in accordance with Part 4, Section 4.17 of the current regulations.

Part 8, Section 8.1.6 and Part 5, Section 5.1.5

Similar to other recent radiation regulation amendments, changes are also proposed to make technical and formatting updates to the rule for consistency with the Colorado Administrative Procedure Act with regard to documents incorporated by reference. A number of similar changes were made to the radiation regulations in 2020.

These revised sections incorporate the updated standard incorporation by reference language, consistent with recently amended radiation control regulations.

Part 5, Section 5.20

This section is updated, consistent with recently amended federal regulations to eliminate references to National Voluntary Laboratory Accreditation Program (NVLAP) processing. This change will allow use of dosimetry systems that can be read directly by the licensee facility. This is not a requirement, but rather provides additional dosimetry options for the regulated facility.

Throughout Part 8 and Part 5

Minor typographical and formatting errors are corrected, or due to new sections or provisions being added to or removed from the rules.

Part 2

Minor changes are made to clarify the applicability of training requirements pertinent to Part 8 and Part 5, consistent with other proposed changes.

Specific Statutory Authority. Statutes that require or authorize rulemaking:

25-1.5-101(1)(k), 25-1.5-101(1)(l), 25-11-103, 25-11-104, and 25-1-108, C.R.S.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.

__X___ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

__X___ Yes ___ URL

_____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

__X___ No

Does the proposed rule language create (or increase) a state mandate on local government?

_____ Yes

__X___ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;

- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1007-1,
Part 8, Radiation safety requirements for RGDs not used in the healing arts
Part 5, Radiation safety requirements for industrial radiographic operations
Part 2, Registration of radiation machines, facilities, and services

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

   The classes of persons affected by the proposed rule includes those facilities that use x-ray based radiation generating devices for non-healing arts applications. This includes a wide range of industries, applications, and facility types, including research and testing facilities, correctional institutions, analytical laboratories, food processing and production activities, educational institutions, and manufacturing among others.

Group of persons/entities Affected by the Proposed Rule	**Size of the Group**	**Relationship to the Proposed Rule Select category: C/CLG/S/B**
Registrant facilities using RGDs for non-healing arts purposes and their employees	Approx. 428	C* / B
Industrial radiography registrants/licensees and their employees	Approx. 16	C* / B
Registered service companies and qualified inspectors who provide services to registered RGD users	Approx. 174	C*
Other stakeholders having an interest in industrial use x-ray (and radioactive materials regulations)	243+	S

*Note: No direct impact on GLG. Any facility that possesses an RGD in the state of Colorado is required under current regulations to register with the department.

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please refer to the following relationship categorization key:

C = individuals/entities that implement or apply the rule.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

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.

   <u>Economic outcomes</u>

Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, and any financial benefits.

For facilities that must implement the requirements of Part 8 (groups C and B in item 1 above), the following are the anticipated financial costs and benefits for specific provisions.

Anticipated financial cost(s):	**Anticipated financial benefit(s)**
Proposed 8.4.10 requires registrants to test the safety devices (interlocks, warning lights, etc.) every 6 months and document this). The cost will vary depending upon the number of RGDs and complexity of the device. Some RGDS may have self-test/self-check systems that will require <u>Cost or cost range estimate:</u> Facility with 1 RGD: $30 per year Facility with 5 RGDs: $150 per year Facility with 10 RGDs: $300 per year [Est based on 0.3h per device @ $50 per hour] Note: Cost estimates may not apply to all RGDs. Some advanced RGDs may have the capability for self-checks and can determine when certain safety systems are not operating properly.	N/A
N/A	Proposed provision 8.4.5.B reduces the need/requirement for an RGD registrant to possess a survey instrument (as required by current rule in 8.6.2), and instead allows greater flexibility for a RGD facility/registrant to instead have access to a survey instrument. This will allow additional flexibility for the facility in implementing the requirement. Registrants having RGDs at different locations or portions of their campus would not need to purchase survey instruments for each location and could instead share survey instruments. While this may or may not benefit current facilities that already possess a survey instrument, it may result in a cost savings for some future RGD registrants and allow them to rely on another facility or entity for a survey instrument needs.

	Savings or range of savings: $500 - $3,500 per instrument ($1,523 ave)
Proposed 8.9 specifies registrants who are operating a RGD that cannot meet the public dose limits of 4.14 can operate the device in a shielded room. This may require the facility to additional safety controls to meet the requirements of 8.9. It is not known whether many facilities currently operating such a system in Colorado or what additional controls would be necessary. Cost or cost range estimate: Unknown/not available.	N/A

For facilities that are interested in the requirements of Part 8 (groups S and B in item 1 above), the following are the anticipated financial costs and benefits.

Anticipated financial cost(s):	**Anticipated financial benefit(s)**
None.	None.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

For the proposed Part 8 changes, the anticipated favorable non-economic outcome is that the rule will be updated to better address the safety considerations for a wide variety of uses of RGDs for non-medical purposes. In addition, the changes will better align our regulatory program with the model rule and other states that have implemented the model regulation or similar requirements.

For the proposed Part 5 changes, the anticipated favorable non-economic outcome is that the approximately 16 licensees who fall under the requirements of this regulatory part will have added flexibility in how they monitor the radiation dose of their employees. Although some facilities have requested specific authorization to utilize instant read dosimetry systems through their license, the proposed change will make this dosimetry option available to all licensees who fall under this regulatory part and without the need for special authorization.

There are believed to be no non-favorable non-economic outcomes as a result of the proposed rule changes.

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.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

There are no to minimal anticipated costs to CDPHE associated with the proposed changes.

B. Anticipated CDPHE Revenues:

There are no change in revenues as a result of the proposed changes. The proposed changes are not expected to increase or decrease revenues.

C. Anticipated personal services, operating costs or other expenditures by another state agency:

There are no anticipated personal services, operating costs or other expenditure by another state agency.

D. Anticipated Revenues for another state agency:

None. No other state agency has regulatory authority over RGDs.

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

Along with the costs and benefits discussed above, the proposed revisions:

_X_ Comply with a statutory mandate to promulgate rules.
_X_ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X_ Maintain alignment with other states or national standards.
_X_ Implement a Regulatory Efficiency Review (rule review) result
_X_ Improve public and environmental health practice.
_X_ Implement stakeholder feedback.

The proposed rule will advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the

oil and gas industry.
___ Supports local agencies and COGCC in oil and gas regulations.
___ Reduces VOC and NOx emissions from non-oil and gas contributors

3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.

___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes.
___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation.
___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.

4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.

___ Ensures access to breastfeeding-friendly environments.

5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.

___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.
___ Performs targeted programming to increase immunization rates.
___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).

6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023. ___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident. ___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment. ___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.
9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023. ___ Implements the CDPHE Digital Transformation Plan. ___ Optimizes processes prior to digitizing them. ___ Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations
11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment ___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

Retaining the current Part 8 rule as is with no amendment would not be beneficial as it is primarily limited to analytical type RGDS and does not specifically address requirements or safety considerations of the many other uses of non-healing arts (non-medical) uses of x-ray machine RGDs.

For the proposed Part 5 change pertaining to dosimetry systems, the cost of inaction will make parts of the rule inconsistent with federal regulations and the national framework for radiation regulation. Inaction will also result in licensed facilities having fewer options with implementing their radiation dosimetry program. Similarly, not implementing the updated provisions pertaining to documents incorporated by reference will potentially make the rule incompatible with the Colorado Administrative Procedure Act.

There are no benefits of inaction.

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

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute. By making the rule more consistent with the national framework of regulation described in the CRCPD Part H model rule, the regulation of these RGDs is brought into further consistency with the national framework of regulation for those states that have adopted requirements of the model rule.

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

No alternatives to this rulemaking were considered.

For proposed changes applicable to most of Part 8, the intent is to make the rule consistent with the model rule of the CRCPD. The current Part 8 rule is generally inadequate in that it does not address the many uses and applications and safety considerations unique to different industrial (non-healing arts) RGDs.

For the applicable rule and sections of Part 5, failure to implement requirements that are consistent with federal rule will potentially make Colorado's Agreement State program incompatible with our NRC agreement.

For the applicable rule and sections of Part 8 and Part 5, failure to implement requirements that are consistent with the requirements of the Administrative Procedure Act for documents incorporated by reference may result in the rule being negated or invalidated by the legislature.

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 proposed changes did not require a data based evaluation or analysis.

The proposed language and approach pertaining to the regulation of non-healing arts RGDs is consistent with the national model rule for such devices.

The proposed language and approach pertaining to documents incorporated by reference are consistent with information found in statute and other Department rules and regulations.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1007-1,
Part 8, Radiation safety requirements for RGDs not used in the healing arts
Part 5, Radiation safety requirements for industrial radiographic operations
Part 2, Registration of radiation machines, facilities, and services

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Approximately 1,012 stakeholders were notified via email of the opportunity to comment on the proposed draft rules, which were posted on the Department website for a 30 day period in February-March 2021. The stakeholders consist of industrial x-ray registrants/user facilities, companies that provide services to industrial x-ray machine facilities, qualified inspectors for x-ray machines, individuals having an interest in radiation regulations applicable to industrial uses of radiation, and industrial radiography licensees.

Two virtual stakeholder meetings were held during the comment period in early March. A total of 48 individuals attended the two meetings. Attendees appeared to represent a variety of RGD uses regulated under the proposed regulations. By the end of the comment period, the department received approximately 7 written comment letters/emails containing a number of questions and comments. The program reviewed the comments and where feasible, addressed those concerns to the extent possible in the proposed rule provided to the Board of Health. Some other concerns identified were more process/programmatic related and will be address outside of regulation.

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

___ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

_X__ Yes.

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.

The major factual or policy issues encountered during the stakeholder process included the following:

1. Stakeholders using certain RGDs in a research setting at an institute of higher education expressed concerns over the originally proposed definition and applicability of "industrial radiography" to their activities. Commercial industrial radiography most commonly involves use of high activity radioactive sources in a field setting at a temporary jobsite where images of pipes, and similar items are made to find flaws following repair or assembly. Such activities can often involve many exposures in a short amount of time. Industrial radiography is and has been regulated under Part 5 of the regulations for many years. Due to the risk involved for operators in industrial radiography, and the potential for exposure to members of the public, the training and certification requirements for industrial radiographers is fairly extensive. Commercial industrial radiography may also involve use of pulsed or non-pulsed x-ray based systems used at temporary field locations or in a shielded room at the licensee facility.

Similar x-ray based systems used for research and education in a non-commercial environment at a university or college, generally allows additional oversight and control and a reduction in risk to operators and others. We therefore feel that clarifying the requirements applicable this particular use was warranted. As a result of this stakeholder concern, the proposed Part 8 and Part 5 rules were modified to clarify that open beam RGD systems used for research or higher education purposes will not be considered industrial radiography and will be regulated under Part 8.

2. Stakeholders in the bomb squad community (regulated under the originally proposed Section 8.10) expressed concerns over proposed requirements – including the requirement to maintain a utilization log each time the x-ray system is used. As a result, the original section of the rule that addressed use of RGDs for bomb detection has been removed from the rule and placed in a reserved status. The Division needs additional time to evaluate the issues surrounding this type of use further and will work with stakeholders to hopefully come to a consensus to moving forward to address use of these types of RGDs.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	X	Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	X	Ensures a competent public and environmental health workforce or health care workforce.
X	Other: Benefits stakeholders with additional information where to locate documents incorporated into the rule to help aide compliance with the requirements.	X	Other: Improves the ability for certain specific licensees to monitor occupational exposure of their workers.

DRAFT 2 05/27/2021

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - RADIATION SAFETY REQUIREMENTS FOR RADIATION GENERATING DEVICES NOT USED IN THE HEALING ARTS

6 CCR 1007-1 Part 08

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

Adopted by the Board of Health June 16, 2021; effective August 14, 2021

PART 8: RADIATION SAFETY REQUIREMENTS FOR RADIATION GENERATING DEVICES NOT USED IN THE HEALING ARTS

8.1 Purpose and Scope.

8.1.1 Authority.

~~8.1.1.1~~**A.** Rules and regulations set forth herein are adopted pursuant to the provisions of sections 25-1-108, 25-1.5-101(1)(l), and 25-11-104, CRS.

