COLORADO
Department of Public Health & Environment

Dosimetry monitoring for x-ray facilities

The Colorado Department of Public Health and Environment (Department), Radiation Control Program, recently revised the requirement in Part 4, section 4.18.3. The effective date for this change was December 15, 2023.

The revision eliminated the dosimetry waiver application process and department approval via the application form R-400 for x-ray facilities. X-ray facilities that wish to discontinue dosimetry badge monitoring still must determine if employee radiation monitoring is required. Facilities must keep the determination to discontinue monitoring and any supporting documentation on file at the facility for review at time of inspection. (Part 4, section 4.18.3)

Using personal dosimeters and monitors can help a facility track cumulative and individual radiation exposure over time, as well as identify and avoid situations or areas with elevated radiation levels. Additionally, the use of badges can provide evidence of personnel exposure in cases of an accident, incident, or legal claim. The use of radiation badges can improve overall radiation awareness, responsibility, safety and health of workers. A dosimetry-monitoring program can assist a facility with compliance with occupational health and safety standards for radiation workers.

What is the revised regulatory requirement regarding dosimetry monitoring?

Part 4, section 4.18.3

> Registrants shall maintain records of the evaluation of likely external dose and the determination to monitor or not monitor individuals to demonstrate compliance with the occupational dose limits of Part 4. The registrant shall retain the record required by 4.18.3 for inspection until the Department terminates the registration requiring the record.

What are the monitoring thresholds?

Each registrant shall monitor occupational exposure to radiation from radiation sources under the control of the facility and shall supply and require the use of individual monitoring badges for anyone listed below:

- Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 4.6.1.
- Minors likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1mSv), a lens dose equivalent in excess of 0.15 rem(1.5 mSv) or a shallow dose equivalent to the skin or to the extremities in excess 0.5 