8.1.2 Basis and Purpose.

~~8.1.2.1~~**B.** A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

8.1.3 Scope.

~~8.1.3.1~~**A.** This part provides special requirements for non-healing-arts radiation generating devices (**RGDs**)~~, such as analytical equipment used for x-ray diffraction or fluorescence analysis~~. **operating between 5 kiloelectron volts (keV) and 1 million electron volts (MeV). For machines operating at energies greater than 1 MeV, see Part 9.**

B. The following machines and equipment are exempt from these regulations:

1. Domestic television receivers.

2. Cold-cathode gas discharge tubes, providing the exposure rates shall not exceed 10 mrem (0.1 mSv) per hour at a distance of thirty (30) centimeters from any point on the external surface of the tube.

3. Other electrical equipment that produces radiation incidental to its operation for other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding not integral to the equipment is removed, does not exceed 25 mrem (0.25 mSv) per year. The production testing or factory servicing for such equipment shall not be exempt.

4. Equipment described in 8.1.3.B shall not be exempt if it is used or handled in such a manner that any individual might receive a dose of radiation in excess of the limits specified in Part 4 of these regulations.

Commented [JSJ1]:
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: The proposed changes to this rule are primarily modeled after the Conference of Radiation Control Program Managers, Inc. (CRCPD) Part H model rule which was amended in 2016. By Colorado law (statute), the rules and regulations pertaining to radiation control must be consistent with the CRCPD model rule(s), except if the Board of Health determines a substantial deviation, substitute rule or no rule is appropriate.

Editorial note 4: The current Part 8 rule make reference to radioactive materials, radioactive sources, and licensees in a few instances. Upon further evaluation by the program, it was determined that the Part 8 rule is not used in the licensing of radioactive materials facilities and should not apply to RGDs containing radioactive materials. RGDs containing radioactive materials are regulated through other regulatory parts and through requirements identified in the radioactive materials license.

Editorial note 5: Consistent with Board of Health policy and practice, items highlighted in yellow have been added or modified since the request for rulemaking in April 2021.

Commented [JSJ2]: The stated adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule by the Board, and the Colorado Register publication dates.

The anticipated dates are based on the annual rulemaking schedule (regulatory agenda) for the Department which may be found online.

Commented [JSJ3]: The acronym "RGD" added here for clarity since it is not used in the rule title, but is used throughout the rule body.

Commented [JSJ4]: Provision added for consistency with the model rule SSRCR Part H (2016), Section H.5.c.

NOTE: The proposed language of B.1 is aligned with state statute - the Radiation Control Act (25-11-107(2)) rather than the Part H model rule. The model rule includes an exposure rate that is not found in Colorado statute.

C. In addition to the requirements of this Part, all registrants are subject to the requirements of Parts 1, 2, 4, 10 and 13 of these regulations. This Part does not pertain to radiation safety requirements for x-ray equipment that is explicitly covered in other sections of these regulations, such as Part 5 (Radiation safety requirements for industrial radiographic operations), Part 6 (X-ray imaging in the healing arts), and Part 9 (Radiation safety requirements for particle accelerators not used in the healing arts).

D. Radiography that meets the definition of "cabinet radiography" as defined in 8.2 shall be regulated under this Part. This includes certified x-ray systems.

E. Radiography (excluding industrial radiography) that occurs in a shielded room as defined in 8.2 shall be regulated under this Part.

F. Industrial radiography that is open-beam, and not in a shielded room and not otherwise listed in this section, shall be regulated under Part 5 of these regulations.

8.1.4 Applicability.

~~8.1.4.1~~**A.** The requirements and provisions of these regulations apply to applicants, ~~licensees~~ and registrants within the scope of by Part 8 unless specifically exempted by Part 8.

~~8.1.4.2~~**B.** The applicable special requirements of Part 5 also apply if an image receptor is used to transform incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformation.

~~8.1.4.3~~**C.** The requirements of ~~by~~ Part 8 are in addition to, and not in substitution for, applicable requirements in other parts of these regulations.

8.1.5 Intent.

RGDs are a broad class of equipment that generate x-rays or particle radiation having energies between 5 keV and 1 MeV, and not intended for medical use on humans. If applicable, all RGDs shall comply with FDA performance standards as defined in Title 21 Code of Federal Regulations, parts 1010 thru 1050.

Examples of RGDs include, but are not limited to:

A. Open and closed analytical x-ray equipment (table top and hand-held);
B. X-ray gauges;
C. Cabinet x-ray radiography;
D. Security screening units;
E. Quality or process control devices;
F. Ion implantation devices;
G. Electron beam welders; and
H. Non-human use x-ray fluoroscopy.

~~8.1.5~~**8.1.6** Published Material Incorporated by Reference.

~~8.1.5.1 Published material incorporated in Part 8 by reference is available in accord with Part 1, Section 1.4.~~**A. Throughout this Part 8, 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**

Commented [JSJ5]: Added for consistency with Part H, Section H.3.

Commented [JSJ6]: The proposed language of "E" deviates slightly from the Part H model rule language, which reads "Quality application devices". The proposed language has been modified from Part H for clarity.

Commented [JSJ7]: Language in section 8.1.5, 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.

effective date of this Part 8 (August 2021), and not later amendments or editions of the incorporated material.

B. 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.

C. 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.

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.

8.2 Definitions.

8.2.1 Definitions of general applicability to these regulations are in Part 1, ~~s~~Section 1.2.

8.2.2 As used in Part 8, each term below has the definition set forth.

Commented [JSJ8]: In 8.2.2, definitions have been added, modified or deleted, consistent with SSRCR Part H (2016), unless otherwise noted.

The developers of the model rule added or modified definitions which originate from multiple sources, including: the prior (1991) Part H rule; 21 CFR 1020.20, and .40 (federal rule); American National Standards Institute (ANSI) standard 43.2, 43.5, and 43.17; and the International Electrotechnical Commission (IEC) standard 62495;

"Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer. This includes high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across the exterior edge of any opening.

~~"Analytical x-ray system" means a group of components utilizing x-rays or gamma rays to determine the elemental composition, examine the microstructure, and/or ascertain characteristics of materials.~~"Analytical x-ray equipment" means equipment that generates (by electronic means) and uses ionizing radiation for the purpose of examining the microstructure of materials, i.e., diffraction and spectroscopy (including fluorescence).

"Baggage unit". See "Security Screening Unit".

"Beam-port" means an opening on the x-ray apparatus designed to emit a primary beam. This does not include openings on baggage units.

"Cabinet radiography" means industrial radiography using radiation machines not subject to FDA performance standard for cabinet x-ray systems, in an enclosed, interlocked cabinet in which the portion of a material being irradiated is contained, and in which:

A. The radiation machine will not operate unless all openings are closed with interlocks activated;

B. The cabinet is shielded such that every location on the exterior meets the conditions for an unrestricted area as defined in Part 4 of these regulations; and

C. The cabinet is constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of bags, packages, and personal items at airline, railroad, and bus terminals, and at other facilities for similar purposes. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not a cabinet x-ray system.

"Cathode ray tube" means any device used to accelerate electrons for demonstration or research purposes, except where such cathode ray tube is incorporated into a television or display monitor that is subject to, and has met applicable federal radiation safety performance standards in 21 CFR 1010 and 1020.10.

"Certified cabinet x-ray system" means a RGD certified by the manufacturer in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of applicable federal radiation safety performance standards 21 CFR 1010 and 1020.40.

"Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

"Closed-beam x-ray equipment" means a system in which the beam path cannot be entered by any part of the body during normal operation.

"Cold-cathode gas discharge tube" means an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

"Collimator" means a device for restricting the useful radiation in one or more directions.

"Control panel" means a device containing means for regulation and activation of a RGD or for the preselection and indications of operating factors.

"Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of an individual in excess of administrative or regulatory limits. This procedure shall include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring devices.

~~"Fail-safe characteristic" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.~~"Fail-safe design" means a design in which all realistically anticipated failures of indicators or safety components result in a condition in which individuals are safe from exposure to radiation. For example, if a light indicating "X-RAY ON" fails, the production of x-rays shall be prevented, or if a shutter status indicator fails, the shutter shall close.

"General-use system" means a human body screening system that delivers an effective dose equal to or less than 25 µrem (0.25 µSv) per screening. Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year.

Commented [JSJ9]:
Language is added beyond the definition in Part H, to include language found in FDA regulation. Specifically, the sentence "Included are all x-ray systems designed…" was added to the definition for clarity.

Commented [JSJ10]:
This definition is replaced by the more detailed "Fail-safe design" definition which follows.

This definition parallels the definition found in ANSI 43.2.

"Hand-held x-ray system" means a portable instrument that is designed to operate when held in the hand, such as a hand-held x-ray fluorescence (XRF) analytical device.

"Human body security screening system" means any x-ray equipment used on humans for security evaluation purposes.

"Industrial radiography" means an examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images for the purpose of detecting structural flaws in objects. Industrial radiography does not include such imaging for education or research purposes at a fixed location.

"Interlock" means a device or engineered system that precludes access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

"Leakage radiation" means all radiation coming from within the source housing, except the useful beam.

"Limited-use system" means a human body screening system that is capable of delivering an effective dose greater than 25 µrem (0.25 µSv) per screening but cannot exceed an effective dose of 1 mrem (10 µSv) per screening. Limited-use systems require additional controls and documentation to ensure that annual individual dose limits required by 8.11.5 are not exceeded.

"Local components" means ~~a part of an analytical~~**parts of a RGD** x-ray system ~~in an area that is~~**and include areas that are exposed to** x-rays, such as radiation source housings, **beam** port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, ~~not including~~**but do not include** power supplies, transformers, amplifiers, readout devices, and control panels.

"Mobile equipment". See "Radiation generating device."

"Normal operating procedures" means a set of step-by-step instructions necessary to accomplish the ~~analysis~~**task**. **These procedures may include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures, which are related to radiation safety.**

~~"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of the body in the primary beam path during normal operation.~~**"Open-beam x-ray equipment" means an open-beam x-ray system in which the beam path could be entered by any part of the body at any time.**

"Portable equipment". See "Radiation generating device."

~~"Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.~~**"Primary beam" means the ionizing radiation coming directly from the radiation source through a beam port into the volume defined by the collimation system.**

"Qualified inspector" means an individual as defined in Part 1 of these regulations.

"Radiation generating device (RGD)" for purposes of Part 8, means any system, device, subsystem, or component thereof, which may generate x-rays or particle radiation between 5 keV and 1 MeV, and not intended for healing arts use for humans or animals. A RGD is x-ray equipment (as defined in Part 1 of the regulations) that may be mobile, portable, or stationary.

Commented [JSJ11]: The proposed language of the definition "Hand-held x-ray system" deviates slightly from the Part H model rule language in the following manner: The phrase "such as" is used in lieu of "e.g." for clarity, and, since this is the first occurrence of the acronym "XRF" in the body of the rule, it is spelled out.

Commented [JSJ12]: The proposed definition "Human body security screening system" replaces the definition "Personnel security screening system" found in the revised Part H model rule.

The radiation program feels that the Part H definition does not reflect the actual use of these types of systems in practice. There are a number of these types of systems registered in Colorado that are used in prison/jail situations for inmate and other screening. Limiting the title to "personnel" would imply that only employees are being screened, which is likely inaccurate. The RP believes the revised definition title better reflects actual use in facilities.

Commented [JSJ13]: The proposed language of the definition "Industrial radiography" deviates from the Part H model rule language in the following manner: The phrase "for the purpose of detecting structural flaws in objects" is added for clarity. The intent is to help delineate what is and is not considered industrial radiography.

Commented [JSJ14]: The proposed language of the definition Local component" deviates slightly from the Part H model rule language in the following manner: The phrase "struck by" in the model rule is replaced by "exposed to" for clarity.

Commented [JSJ15]: This definition is added for consistency with its use within the body of the rule.

Commented [JSJ16]: Here, within this RGD definition, the Part H model rule includes sub-definitions for "mobile", "portable", "stationary" and "transportable". For consistency with other existing rule parts, these are not repeated here and instead the proposed definition defers to the exiting Part 1 definition for x-ray equipment.

"Radiation Safety Officer (RSO)" means an individual as defined in Part 1 of these regulations.

"Radiation source (or x-ray tube) housing" means that portion of an x-ray system which contains the x-ray tube and/or secondary target. Often the housing contains radiation shielding material or inherently provides shielding.

"Radiograph" means a permanent film or digital image produced on a sensitive surface by a form of radiation other than direct visible light.

"Radiography" is the process of creating radiographic images.

"Safety device" means a device, interlock or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that causes the beam to shut off upon entry into its path.

"Scattered radiation" means radiation that has been deviated in direction and / or energy by passing through matter.

"Security screening unit" means a non-human use open-beam or cabinet x-ray system with accessible openings designed for the detection of weapons, bombs, or contraband concealed in baggage, mail, packages or other commodities or structure.

"Shielded room" means a room housing a RGD where, with the RGD at maximum exposure setting, the exterior room environs meets the unrestricted area limits of 2 mrem (0.02 mSv) in any one hour and 100 mrem (1 mSv) in a year at 30 centimeters from the barrier. A shielded room does not include a RGD which meets the definition of cabinet x-ray systems.

"Shutter" means a moveable device used to block the useful (or primary) beam emitted from an x-ray tube assembly.

"Source" means the point of origin of the radiation, for example, the focal spot of an x-ray tube.

"Stationary equipment". See "Radiation generating device."

"Stray radiation" means the sum of leakage and scatter radiation.

"Warning device" means a visible or audible signal that warns individuals of a potential radiation hazard.

"X-ray generator" means that portion of an x-ray system which provides the accelerating high voltage and current for the x-ray tube.

"X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location.

~~**General Regulatory Provisions and Specific Requirements**~~

8.3 Administrative Requirements.

8.3.1 Each non-healing-arts radiation machine in the State of Colorado shall be registered with the Department as required by **Part 2, Section** 2.4.~~ and inspected as prescribed in 2.5.~~

A. In accordance with Part 2, such registration shall require:

Commented [JSJ17]: Based on stakeholder feedback, language is modified slightly from Part H for clarity and understanding. "Exposure setting" is used instead of "techniques" (as found in Part H).

Commented [JSJ18]: This section is expanded and clarified to restate the key existing registration requirements, and to clarify exclusions from such requirements, where applicable.

The requirements in 8.3.1.A are not new and are currently required by existing requirements in Part 2.

1. **Designating a RSO;**

2. **Maintaining documentation that a written shielding design has been completed, as applicable.**

   Certified cabinet RGDs, hand-held XRF RGDs, and other systems as designated in writing by the Department are not required to have a shielding design; and

3. **Inspection by a Qualified Inspector as required by Part 2, Section 2.5.**

8.3.2 ~~The registrant shall direct operation of the x-ray equipment under the registrant's administrative control.~~ **The registrant shall be responsible for directing the operation of the RGD(s) under their administrative control and shall assure that the requirements of Parts 1, 2, 4, and 10 are met in the operation of the system.**

~~8.3.3 The registrant or the registrant's agent shall assure that all applicable requirements of Parts 1, 2, 4, 5, 6 and 10 are met in the operation of the x-ray equipment.~~

8.3.~~4~~**3** As provided in **Part 2, Section** 2.6.1.15, for any analytical, industrial or other non-healing-arts ~~radiation machine~~**RGD**, "adequately trained" shall mean that the individual operator has met the requirements of Part 2, Appendix 2N **and any additional training requirements of Part 8**.

~~**8.4 Equipment Requirements.**~~

~~8.4.1 Safety Device.~~

~~8.4.1.1 A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path, or which causes the beam to be shut off upon entry into its path, shall be provided on all open-beam configurations.~~

~~8.4.1.2 A registrant or licensee may apply to the Department for an exemption from the requirement of a safety device, including in the application:~~

~~(1) A description of the various safety devices that have been evaluated;~~

~~(2) The reason each of these devices cannot be used; and~~

~~(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.~~

8.3.5 Application for Exemptions.

Any RGD registrant that cannot meet the applicable requirements of this Part shall submit to the Department a request for an exemption to the specific regulation or requirement in question. The exemption request shall demonstrate to the Department's satisfaction:

A. That the use of the RGD will not result in undue hazard to public health and safety or property;

Commented [JSJ19]: Language is updated for consistency with the language used in Part 6 of the regulations.

Commented [JSJ20]: The requirement of 8.3.3 is combined in 8.3.2.

The reference to Part 6 was not retained since it pertains to medical use of x-ray systems which are not regulated under Part 8.

Commented [JSJ21]: The definition "Safety device", which is similar to the language here has been added to the definitions Section 8.2., consistent with Part H.
Additional language has been added to new Section 8.7 regarding open beam systems.

Commented [JSJ22]: The requirements of 8.4.1.2 are replaced with the revised and updated language in (new) 8.3.5 (below).

Commented [JSJ23]: This provision will replace the requirements found in the current 8.4.1.2 (above).

This provision incorporates the requirements of Part H, Section H.13 with the following modifications/differences:

1. The language of the first sentence "Any RGD user or manufacturer…" is modified to limit the exemption requirements to **users** of RGDs only. Part H includes users and manufacturers. The manufacturing of RGDs falls within the regulatory purview of the U.S. Food and Drug Administration (FDA) and should not be included here. Any manufacturers of RGDs should apply to FDA for an exemption from regulatory requirements.

Commented [JSJ24]: The term "registrant" is used in lieu of the term "user" as found in Part H, since a request for an exemption would come from the facility/regulated entity rather than an individual user. This approach is consistent with the (existing) wording in 8.3.5.C.

Also, for this provision, the language of part H is more broad/general than that of the current rule with regard to exemptions from requirements. The current language of part 8 limits the exemptions to "safety devices". This would potentially allow additional options for registrants who are unable to comply with certain requirements.

B. That compliance would require replacement or substantial modification of the RGD;

C. That the registrant will achieve, through other means, radiation protection equivalent to that required by the regulation; and

D. Why the regulatory standard or requirement could not be met.

8.4 General regulatory requirements.

Unless otherwise provided in this Part, this Section 8.4 applies to all RGDs. Certified and Certifiable Cabinet X-ray Systems as defined in this Part shall also meet the requirements of 21 CFR 1020.40.

8.4.~~2~~**1** Warning Devices.

A. Warning devices shall be labeled so that their purpose is easily identified.

B. An easily visible warning light labeled with the words "X-RAY ON", or words/displays having a similar intent, shall be located near any switch or control system that energizes an x-ray tube and shall be illuminated only when the tube is energized. This warning light/display shall be of a fail-safe design.

~~8.4.2.1 Open-beam configurations shall be provided with a readily discernible indication of:~~

~~(1) X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or~~

~~(2) Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.~~

~~8.4.2.2 An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:~~

~~(1) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or~~

~~(2) In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.~~

~~8.4.2.3 Warning devices shall be labeled so that their purpose is easily identified.~~

~~(1) Warning devices shall have fail-safe characteristics.~~

~~8.4.3 Ports.~~

~~8.4.3.1 Unused ports on radiation source housings shall be secured in the closed position, in a manner that will prevent casual opening.~~

8.4.~~4~~**2** Labeling.

~~8.4.4.1~~**A.** All ~~analytical x-ray~~**RGD** equipment shall be labeled with a readily **visible and** discernible sign or signs bearing the radiation symbol **(in accordance with Part 4, Section 4.27)** and the words: **"CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube.**

Commented [JSJ25]: Requirements are relocated and reformatted from prior 8.4.2.2 below.

Language is modified slightly from Part H to incorporate considerations for RGDs that are computer controlled rather than those with a separate control panel.

Commented [JSJ26]: Requirements in (prior) 8.4.2.1 – 8.4.2.3 that are related to fail-safe designs for lighting and safety devices are retained, expanded and relocated to (new) Sections 8.4.1.A, 8.7.2.B (warning/status lights), and 8.6.3, 8.4.8.C (for interlocks).

Commented [JSJ27]: As indicated earlier in this proposed rule, references to radioactive materials, radioactive sources, and licensees are removed as the rule is intended for x-ray radiation generating devices (RGDs) only.

Commented [JSJ28]: Language is updated, consistent with SSRCR Part H (2016), Section H.6b.

~~(1) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and~~

~~(2) "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or~~

~~(3) "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with 4.30 of these regulations if the radiation source is a radionuclide.~~

B. For RGDs with designed openings, for object entries (such as baggage units), the following shall be posted at or near each opening: "CAUTION – X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED", or words having similar intent.

~~8.4.5 Shutters.~~

~~8.4.5.1 On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.~~

8.4.~~6~~3 Radiation Source Housing.

~~8.4.6.1~~**A.** Each radiation source housing shall be subject to the following requirements:

~~(1)~~**1.** ~~Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing, or if the housing is disassembled.~~ **Interlock.**

When the x-ray tube housing is the primary shielding for the x-ray tube, and is intended to be opened for normal use or maintenance, the housing shall be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened; and

~~(2)~~**2. Radiation emission limit.**

~~Each radioactive source housing, or port cover or each~~**Each** x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from ~~its~~**the x-ray tube housing** surface ~~is not capable of producing a dose in excess of~~ **does not exceed 2.5 mrem** (0.025 mSv) ~~(2.5 millirem)~~ ~~in one~~ **per** hour. **This limit shall be met at the maximum tube rating.**

a. For closed-beam RGDs, this requirement can be met by complying with 8.6.4, radiation emission limit (0.5 mrem or 0.005 mSv in one hour at five centimeters outside any accessible surface).

b. For a RGD in a shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD.

c. For open-beam RGDs designed to be hand-held during operation, this requirement can be met by complying with the limits in 8.8.3, radiation emission limit (2.5 mrem or 0.025 mSv per hour at 5 centimeters.

~~(a) For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.~~

Commented [JSJ29]: This provision is removed as it is not found in the 2016 Part H revision.

Commented [JSJ30]: This provision is retained but relocated/incorporated into 8.4.2.A (above).

Commented [JSJ31]: As indicated previously in the rule, references to RGDs containing radioactive materials are being removed from this rule.

Commented [JSJ32]: This provision is added for consistency with Part H, Section H.6b.ii.

Commented [JSJ33]: This requirement is retained and has been relocated to Section 8.7.5, applicable to open-beam systems.

Commented [JSJ34]: The current provision is updated, consistent with Part H, Section H.6c.i.

Commented [JSJ35]: To aide users of the rule, radiation limits are restated here rather than only reference another section in the rule (unlike the Part H structure).

Following issuance of draft 1 in the request for rulemaking package, language was modified for consistency with the format/approach of 8.4.4.

Commented [JSJ36]: To aide users of the rule, radiation limits are restated here rather than only reference another section in the rule (unlike the Part H structure).

8.4.~~7~~4 Generator Cabinet~~.~~ or High Voltage Source Radiation Emission Limits

~~8.4.7.1~~**A.** ~~Each x-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 2.5 µSv (0.25 millirem) in one hour.~~**Each x-ray generator or high-voltage source associated with an RGD shall be supplied with a protective cabinet which limits leakage radiation to 0.25 mrem (2.5 µSv) per hour at a distance of 5 centimeters measured at the nearest accessible surface.**

1. **For closed beam systems, this requirement can be met by complying with Section 8.6.4, radiation emission limit (0.5 mrem or 0.005 mSv in one hour at five centimeters outside any accessible surface).**

2. **For a RGD in a shielded room with the high-voltage generator also inside the shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD.**

3. **For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in 8.8.3, radiation emission limit (2.5 mrem or 0.025 mSv per hour at 5 centimeters).**

8.4.5 Surveys.

A. **The registrant shall document performance of radiation surveys, as required by Part 4, Section 4.17 of these regulations and shall be sufficient to show compliance with radiation emission requirements of this Part, and as required by Part 4, Section 4.6 and Part 4, Section 4.14 of these regulations. The radiation surveys shall be sufficient to evaluate the magnitude and extent of radiation emissions and the potential radiological hazards that could be present.**

At a minimum, surveys shall be performed:

1. **Upon installation of the equipment, and at least once during each routine certification evaluation thereafter;**

2. **Following any change in the initial arrangement, number, or type of local components in the system;**

3. **Following any maintenance requiring the disassembly, removal, or repair of a local component in the system;**

4. **During the performance of maintenance, calibration and other procedures if the procedures require the activation of a primary x-ray beam while any local component in the system is disassembled or removed;**

5. **Following the temporary bypass and restoration of a safety device or interlock required by 8.4.7.B.**

6. **Any time a visual inspection of the local components in the system reveals an abnormal condition; and**

7. **Whenever a personnel monitoring device shows a significant increase over the previous monitoring period, or the readings are approaching the limits specified in 4.6 of these regulations.**

Commented [JSJ37]: The phrase "…associated with an RGD…" is not found in Part H but is added for clarity.

Commented [JSJ38]: Some requirements of this section have been relocated from 8.6.3.

Commented [JSJ39]: This section is updated for consistency with Part H, Section H.6e. Most requirements of this section can be found in the current Part 8 at 8.6.3.

Commented [JSJ40]: The proposed introductory sentence in this provision is modified to be a hybrid between the current part 8 (in 8.6.3) and part H (H.6e) to be more direct.

Commented [JSJ41]: This same survey frequency is found in the current rule at 8.6.3.1(1).

The 12 month survey frequency of Part H is modified to align with the routine certification evaluation frequency of 24 months for most RGDs so that this activity may be performed at the same time as a routine machine inspection/certification.

Commented [JSJ42]: For clarity, the word "activation" replaces the word "presence" as found in Part H.

Commented [JSJ43]: The language of H.6.e.i(5) is incorporated, with the following exception: The phrase "Following the temporary bypass and restoration…" is used instead of "Post bypass…" for clarity.
The new provision clarifies that if a required safety device or interlock is bypassed temporarily to perform a maintenance or repair activity (and then subsequently reset/restored), radiation surveys must be performed to ensure that radiation levels have returned to normal and the safety device or interlock is operating properly.

B. The registrant shall have access to sufficiently calibrated, appropriate and operable radiation survey instruments to make physical radiation surveys as required by this Part. The instruments shall be capable of detecting and measuring the types and levels of radiation involved (including primary, scattered, and leakage radiation).

C. The registrant shall assure the maintenance and calibration of all monitoring and survey instruments per Part 4, Section 4.17 of the regulations.

D. Radiation survey measurements shall not be required if a registrant can otherwise demonstrate compliance with the requirements of this Part to the satisfaction of the Department.

8.4.6 Posting.

A. Each area or room containing an RGD where an individual may receive 2 mrem (0.02 mSv) in any one hour or 100 mrem (1 mSv) per year shall be conspicuously posted with a sign or signs bearing the radiation symbol (which meets the requirements of Part 4, Section 4.27) and the words "CAUTION – X-RAY EQUIPMENT," "CAUTION – RADIATION GENERATING DEVICE" or words having a similar intent.

B. Unless used in a dedicated location, hand-held RGDs are exempt from the requirements of 8.4.6.A.

8.4.7 Security.

A. When not in operation, RGDs shall be secured in such a way as to prevent access or operation by unauthorized personnel.

~~8.5~~**8.4.8 Operating Requirements.**

~~8.5.1~~**A.** Procedures.

~~8.5.1.1~~**1.** Normal operating procedures shall be written and available to all ~~analytical x-ray equipment workers~~**RGD operators**.

~~8.5.1.2 The written operating procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, emergencies such as a power failure, and data recording procedures which are related to radiation safety.~~

~~8.5.1.3~~**2.** No individual shall be permitted to operate ~~analytical x-ray equipment~~**a RGD** in any manner other than that specified in the procedures unless such

Commented [JSJ44]: EDITORIAL NOTE: Additional spaces have been added to the draft rule to allow fully visualizing these side margin comments. These unneeded spaces will be removed during formatting prior to final publication.

Commented [JSJ45]: Similar requirements are found in the (prior) 8.6.2.

The revised/added language of 8.6.2 is less specific than that in the original provision in that it does not require an instrument with a specific detection range. This allows the RGD registrant to determine the best instrument based on other criteria found in the rule, which is a similar approach used in most other radiation regulations.

Additionally, the Part H language is less stringent that the current Part 8 rule in that it allows registrants to have "access to" survey instruments rather than be in possession of a survey instrument.

Commented [JSJ46]: The language of H.6.e.iv is incorporated, with the following exception: the Part H phrase "…to the satisfaction of the Department" is replaced by "…when approved in writing by the Department" at the end of the provision.
As the current rule language is vague, the proposed language will clarify that authorization by the Department in writing is necessary when deviating from radiation survey requirements.

Commented [JSJ47]: A similar requirement appears in the (prior) 8.5.5.1, but is updated/expanded for consistency with SSRCR Part H, Section H.6f.

Commented [JSJ48]: For clarity, this exemption is incorporated into the general posting requirements section (rather than a specific stand-alone "exemption" section found in Part H, Section H.5.b.)

Commented [JSJ49]: Provision added, consistent with the intent of Part H, Section H.6g, but with the exception that the phrase is reworded for clarity.
(The original Part H wording is as follows: "RGDs shall be secured in such a way as to be accessible to, or operable by, only authorized personnel when not in operation".)

Commented [JSJ50]: Section 8.4.8 updated for consistency with Part H, Section H.6.h

Commented [JSJ51]: "Equipment workers" is replaced by "RGD operators" for clarity.

Commented [JSJ52]: The requirements of this provision have been incorporated in the added definition for "Normal operating procedures" in Section 8.2.

individual has obtained written approval of the ~~radiation safety officer~~**RSO** and Department.

3. Except as authorized under Part 6 for authorized medical purposes, or Section 8.11 for security screening purposes, intentional exposure of a living human to a RGD for any purpose is strictly prohibited.

~~8.5.2~~**B.** Bypassing **safety equipment**.

~~8.5.2.1~~**1.** No individual shall bypass a safety device or interlock, unless such individual has obtained the written approval of the ~~radiation safety officer~~ **RSO** and Department.

~~(1)~~ Such approval shall be for a specified period of time.

~~(2)~~**2.** When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing **and at the control switch**.

3. A record of any bypass of a safety device or interlock shall be maintained; the record shall contain such information as the date the alteration was made, type of alteration, length of time the unit remained in the altered condition, post bypass survey and signed by the RSO, the individual who made the alteration, and the individual who restored the unit to original condition.

4. Control panel.

a. The RGD can only be activated from a control panel.

b. All indicators and controls that control the primary beam shall be identifiable and discernible through the use of labels, symbols, software displays or the equivalent.

C. Interlocks.

1. An interlock shall not be used to de-activate the x-ray tube or RGD, except in an emergency or during testing of the interlock system.

2. After triggering any interlock, it shall be possible to reset the RGD to full operation only from a control panel.

3. All interlocks shall be of a fail-safe design.

4. When the system is in normal use, interlocks, including emergency shut off controls, shall not be defeated, or otherwise made inoperable or inaccessible such that the operability or primary purpose is impacted.

D. Multiple sources.

If more than one x-ray tube assembly(s) or focal spot can be operated sequentially or simultaneously from a control panel, visual indicators shall identify which tube assembly(s) or focal spot has been selected. The selectors shall be identified as to their function. If a letter or number is used, a reference card or table explaining the code shall be affixed to the control panel.

Commented [JSJ53]: Note: This is a current regulatory requirement. The requirement to notify and obtain written approval of the Department **only applies** when a system is operated in a manner that **differs** significantly from written procedures.

Commented [JSJ54]: This provision is added for radiation safety purposes, and consistent with the language of other regulations.

Commented [JSJ55]: Although Part H continues to use "Bypassing" as the section header, "safety equipment" is added for clarity.

Commented [JSJ56]: "Department" is retained although this is not included in Part H.

Commented [JSJ57]: This is a new recordkeeping requirement, consistent with SSRC Part H.

Commented [JSJ58]: This is a new requirement, consistent with SSRC Part H, Section H.6.h.iii

It is expected that all designs of RGDs will have some form of control panel, whether it is or is not integral to or separate from the device/beam producing portion of the device. It is only from this control panel that the device can be operated.

The added language also brings the rule up to date with those RGDs that may be computer based where the "control panel" may be on a touch screen or keyboard or equivalent.

Commented [JSJ59]: This is a new requirement, consistent with SSRC Part H, Section H.6.h.iv

Interlocks are intended as a safety device and not as the primary mechanism to terminate (or start) a beam/radiation.

Commented [JSJ60]: Based on stakeholder feedback, this proposed provision would prohibit an interlock, such as an emergency stop button, from being covered or otherwise impacted from proper operation during periods of normal use. Some inspectors have observed facilities covering or otherwise impinging on emergency stop buttons in order to prevent accidental shut down, which may put systems out of service for some period. Note that normal use would not include maintenance/repair activities by authorized personnel.

Commented [JSJ61]: This is a new requirement, consistent with SSRC Part H, Section H.6.h.v.

~~8.5.3~~**8.4.9.** Repair or Modification of X-ray Tube **or RGD** Systems.

~~8.5.3.1 Except as specified in 8.5.2, no operation involving removal of covers, shielding materials, or tube housings, or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored.~~

~~8.5.3.2 The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.~~

A. Only registered service companies shall be permitted to install, repair, calibrate, or make modifications to an RGD and only Qualified Inspectors shall perform machine inspections.

B. No operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored.

C. The main power switch with a lock-out / tag-out, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

~~8.5.4 Radioactive Source Replacement, Testing, or Repair.~~

~~8.5.4.1 Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.~~

~~8.5.4.2 The registrant or the registrant's agent shall use licensed/certified/registered providers of services, including but not limited to operation of equipment, inspection of radiation machines and facilities, and assembly, installation, service and/or calibration of radiation machines.~~

~~8.5.5 Posting.~~

~~8.5.5.1 Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign, or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent in accordance with 4.28 of these regulations.~~

8.4.10. Testing of Safety Devices.

A. Tests of all safety devices, such as interlocks, shutters, warning lights, and required emergency shut-off switches shall be conducted at intervals not to exceed 6 months on all operable RGDs. Cabinet integrity, where applicable, shall be evaluated at the same time and frequency as safety device tests.

B. If any safety device fails during testing, the RGD shall be removed from service until the safety device failure is corrected or proper temporary administrative controls established and approved in writing by the RSO.

C. Records of safety device tests, check dates, findings and corrective actions shall be available for inspection and maintained for 3 years.

D. Records shall include the date of the test, a list of the safety devices tested, survey instrument information, calibration date, the results of the test, the name of the

Commented [JSJ62]: The requirements of 8.5.3.1 and 8.5.3.2 are retained in the renumbered and rephrased section below.

Commented [JSJ63]: For consistency with terminology used in other regulatory Parts, "registered service companies" replaces "registered service providers".

Additionally, the proposed Part 8 excludes the Part H language which would allow "trained personnel" to install, repair, or make modifications to the RGD.

Commented [JSJ64]: As discussed earlier in the side margin comments, references to radioactive materials are removed from the proposed Part 8.

Commented [JSJ65]: This provision is retained and relocated to 8.4.9.A above.

Commented [JSJ66]: This requirement has been relocated to the administrative requirements section in 8.4.6.A

Commented [JSJ67]: This is a new provision which parallels Part H, Section H.6.j.

The routine testing proposed as part of this provision would likely have to be performed by the registrant and not the Qualified Inspector (QI) as the routine inspection frequency for RGDs is 1-2 years per Part 2, depending upon the device.

A periodic check of cabinet integrity is not found in Part H but was added based on stakeholder feedback.

Commented [JSJ68]: Based on stakeholder feedback, this has been modified from 5 years (as found in the Part H model rule) to 3 years. This approach is more in-line with other recordkeeping retention schedules. Non-healing arts RGD inspection (certification) frequencies are on a 1 or 2 year cycle.

person performing the tests and corrective actions taken for safety devices that fail the required test.

E. Testing of safety devices may be deferred if the unit and/or installation is clearly marked and kept out of service; units and/or installations brought back into service after exceeding the 6 month interval shall be tested prior to use.

F. If testing of a safety device cannot be performed due to manufacturer design, the registrant shall document that the safety device will not be tested and specifically why the safety device cannot be tested.

8.4.11 Instruction and Training.

The registrant shall document the scope of training required for the RGD they possess in accordance with this section. No individual shall be permitted to operate or maintain an RGD, or enter a shielded room without appropriate instruction and training. Records of all required training and instruction shall be maintained onsite for a minimum of 3 years after the individual terminates employment. Records shall be made available for review by the Department.

Each individual shall receive instruction in and demonstrated competence as to:

A. Types of radiation and identification of radiation hazards associated with the use of the RGD and associated equipment and precautions or measures to take to minimize radiation exposure;

B. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

C. Commensurate with potential hazards of use, biological effects of radiation, radiation risks, and recognition of symptoms of an acute localized exposure;

D. Normal operating procedures for each type of RGD and associated equipment, including having received hands-on training, and procedures to prevent unauthorized use;

E. Procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation; and

F. Performing surveys where applicable.

8.4.12. Radiation Protection Responsibility.

A. The registrant's senior management shall make the ultimate decision to use any RGD and ultimately be responsible for radiation safety.

B. The registrant's senior management shall designate an individual responsible for radiation safety, or a RSO. This individual shall have direct access to senior management for radiation safety issues. This individual shall have training and experience commensurate with the scope of the radiation safety program to carry out the responsibilities as indicated below.

1. Ensuring that all RGDs are operated within the limitations of the established radiation safety program and operating procedures.

Commented [JSJ69]: This proposed requirement will expand the training requirements associated with RGD use, beyond that currently required by Part 2.

Commented [JSJ70]: The draft originally proposed to stakeholders did not include a retention period for training records. Based on stakeholder feedback, a recordkeeping retention period of 3 years is added for these records. The 3y period is consistent with training record retention requirements found in other industrial use radiation regulations, including Parts 5, 9, 16, and 19.

2. Instructing personnel with regard to safe working practices and ensuring all personnel are trained in radiation safety commensurate with the hazards of the job.

3. Investigating any incident of abnormal operation or exposure or suspected overexposure of personnel to determine the cause, take remedial action, and report the incident to the proper authority.

4. Ensuring that safety devices, interlocks, warning signals, labels, postings, and signs are functioning and located where required.

5. Maintain all radiation safety records.

~~8.5.6 Hand-held Devices.~~

~~8.5.6.1 The operator shall be protected from direct scatter radiation by material of not less than 0.25 millimeter lead equivalent unless the radiation safety officer and Department determine that no added protection is needed for the device use and/or model.~~

8.5~~6~~ ~~Measurements, Monitoring and Surveys.~~Radiation levels and dosimetry monitoring.

8.~~6~~5.1 Radiation Levels.

~~8.6.1.1~~**A.** X-ray equipment shall be located and arranged with sufficient shielding and area access control to ensure compliance with Part 4.

~~8.6.1.2~~**B.** The registrant shall assure that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits in **Part 4, Sections** 4.14 or 4.15.

~~8.6.2 The registrant shall possess (unless determined by the radiation safety officer and Department to be unnecessary) at least one portable radiation detection survey instrument that is:~~

~~8.6.2.1 Capable of detecting dose rates over the range 1.0 µSv (0.1 mrem) per hour to 500 µSv (50 mrem) per hour;~~

~~8.6.2.2 Operable; and~~

~~8.6.2.3 Calibrated in accordance with 2.4.4.4.~~

~~8.6.3 Surveys.~~

~~8.6.3.1 [The registrant shall document performance of radiation surveys, as required by 4.17 of these regulations, sufficient to show compliance with 8.6.1:]~~

~~(1) Upon installation of the equipment, and at least once every 12 months thereafter;~~

~~(2) Following any change in the geometrical arrangement, number, or type of local components in the system;~~

~~(3) Following any maintenance requiring disassembly, or removal of a local component in the system;~~

~~(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled, or removed;~~

Commented [JSJ71]: This provision has been relocated to Section 8.8.5.

Commented [JSJ72]: This provision is replaced with the revised Section 8.4.5.B (above), consistent with the requirements in Part H, Section H.6e.ii through iii.

Commented [JSJ73]: The requirements of this section have been relocated to (new) Section 8.4.5 to parallel the flow of Part H, Section H.6e.

~~(5) Any time a visual inspection of the local components in the system reveals an abnormal condition; and~~

~~(6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period, or the readings are approaching the limits specified in 4.6 of these regulations.~~

8.~~6~~5.~~4~~2 Personnel Monitoring Requirements.

~~8.6.4.1~~**A.** Each individual who is associated with the operation of a~~n~~ non-healing-arts radiation generating device shall meet the requirements of **Part 4, Sections** 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18.

~~(1)~~**1.** When personnel dosimetric monitoring devices are required, they shall be worn in accordance with **Part 4, Section** 4.6.3.

~~(2)~~**2.** Each operator of portable hand-held x-ray equipment shall wear **separate** whole body and extremity personnel dosimetric monitoring devices**, unless otherwise exempted by the Department or by regulation**.

~~(3)~~**3.** Deliberate exposure of a personnel dosimetric monitoring device to deceptively indicate a dose delivered to an individual is strictly prohibited.

~~8.6.4.2~~**B. In addition to the requirements of Part 4, Section 4.6,** ~~Finger or wrist dosimetric devices~~ **extremity dosimetry** shall be provided to and shall be used by:

~~(1)~~**1.** ~~Analytical x-ray equipment operators using systems having an open-beam configuration if and when a safety device is not present, is not in use or is disabled; and~~**Personnel working with or routinely working near and having potential for extremity exposure to, the primary beam of an open-beam RGD; and**

~~(2)~~**2.** Personnel maintaining ~~analytical x-ray equipment~~**RGDs** if the maintenance procedures require the **activation** of a primary x-ray beam when any local component in the ~~analytical~~ x-ray system is disassembled or removed.

~~8.6.4.3 Reported dose values shall not be used for the purpose of determining compliance with 4.6 unless evaluated by a qualified expert.~~

8.6 Additional Requirements for Closed-Beam RGDs.

In addition to the requirements of 8.3, 8.4, and 8.5, the following applies to all closed-beam x-ray RGDs:

8.6.1 System Enclosure.

The radiation source, sample or object, detector, and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

8.6.2 Interlocks.

All doors and panels accessing the RGDs shall be interlocked. The interlocks required by this section shall be of a fail-safe design.

8.6.3 Interlock Functions.

Commented [JSJ74]: The added language pertaining to exemptions is added for consistency with other changes in Part 8.

Commented [JSJ75]: Updated for consistency with Part H, Section H.8.k.

Commented [JSJ76]: Similar to an earlier change, "activation" is used instead of "presence" for clarity.

Commented [JSJ77]: This section is added, consistent with Part H, Section H.7 to address requirements associated with closed-beam RGDs.

The system enclosure, sample chamber, etc. closure shall be interlocked with the x–ray tube high voltage supply and/or a shutter in the primary beam so that no x-ray beam can enter the sample or object chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail–safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.

8.6.4 Radiation Emission Limit.

The radiation emission for all closed beam RGDs shall not exceed a dose rate of 0.5 mrem (0.005 mSv) in one hour at five centimeters outside any accessible surface.

8.6.5 Security Screening Units.

During operation and generation of radiation, security screening units shall require operator presence at the control panel and shall permit surveillance of openings and doors.

A. During an exposure or preset succession of exposures of one-half second or longer, means shall be provided to terminate the exposure or preset succession of exposures at any time.

B. During an exposure or preset succession of exposures of less than one-half second, means shall be provided to permit completion of the exposure in progress, but shall allow the operator to prevent or terminate additional exposures.

8.7 Additional Requirements for Open Beam RGDs.

In addition to the requirements in 8.3, 8.4, and 8.5, the following requirements apply to all open beam RGDs not otherwise addressed in this Part.

8.7.1 Safety Devices.

A. The registrant shall document their justification of the use of open-beam instead of closed-beam systems.

B. If the registrant needs to use an open-beam system, the registrant shall require a safety device which prevents the entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path.

C. If the registrant's use of the open-beam RGD does not permit the use of a safety device to prevent direct body exposure, the registrant shall maintain a written record of a description of the various safety devices that have been evaluated and document why these devices cannot be used. These records shall be available onsite for inspection.

D. In lieu of the safety device described in 8.7.1.B, the registrant shall employ alternative methods (such as policies and procedures) to minimize the possibility of unnecessary exposure. These alternative methods shall be documented. The documentation shall include information about the absence of safety devices. This documentation shall be available for inspection as long as these methods are employed, plus an additional 5 years.

E. For portable open-beam RGDs that are manufactured to be used hand-held, or potentially used as a hand-held, without such safety devices, the requirements of 8.7.1 may be met by complying with all the requirements in 8.8.

Commented [JSJ78]: Language of Section 8.6.5 is modified and clarified from what is contained in Part H.

The wording of Part H was found to be unclear and confusing.

Commented [JSJ79]: This section is added, consistent with Part H, Section H.8 to address requirements specific to open beam RGDs.

Commented [JSJ80]: Reworded slightly for clarity from original Part H model rule language.

8.7.2 X-ray On Status.

For open beam equipment, RGDs shall be provided with a readily discernible and active indication of:

A. X-ray tube "on-off" status located near the radiation source housing. The warning lights as required by 8.4.1.B can meet this requirement if the warning lights are readily discernible and viewable by anyone near the primary beam; or

B. Shutter "open-closed" status located at the control panel and near each beam port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device shall be clearly labeled as to the meaning of the status device (i.e., whether the shutter is open or closed). The status light at the control panel can meet the requirement for the status light at the beam port if the status light at the control panel is readily discernible and viewable by anyone near the primary beam; and

C. The x-ray tube “on-off” status indicator and the shutter “open-closed” status indicators shall be of a fail-safe design.

8.7.3 Labeling.

Each unit will be labeled at or near the x-ray exit beam port to identify the location of the beam with the words, "CAUTION - X-RAY BEAM", “CAUTION - HIGH INTENSITY X-RAY BEAM”, or words having a similar intent.

8.7.4 Beam Ports.

Unused beam ports on radiation source housings shall be secured in the closed position in a manner which will prevent unintentional opening.

8.7.5 Shutters.

On open-beam RGD configurations that are designed to accommodate interchangeable components, each beam port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling has been connected to the beam port.

8.7.6 Radiation Emission Limits.

The local components of an open-beam RGD shall be located and arranged and shall include sufficient shielding or access control such that no radiation emissions exist (exclusive of the primary beam) in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits as outlined in Part 4, Section 4.14 of these regulations. These emissions shall be met at any specified tube rating.

8.7.7 Primary Beam Attenuation.

In cases where the primary x-ray beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding or administrative procedures, to avoid exposure to any individual from the transmitted primary x-ray beam.

8.7.8 Operator Attendance.

The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked or the equipment is secured to protect against unauthorized or accidental entry.

8.7.9 Controlling Access.

A. If the RGD is not in a restricted area as defined in Part 1 of these regulations, the operator shall be able to control access to the RGD at all times during operation.

B. If the RGD is not in a restricted area and the RGD is capable of creating a radiation area or a high radiation area as defined in Part 1 of these regulations, the operator shall be able to control access to the RGD at all times during operation, and:

1. Radiation areas shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent rate exceeds 5 mrem (0.05 mSv) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION - RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the radiation area during operation of the RGD;

2. High radiation areas shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent rate exceeds 1 mSv (100 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION - HIGH RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the high radiation area during operation of the RGD;

3. The operator shall perform a visual check of the controlled area to ensure it is free of all unauthorized personnel immediately prior to activating or exposing the radiation source;

4. Surveillance of the exposure area shall be maintained during operation, either by visual or by other reliable means to ensure that no person enters the area;

5. Excluding hand-held x-ray systems, when approaching the radiation source, following the conclusion of an exposure, the operator shall use a suitable calibrated and operable radiation detection instrument to verify that the x-ray tube has been de-energized;

Commented [JSJ81]: Language is slightly modified for clarity. ("Excluding" replaces "With the exception of").

6. A personal alarming dose rate meter may be worn to approach the work area if the device is appropriately designed and calibrated for the type of x-ray emitted (i.e., pulse or continuous), set at an appropriate level to detect the presence of the source, for example 2 mrem (0.02 mSv) per hour, and has been source-checked prior to use. The radiation in the work area must be reasonably uniform so that the device responds to radiation exposure to any part of the body. It may not be used to measure radiation levels, nor may it be used to indicate the presence of the source for potential non-uniform exposure, such as may occur during machine maintenance or work in a RGD target area;

7. Measurement of radiation levels for a radiation survey shall be performed using an appropriate calibrated radiation survey meter. A radiation survey meter shall also be used when there is potential for non-uniform exposure

to personnel, such as may occur during machine maintenance or work in a RGD target area;

8. During the initial exposure, the radiation levels shall be measured around the perimeter of the controlled area. The perimeter shall be adjusted accordingly to meet the access control requirement for radiation areas or high radiation areas; and;

9. The survey around the perimeter shall be made for each new operating condition and the perimeter adjusted accordingly. The area of operation shall be monitored periodically if radiation levels are variable.

8.7.10 Instruction and Training.

In addition to the requirements in 8.4.11, no individual shall be permitted to operate or maintain an open-beam RGD unless such individual has received specific and detailed instruction in and demonstrated competence as to:

A. Sources and magnitude of common radiation exposure;

B. Units of radiation measurement;

C. Radiation protection concepts of time, distance, shielding, and ALARA;

D. Procedures and rights of a declared pregnancy;

E. Regulatory requirements and area postings;

F. Worker, embryo/fetus, and public dose limits;

G. Proper use of survey instruments and dosimetry; and

H. The policies and procedures required by 8.7.1.

8.8 Additional Requirements for Open-beam, Hand-held RGDs.

Commented [JSJ82]: This section is added, consistent with Part H, Section H.9, with minor wording changes for clarity.

In addition to the applicable requirements in 8.3, 8.4, 8.5 and 8.7, the following requirements in this Section apply to open-beam, RGDs intended or designed to be hand-held during operation.

8.8.1 Procedures.

All registrants possessing open-beam, hand-held RGDs shall have available for review by the Department, operating policies and procedures that contain measures to insure that:

A. Radiation protection is provided equivalent to that afforded in Part 4, Section 4.14 of these regulations (Dose Limits for Individual Members of the Public);

B. Radiation protection is provided equivalent to that afforded in 8.7.7 (Primary Beam Attenuation);

C. The operator will not hold the sample during operation of the RGD and that the operator's hands will not approach the primary beam;

D. The operator will not aim the primary beam at him/herself or at any individual during operation of the RGD; and

E. Operator radiation exposure is as low as reasonably achievable (ALARA), for example, by use of ancillary equipment that will reduce exposure.

8.8.2 Training.

In addition to the training requirements of 8.4.11 and 8.7.10 above, the registrant shall provide training for all users and operators on the subjects in section 8.8.1. Records shall be maintained of all user and operator training.

8.8.3 Radiation Emission Limit.

For hand-held RGDs, the limits of 8.4.3.A and 8.4.4, excluding the primary beam, shall be met if the radiation emission at any accessible surface of the RGD does not exceed 2.5 mrem (0.025 mSv) per hour at 5 centimeters.

8.8.4 Extremity Monitoring.

For the purposes of the requirements in 8.5.3 (extremity monitoring), operators of hand-held RGDs shall be considered as working near the primary beam and shall be required to wear extremity dosimetry, unless explicitly exempted by the Department.

8.8.5 Excluding hand-held XRF units, and other units exempted in writing by the Department, the operator of a hand-held RGD shall be protected from scatter radiation by material of not less than 0.25 millimeter lead equivalent unless the RSO and Department determine that no added protection is needed for the device use and model.

8.9 Shielded Room RGDs.

For RGDs that do not meet the limits of Part 4, Section 4.14, the RGD can be maintained inside a shielded room such that the exterior of the room meets the limits of Part 4, Section 4.14 of these regulations when the RGD is activated. RGDs in a shielded room shall be required to meet only the requirements of 8.3, 8.4, and 8.5 and the following:

8.9.1 Posting.

The door to the room containing the RGD shall be posted "CAUTION – RADIATION AREA", or "CAUTION – HIGH RADIATION AREA", or "GRAVE DANGER – VERY HIGH RADIATION AREA", as required by Part 4 of these regulations.

8.9.2 Entrance Interlocks.

All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.

8.9.3 Entrance Warning Devices.

All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced. The warning device shall be labeled in accordance with H.6a.

8.9.4 Room Warning Lights.

The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be positioned so that they can be observed from any position or orientation within the room.

Commented [JSJ83]:
Part H requires extremity dosimetry for all users of a;; hand-held RGDs, including XRF units. However, our experience with such XRF units is that they have controls in place to prevent/limit direct hand/extremity exposure. Additionally, when used properly, these XRF units result in very low exposure to the operator, and typically well below regulatory limits that require extremity dosimetry. Therefore, we have proposed an exception process for this category of hand-held RGD.

Commented [JSJ84]:
This provision is a current requirement, but is relocated from 8.5.6. The provision has been modified to exempt certain devices that have been shown to have low occupational exposure potential.

This is not a provision found in the current Part H, but is retained for safety purposes, but with allowance for some explicitly authorized exceptions.

The lights shall be posted indicating the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.

8.9.5 Audible Room Warning Device.

An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel. The registrant shall post the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.

8.9.6 Emergency Shut-off.

If dose rates exceed the High Radiation Area limits as defined in Part 1 of these regulations, emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein within 10 seconds. These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut-off switches shall include a manual reset that must be reset at the switch before x-rays can again be produced from the control panel. After an emergency shut-off switch has been activated, it shall be possible to produce x-rays again only from the control panel.

8.9.7 Separate Electrical Systems.

The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.

8.9.8 Exit from Shielded Room.

A person within the room housing a RGD shall be able to exit at all times.

8.9.9 Entry into the Shielded Room.

A. After each exposure and before entry of any personnel, a survey shall be performed upon entry to the shielded room to determine that the RGD is no longer producing radiation.

B. Personnel devices providing an audible signal when activated by radiation will be acceptable for the survey requirement of 8.9.9.A.

1. Proper operation of the audible detection device shall be checked daily and a record maintained of this check.

2. The audible device shall be designed so as to clearly indicate entry into a 2 mrem (0.02 mSv) per hour or greater radiation field.

3. All personnel working with the RGD shall be provided with such a device.

C. Stationary area monitors providing an audible signal when activated by radiation will be acceptable for the survey requirement of 8.9.9.A.

1. Proper operation of the stationary detection device shall be checked daily and a record maintained of this check.

2. The stationary device shall be designed so as to clearly indicate entry into a 2 mrem (0.02 mSv) per hour or greater radiation field.

3. Stationary area monitors shall be calibrated annually to determine that the audible signal operates at a 2 mrem (0.02 mSv) per hour radiation field.

8.9.10 Personnel Monitoring.

All personnel associated with the x-ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x-ray energies being utilized. Records of personnel exposure shall be maintained.

8.9.11 Training.

No registrant shall permit any individual to operate a RGD in a shielded room until such individual has received a copy of, instruction in, and demonstrated an understanding of, operating and emergency procedures for the unit and competence in its use. Records shall be maintained of all operator training.

8.9.12 Control Panel Security.

The equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of radiation by the equipment.

8.9.13 Malfunctions.

If a safety or warning device malfunctions, the control panel shall be locked in the "off" position. The control panel shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

8.10 Reserved.

8.11 RGDs Used in Human Body Security Screening or Vehicle Screening for Public Protection. The requirements in this section are in addition to the General Requirements in 8.4, 8.5, and 8.6.

A person must request Department approval for a RGD to be used for Human Body Security Screening or Vehicle Screening involving intended exposure of human occupants to the primary beam for public protection purposes. Such persons shall submit the appropriate form or submit in writing the following information to the Department for evaluation and approval, and demonstrate how the dose limits in 8.11 will be met:

8.11.1 Efficacy Evaluation.

An evaluation of all known alternate methods that could achieve the goals of the security screening program, and why these methods will not be used in preference to the proposed approach utilizing ionizing radiation.

8.11.2 Equipment Evaluation.

RGDs used for human body security screening shall be evaluated every 12 months by a Qualified Inspector for radiation dose and optimization of image quality. Evaluation of optimization of image quality shall be done in accord with the system manufacturer's specifications, recommendations, and quality assurance procedures or, in the absence of manufacturer provided information on image quality, the recommendations of a nationally recognized organization or Qualified Inspector.

8.11.3 Dose Limits for General-Use Systems.

Commented [JSJ85]: This section is added, consistent with Part H, Section H.12, with the exception that the section "title" is changed from "personnel security" screening to "human body" security screening, as discussed in the definitions section. The use of these devices typically involves individuals other than those who would be considered personnel.

Commented [JSJ86]: This requirement specifies that x-ray systems to be used for human body screening be evaluated by the department, which is the process currently in use since current regulations do not specifically address human screening systems.

The language is modified slightly from Part H to clarify that registrants may submit/utilize a form to submit the necessary information.

Slight language modifications from that found in Part H are made for clarity.

Commented [JSJ87]: Based on feedback from the stakeholder process, additional language pertaining to optimizing image quality and dose is added to include manufacturer's instructions and accepted standards. Similar language is used in other regulatory parts.

For general-use screening systems, where the system is used without regard to the number of individuals scanned or number of scans per individual in a year, an effective dose for a single complete screening shall be limited to 25 µrem (0.25 µSv).

8.11.4 Dose Limits for Limited-Use Systems.
For limited-use screening systems, where the system is capable of operation greater than 25 µrem (0.25 µSv) per screening, and is used with discretion, the effective dose per screening shall be less than or equal to 1 mrem (0.01 mSv).

8.11.5 Dose Limits for Repeat Security Screenings.
Individuals subject to repeat security screening at a single venue shall not receive an effective dose greater than 25 mrem (0.25 mSv) in any one year at the registrant's facility.

8.11.6 Requirements for vehicle or container screening systems.

A. When the procedures for operation of a RGD used for security screening of vehicles includes knowingly exposing human occupants to the primary beam when screening vehicles, structures or containers, the system shall be subject to the same requirements as general-use or limited-use systems as provided in 8.11.1 through 8.11.5.

B. If the requirements in 8.11.3 through 8.11.5. cannot be met if vehicle occupants are knowingly exposed to the primary beam of a security screening system, then there shall be means to assure the occupied portion of the vehicle is outside of the scan area while the primary beam is emitted or procedures shall be established and implemented to assure that no occupants are present in the vehicle during screening.

C. The effective dose to an individual for a single inadvertent exposure to the primary beam shall not exceed 500 mrem (5 mSv) and should not exceed 100 mrem (1 mSv). The reliability of the procedure used to assure that there are no occupants of a vehicle to be scanned shall be commensurate with the potential severity of an inadvertent exposure. If the 500 mrem (5 mSv) limit cannot be assured, a pre-screening with a mode or system which can meet the limits in 8.11.3 through 8.11.6 shall be used to verify there are no occupants in the vehicle being examined.

~~8.7 Quality Assurance Requirements.~~

~~8.7.1 Each non-healing arts radiation generating device shall have written quality control and quality assurance procedures that follow:~~

~~8.7.1.1 Specifications of the manufacturer; and~~

~~8.7.1.2 Specifications of the radiation safety officer; and/or~~

~~8.7.1.3 Standards of an appropriate nationally recognized organization.~~

_____

END OF RULE

Commented [JSJ88]: This section is added, consistent with Part H, Section H.12.d, with the exception that "the system" replaces "equipment", for consistency with the language used in provision 8.11.3 (above).

Commented [JSJ89]: For clarity, this section is retitled from "Vehicle limitations" (from Part H) to the current title.

Commented [JSJ90]: The language of Part H, Section H.12.f is incorporated with the exception that the phrase "When procedures for operation of a mobile or fixed…" excludes "mobile or fixed", since the requirement is the same and applies to all vehicle security screening RGDs.

Commented [JSJ91]: This section/requirement is not found in Part H and is therefore deleted.

DRAFT 1 04/08/2021

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

RADIATION CONTROL - RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

6 CCR 1007-1 Part 05
[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health on June 16, 2021; effective August 14, 2021.

PART 5: RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

5.1 Purpose and Scope.

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

* * *

5.1.4 Applicability.

5.1.4.1 Part 5 applies to all licensees or registrants who use sources of radiation for industrial radiography. Radiation machines and sealed radioactive sources are both covered by Part 5, except for sections which are applicable only to sealed radioactive sources.

5.1.4.2 The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the general requirements and provisions of Parts 1, 2, 3, 4, **8,** 10, **17,** and ~~17~~**22** apply to applicants, licensees and registrants subject to this part. Parts 3 and 17 apply to licensing and transportation of radioactive material. Part 2 applies to the registration of radiation machines. Part 5 does not apply to medical uses of **x-ray** sources of radiation that are governed by Parts 6 and **24**~~20~~.

5.1.5 Published Material Incorporated by Reference.

~~Published material incorporated in Part 5 by reference is available in accord with 1.4.~~

5.1.5.1. Throughout this Part 5, 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 5 (August 2021), and not later amendments or editions of the incorporated material.

5.1.5.2. 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

Commented [JSJ92]:
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.

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: The acronym "RATS 2020-1" refers to the U.S. Nuclear Regulatory Commission (NRC) regulatory action tracking system (RATS). This system is used to identify and summarize changes to federal regulations that may be required for adoption by an NRC agreement state. To maintain agreement state status, Colorado's radiation regulations must be compatible with federal regulations of the NRC.

Colorado statute also prescribes that the radiation control regulations must be consistent with the model regulations of the Conference of Radiation Control Program Directors, Inc. (CRCPD). The CRCPD model regulation equivalent to part 5 was last updated in 2015.

Commented [JSJ93]:
These dates reflect anticipated adoption and effective dates based on the current rulemaking schedule. Dates are subject to change pending additional review, approvals, and department rulemaking and Board of Health schedules.

Commented [JSJ94]: This provision amended to incorporate the requirements of Part 22 related to radioactive materials security, and to update a reference due to a prior change in rule numbering.

Commented [JSJ95]:
This section amended for consistency with the Colorado Administrative Procedure Act (24-4-103(12.5)(a)(2), CRS).

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.

5.1.5.3. 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.

(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.

(3) Copies of the standards or guidelines of outside organizations are available at no cost or for purchase from the source organizations below.

(a) American National Standards Institute, Inc.
25 West 43rd Street
New York, New York 10036
Phone (212) 642-4900
ansi.org

5.2 Definitions.

As used in this part, these terms have the definitions set forth as follows:

* * *

"Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR **Part** 1020.40 ~~(April 1, 2009)~~.

"Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR **Part** 1010.2 ~~(April 1, 2009)~~, as being manufactured and assembled pursuant to the provisions of 21 **Part** CFR 1020.40 ~~(April 1, 2009)~~.

* * *

5.3 Exemptions.

5.3.1 ~~Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of Part 5 except for the following:~~**Certified and certifiable cabinet x-ray systems and other x-ray generating device imaging for education or research purposes at a fixed location are exempt from the requirements of Part 5, but shall follow the requirements of Part 8.**

~~5.3.1.1 For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:~~

~~(1) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records that~~

Commented [JSJ96]: Provision is updated, parallel with the proposed changes to Part 8. Instead of listing the requirements applicable to cabinet x-ray systems in Part 5, the requirements of Part 8 are applied.

Commented [JSJ97]: The requirements for training that are applicable to cabinet x-ray systems are addressed in the proposed Part 8, Section 8.3.3, and 8.4.11.

~~demonstrate compliance with this subparagraph shall be maintained for Department inspection until disposal is authorized by the Department.~~

~~(2) Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests shall be maintained for Department inspection until disposal is authorized by the Department.~~

~~(3) The registrant shall perform an evaluation of the radiation exposure to determine compliance with 4.14.1 and 4.14.3, and 21 CFR 1020.40 (April 1, 2004) (Cabinet X-Ray Systems, 39 Federal Register 12986, April 10, 1974), at intervals not to exceed one year. Records of these evaluations shall be maintained for Department inspection for two years after the evaluation.~~

~~5.3.1.2 Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 (April 1, 2004) (Cabinet X-Ray Systems, 39 Federal Register 12986, April 10, 1974), and no modification shall be made to the system unless prior Department approval has been granted.~~

5.3.~~2~~**1** Industrial uses of hand-held light intensified imaging devices are exempt from the requirements of this Part if the dose rate 45 cm (18 inches) from the source of radiation to any individual does not exceed 0.02 millisievert (2 millirem) per hour. When this dose rate limit is exceeded, such devices shall meet the applicable requirements of this part and the licensing or registration requirements of Part 2 ~~or~~ Part 3, **or Part 8** as applicable.

* * *

5.7 Limits on External Radiation Levels From Storage Containers and Source Changers.

The maximum exposure rate limits for storage containers and source changers are 2 millisievert (200 mrem) per hour at any exterior surface, and 0.1 millisievert (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

* * *

5.10 Leak Testing and Replacement of Sealed Sources.

5.10.1 The replacement of any sealed source fastened to or contained in a radiographic exposure device and the leak testing of any sealed source must be performed by persons authorized to do so by the Department, the Nuclear Regulatory Commission, or another Agreement State.

5.10.2 The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Department, the Nuclear Regulatory Commission, or another Agreement State.

5.10.3 Testing and recordkeeping requirements.

5.10.3.1 Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Department, the Nuclear

Commented [JSJ98]: The requirements for testing of interlocks and other safety devices at 6 month intervals and that are applicable to cabinet x-ray systems are addressed in the proposed Part 8, Section 8.4.10.

Commented [JSJ99]: The requirements for surveys that are applicable to cabinet x-ray systems are addressed in the proposed Part 8, Section 8.2 (cabinet radiography definition), Section 8.4.5, and 8.5.

Commented [JSJ100]: Section 8.4 of the proposed Part 8, requires cabinet x-ray systems to meet the requirements of 21 CFR 1020.40. Additionally, under the exemption section of Part 8 (Section 8.3.5), modifications to the device would require Department approval.

Commented [JSJ101]: Formatted for unneeded spaces/gaps in current rule.

Commented [JSJ102]: Section 5.10 is formatted for alignment of text. No changes to the actual regulatory requirements are being proposed.

Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 µCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

5.10.3.2 The licensee shall maintain records of the leak tests in accordance with 5.27.

5.10.3.3 Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds 6 months.

5.10.4 Any test conducted pursuant to 5.10.2 and 5.10.3 that reveals the presence of 185 becquerel (0.005 µCi) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Department regulations. A report must be filed with the Department within 5 days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

5.10.5 Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months.

5.10.5.1 The analysis must be capable of detecting the presence of 185 becquerel (0.005 µCi) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

5.10.5.2 Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made.

5.10.5.3 Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage.

5.10.5.4 Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months.

5.10.5.5 A record of the DU leak-test must be made in accordance with 5.27.

* * *

5.13 Permanent Radiographic Installations.

5.13.1 Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either.

5.13.1.1 An entrance control of the type described in **Part 4, Section** 4.19 of these regulations that causes the radiation level upon entry into the area to be reduced; or

* * *

5.14 Labeling, Storage, and Transportation.

5.14.1 The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION*

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES [or "NAME OF COMPANY"]

*or "DANGER"

* * *

5.20 Personnel Monitoring.

5.20.1 The licensee or registrant ~~shall~~**may** not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarming ratemeter, and a personnel dosimeter. ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.~~ At permanent radiography~~ic~~ installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the wearing of an alarming ratemeter is not required.

5.20.1.1 Pocket dosimeters must have a range from zero to 2 millisievert (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

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

5.20.1.3 Film badges must be ~~exchanged at periods not to exceed one month~~**replaced at least monthly** and **all** other personnel dosimeters ~~processed and evaluated by an accredited NVLAP processor~~ **that require replacement** must be replaced ~~at periods not to exceed three months~~ **at least quarterly**.

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

5.20.2 Direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 5.34.

Commented [JSJ103]:
5.14.1 is formatted for alignment of text. No changes to regulatory requirements are proposed.

Commented [JSJ104]: The provisions of 5.20 are revised for consistency with 2020 amendments to 10 CFR Part 34.47.

NRC amended this federal rule to authorize the use of modern individual monitoring devices for industrial radiography operations. 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 current rule and may instead be read directly by internet-enabled computers, smartphones, and tablets. 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.

Section 5.20 is also formatted for alignment of text.

NRC RATS 2020-1
NRC Compatibility "C"

5.20.3 Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 5.34. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

5.20.4 If an individual's pocket ~~dosimeter~~**chamber** ~~indicates a reading~~**is found to be** off-scale**,** or if ~~the~~**his or her** electronic personal dosimeter ~~reading exceeds~~**reads greater than** 2 millisievert**s** (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing **and evaluation** within 24 hours. **For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours.**

5.20.4.1 In addition, the individual may not resume work associated with use of sources of radiation until a determination of the individual's radiation ~~exposure~~**dose** has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee.

5.20.4.1 The results of this determination must be included in the records maintained in accordance with 5.34.

5.20.5 If the personnel dosimeter that is required by 5.20.1 is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements of 5.20.1 is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with 5.34.

5.20.6 ~~Reports received from the accredited NVLAP personnel dosimeter processor~~ **Dosimetry results** must be retained in accordance with 5.34.

Commented [JSJ105]: Provision is updated for consistency with the language of 10 CFR Part 34.47(f).

5.20.7 Each alarming ratemeter must:

5.20.7.1 Be checked to ensure that the alarm functions properly before using at the start of each shift;

5.20.7.2 Be set to give an audible alarm signal at a preset dose rate of 5 millisievert (500 mrem) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate;

5.20.7.3 Require special means to change the preset alarm function; and

5.20.7.4 Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with 5.34.

5.21 Radiation Surveys.

Commented [JSJ106]: Section 5.21 is formatted for alignment.
No changes to regulatory requirements are being proposed.

5.21.1 The licensee or registrant shall:

5.21.1.1 Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 5.9;

5.21.1.2 Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube.

(1) The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

(2) Radiation machines shall be surveyed after each exposure to determine that the machine is off;

5.21.1.3 Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in ~~5.35~~.2, to ensure that the sealed source is in its shielded position; and

5.21.1.4 Maintain records in accordance with 5.35.

* * *

5.27 Records of Leak Testing of Sealed Sources and Devices Containing DU.

5.27.1 Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU.

5.27.1.1 The results must be stated in units of becquerel (microcurie).

5.27.1.2 The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

* * *

5.29 Utilization Logs.

5.29.1 Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

5.29.1.1 A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

5.29.1.2 The identity and signature of the radiographer to whom assigned;

5.29.1.3 The location and dates of use, including the dates removed and returned to storage; and

5.29.1.4 For permanent radiographic installations, the dates each radiation machine is energized.

5.29.2 The licensee or registrant shall retain the logs required by 5.29.1 for 3 years.

* * *

Commented [JSJ107]: Correction of cross-reference error.

Commented [JSJ108]: Section 5.27 is formatted for alignment of text. No changes to regulatory requirements are being proposed.

Commented [JSJ109]: Section 5.29 is formatted for alignment of text. No changes to regulatory requirements are being proposed.

5.32 Records of Training and Certification.

5.32.1 Each licensee or registrant shall maintain the following records for 3 years:

5.32.1.1 Records of training of each radiographer and each radiographer's assistant.

(1) The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

5.32.2.1 Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant.

(1) The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees.

(2) For inspections of job performance, the records must also include a list showing the items checked and any noncompliance observed by the radiation safety officer or designee.

* * *

5.34 Records of Personnel Monitoring.

Each licensee or registrant shall maintain the following exposure records specified in 5.20:

5.34.1 Direct reading dosimeter readings and yearly operability checks required by 5.20.2 and 5.20.3 for 3 years after the record is made;

5.34.2 Records of alarming ratemeter calibrations for 3 years after the record is made;

5.34.3 Personnel dosimeter results ~~received from the accredited NVLAP processor~~ until the Department terminates the license or registration; and

5.34.4 Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters, until the Department terminates the license or registration.

* * *

5.37 Location of Documents and Records.

5.37.1 Each licensee or registrant shall maintain copies of records required by this Part and other applicable Parts of these regulations at the location specified in 5.4.11.

5.37.2 Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

5.37.2.1 The license or registration authorizing use of sources of radiation;

5.37.2.2 A copy of Parts 1, 4, 5 and 10 of these regulations;

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Section 5.32 is formatted for alignment of text.
No changes to regulatory requirements are being proposed.

Commented [JSJ111]:
Provision is updated for consistency with the language of 10 CFR Part 34.83(c). See prior side-margin comment pertaining to Section 5.20 for additional information.

Commented [JSJ112]:
Section 5.37 is formatted for alignment of text.
No changes to regulatory requirements are being proposed.

5.37.2.3 Utilization logs for each source of radiation dispatched from that location as required by 5.29;

5.37.2.4 Records of equipment problems identified in daily checks of equipment as required by 5.30.1;

5.37.2.5 Records of alarm system and entrance control checks required by 5.31, if applicable;

5.37.2.6 Records of dosimeter readings as required by 5.34;

5.37.2.7 Operating and emergency procedures as required by 5.33;

5.37.2.8 Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 5.26;

5.37.2.9 Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 5.34;

5.37.2.10 Survey records as required by 5.35 and 4.42 of these regulations as applicable, for the period of operation at the site;

5.37.2.11 The shipping papers for the transportation of radioactive materials required by Part 17 of these regulations; and

5.37.2.12 When operating under reciprocity pursuant to Part 3 of these regulations, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing use of sources of radiation.

NOTIFICATIONS

5.38 Notifications.

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Section 5.38 is formatted for alignment of text.
No changes to regulatory requirements are being proposed.

5.38.1 In addition to the reporting requirements specified in 4.52 of these regulations, each licensee or registrant shall provide a written report to the Department within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

5.38.1.1 Unintentional disconnection of the source assembly from the control cable;

5.38.1.2 Inability to retract the source assembly to its fully shielded position and secure it in this position;

5.38.1.3 Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

5.38.1.4 An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

5.38.2 The licensee or registrant shall include the following information in each report submitted under 5.38.1, and in each report of overexposure submitted under 4.53.2 of these regulations which involves failure of safety components of radiography equipment:

5.38.2.1 Description of the equipment problem;

5.38.2.2 Cause of each incident, if known;

5.38.2.3 Name of the manufacturer and model number of equipment involved in the incident;

5.38.2.4 Place, date, and time of the incident;

5.38.2.5 Actions taken to establish normal operations;

5.38.2.6 Corrective actions taken or planned to prevent recurrence; and

5.38.2.7 Names and qualifications of personnel involved in the incident.

5.38.3 Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 90 days in a calendar year, shall notify the Department prior to exceeding the 90 days.

5.39 Specific Requirements for Personnel Performing Industrial Radiography.

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Section 5.39 is formatted for alignment of text.
No changes to regulatory requirements are being proposed.

5.39.1 At a job site, the following shall be supplied by the licensee or registrant:

5.39.1.1 At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

5.39.1.2 A current whole body personnel dosimeter (OSL dosimeter, TLD or film badge) for each person performing radiographic operations;

5.39.1.3 An operable, calibrated pocket dosimeter with a range of zero to 2 millisievert (200 milliroentgen) for each person performing radiographic operations;

5.39.1.4 An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

5.39.1.5 The appropriate barrier ropes and signs.

5.39.2 Each radiographer at a job site shall have on their person a valid certification identification card issued by a certifying entity.

5.39.3 Industrial radiographic operations shall not be performed if any of the items in 5.39.1 and 5.39.2 are not available at the job site or are inoperable.

5.39.4 During an inspection, the Department may terminate an operation if any of the items in 5.39.1 and 5.39.2 are not available or operable, or if the required number of radiographic personnel are not present.

5.39.4.1 Operations shall not be resumed until all required conditions are met.

PART 5, APPENDIX 5A: CERTIFICATION

5A.1 Requirements for an Independent Certifying Organization.

An independent certifying organization shall:

5A.1.1 Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

5A.1.2 Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;

5A.1.3 Have a certification program open to nonmembers, as well as members;

5A.1.4 Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;

5A.1.5 Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

5A.1.6 Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

5A.1.7 Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

5A.1.8 Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

5A.1.9 Have written procedures describing all aspects of its certification program and maintain records of the current status of each individual's certification and the administration of its certification program;

5A.1.10 Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

5A.1.11 Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

5A.1.12 Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

5A.1.13 Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

5A.2 Requirements for Certification Programs.

All certification programs must:

5A.2.1 Require applicants for certification to

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Prior to final publication, insert a page break at the top of appendix 5A.

All Appendices of Part 5 are formatted for text alignment purposes. No changes to regulatory requirements are being proposed.

(1) Receive training in the topics set forth in Appendix 5C, Section 5C.2, or equivalent State or Nuclear Regulatory Commission regulations, and

(2) Satisfactorily complete a written examination covering these topics;

5A.2.2 Require applicants for certification to provide documentation that demonstrates that the applicant has:

(1) Received training in the topics set forth in Appendix 5C, Section 5C.2 or equivalent State or Nuclear Regulatory Commission regulations;

(2) Satisfactorily completed a minimum period of on-the-job training as specified in Appendix 5C, Section 5C.2.4; and

(3) Received verification by a State licensee or registrant or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.

5A.2.3 Include procedures to ensure that all examination questions are protected from disclosure;

5A.2.4 Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5A.2.5 Provide a certification period of not less than 3 years nor more than 5 years;

5A.2.6 Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

5A.2.7 Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

5A.3 Requirements for Written Examinations

All examinations must:

5A.3.1 Be designed to test an individual's knowledge and understanding of the topics listed in Appendix 5C, Section 5C.2 or equivalent State or Nuclear Regulatory Commission requirements;

5A.3.2 Be written in a multiple-choice format;

5A.3.3 Have test items drawn from a question bank containing psychometrically valid questions based on the material in Appendix 5C, Section 5C.2.

PART 5, APPENDIX 5B: INDUSTRIAL RADIOGRAPHY RADIATION SAFETY OFFICER ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The licensee or registrant shall not permit any individual to act as a radiation safety officer for industrial radiography unless and until the individual:

5B.1 Has provided evidence of valid certification (valid identification) through a radiographer certification program by a certifying organization in accordance with the criteria specified in Appendix 5A;

and

5B.2 Has provided evidence of having:

5B.2.1 Satisfactorily completed 40 hours of training including each of the following:

(1) Fundamentals of radiation safety including:

(a) Characteristics of gamma and x-radiation;

(b) Units of radiation dose and quantity of radioactivity;

(c) Hazards of exposure to radiation;

(d) Levels of radiation from sources of radiation;

(e) Methods of controlling radiation dose (time, distance, and shielding); and

(2) Radiation detection instruments including:

(a) Use, operation, calibration, and limitations of radiation survey instruments;

(b) Survey techniques; and

(c) Use of personnel monitoring equipment; and

(3) Equipment to be used including:

(a) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(b) Operation and control of radiation machines;

(c) Storage, control, and disposal of sources of radiation; and

(d) Inspection and maintenance of equipment; and

(4) The requirements of pertinent state and federal regulations; and

(5) Case histories of accidents in radiography; and

5B.2.2 Successfully completed a written or oral examination after having received copies of and instruction in the:

(1) Requirements of Part 5;

Commented [JSJ116]:
Prior to final publication, insert a page break at the top of appendix 5B.

All Appendices of Part 5 are formatted for text alignment purposes. No changes to regulatory requirements are being proposed.

(2) Requirements of applicable sections of Parts 4, 10 and 17;

(3) License or registration under which the radiographer will perform industrial radiography; and

(4) Licensee's or registrant's operating and emergency procedures; and

5B.2.3 Successfully completed a practical examination which demonstrates understanding of the use of the equipment after receiving training in the:

(1) Use of the registrant's radiation machines; or

(2) Use of the licensee's radiographic exposure devices and sealed sources;

(3) Daily inspection of devices and associated equipment; and

(4) Use of radiation survey instruments; and

5B.2.4 Completed hands on and on the job training in the performance of industrial radiography, including at least 2000 hours of hands on experience, as defined in 5.2, as a qualified radiographer in industrial radiographic operations. The on the job training shall include a minimum of:

(1) 320 hours (2 months) of on the job active participation utilizing radioactive material; and / or

(2) 160 hours (1 month) of on the job active participation utilizing radiation machines; or

(3) 480 hours (3 months) of on the job training for individuals utilizing both radioactive materials and radiation machines; and

5B.2.5 Completed formal training in the establishment and maintenance of a radiation protection program;

or

5B.3 Has demonstrated to the Department an acceptable alternative to 5B.2 when the individual has appropriate training and experience in the field of ionizing radiation, and, in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program for industrial radiography;

and

5B.4 Has provided evidence of annual refresher safety training, as defined in 5.2, at intervals not to exceed 12 months.

PART 5, APPENDIX 5C: INDUSTRIAL RADIOGRAPHER ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The licensee or registrant shall not permit any individual to act as a radiographer unless and until the individual:

5C.1 Has provided evidence of valid certification (valid identification) through a radiographer certification program by a certifying organization in accordance with the criteria specified in Appendix 5A;

and

5C.2 Has provided evidence of having:

5C.2.1 Satisfactorily completed 40 hours of training including each of the following:

(1) Fundamentals of radiation safety including:

(a) Characteristics of gamma and x-radiation;

(b) Units of radiation dose and quantity of radioactivity;

(c) Hazards of exposure to radiation;

(d) Levels of radiation from sources of radiation;

(e) Methods of controlling radiation dose (time, distance, and shielding); and

(2) Radiation detection instruments including:

(a) Use, operation, calibration, and limitations of radiation survey instruments;

(b) Survey techniques; and

(c) Use of personnel monitoring equipment; and

(3) Equipment to be used including:

(a) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(b) Operation and control of radiation machines;

(c) Storage, control, and disposal of sources of radiation; and

(d) Inspection and maintenance of equipment; and

(4) The requirements of pertinent state and federal regulations; and

(5) Case histories of accidents in radiography; and

5C.2.2 Successfully completed a written or oral examination after having received copies of and instruction in the:

(1) Requirements of Part 5;

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Prior to final publication, insert a page break at the top of appendix 5C.

All Appendices of Part 5 are formatted for text alignment purposes. No changes to regulatory requirements are being proposed.

(2) Requirements of applicable sections of Parts 4, 10 and 17;

(3) License or registration under which the radiographer will perform industrial radiography; and

(4) Licensee's or registrant's operating and emergency procedures; and

5C.2.3 Successfully completed a practical examination which demonstrates understanding of the use of the equipment after receiving training in the:

(1) Use of the registrant's radiation machines; or

(2) Use of the licensee's radiographic exposure devices and sealed sources;

(3) Daily inspection of devices and associated equipment; and

(4) Use of radiation survey instruments; and

5C.2.4 Completed hands on and on the job training in the performance of industrial radiography, including hands on experience, as defined in 5.2, as a qualified radiographer in industrial radiographic operations. The on the job training shall include a minimum of:

(1) 320 hours (2 months) of on the job active participation utilizing radioactive material; and / or

(2) 160 hours (1 month) of on the job active participation utilizing radiation machines; or

(3) 480 hours (3 months) of on the job training for individuals utilizing both radioactive materials and radiation machines;

or

5C.3 Has demonstrated to the Department an acceptable alternative to 5C.2 when the individual has appropriate training and experience in the field of ionizing radiation, and, in addition, has adequate formal training with respect to radiation protection for industrial radiography;

and

5C.4 Has provided evidence of annual refresher safety training, as defined in 5.2, at intervals not to exceed 12 months.

PART 5, APPENDIX 5D: INDUSTRIAL RADIOGRAPHER'S ASSISTANT ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

The licensee or registrant shall not permit any individual to act as a radiographer's assistant unless and until the individual has:

5D.1 Received initial radiation safety training;

and

5D.2 Has provided evidence of having:

5D.2.1 Successfully completed a written examination after having received copies of and instruction in the:

(1) Requirements of Part 5;

(2) Requirements of applicable sections of Parts 4, 10 and 17;

(3) License or registration under which the radiographer will perform industrial radiography; and

(4) Licensee's or registrant's operating and emergency procedures; and

5D.2.2 Successfully completed a practical examination under the personal supervision of a radiographer which demonstrates understanding of the use of the equipment after receiving training in the:

(1) Use of the registrant's radiation machines; or

(2) Use of the licensee's radiographic exposure devices and sealed sources;

(3) Daily inspection of devices and associated equipment; and

(4) Use of radiation survey instruments; and

or

5D.3 Has demonstrated to the Department an acceptable alternative to 5D.2 when the individual has appropriate training and experience in the field of ionizing radiation, and, in addition, has adequate formal training with respect to radiation protection for industrial radiography;

and

5D.4 Has provided evidence of annual refresher safety training, as defined in 5.2, at intervals not to exceed 12 months.

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Prior to final publication, insert a page break at the top of appendix 5D.

All Appendices of Part 5 are formatted for text alignment purposes. No changes to regulatory requirements are being proposed.

DRAFT 1 04/05/2021

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

State Board of Health

RADIATION CONTROL - REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

6 CCR 1007-1 Part 02

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

Adopted by the Board of Health ~~August 19, 2020~~June 16, 2021, effective date ~~October 15, 2020~~August 14, 2021

PART 2: REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

[* * * INDICATES UNAFFECTED SECTIONS OR PROVISIONS]

* * *

2.6.1.15 For radiation machines used in non-healing-arts applications, "adequately trained" shall mean that the individual operator meets the requirements of Appendix 2N.

(1) For industrial radiography, the requirements in Part 5 apply, as stated in 2N.1.

(2) The requirements of 2N.2 apply to all non-healing-arts applications **subject to Part 8** (including but not limited to analytical, forensic, morgue, and homeland security uses) **but** not subject to Part 5.

* * *

Commented [JSJ119]: **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: The proposed changes to this rule are intended to align with other changes associated with the 2021 rulemaking activities for Part 8 and Part 5.

Commented [JSJ120]:
The stated adoption and effective dates are tentative and subject to change, pending Board of Health meeting schedule, final adoption of the rule by the Board, and the Colorado Register publication dates.

The anticipated dates are based on the annual rulemaking schedule (regulatory agenda) for the Department which may be found online.

Commented [JSJ121]:
The proposed changes are intended to align the parallel/concurrent rule changes in Part 8 and Part 5.

PART 2, APPENDIX 2N: INDUSTRIAL RADIATION MACHINE OPERATOR ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE

Any person who operates an analytical, industrial or other non-healing-arts radiation generating machine shall be an individual who:

2N.1 For industrial radiography, has complied with all applicable training and experience requirements of Part 5 and these regulations.

2N.2 For all non-healing-arts applications **subject to Part 8** (including but not limited to analytical, forensic, morgue, and homeland security uses) **but** not subject to Part 5, has provided written documentation as evidence of:

* * *

Commented [JSJ122]: Prior to final publication, insert a page break to ensure that Appendix 2N begins on a new page, consistent with current rule formatting.

Commented [JSJ123]: The proposed change is intended to align the parallel/concurrent rule changes in Part 8 and Part 5.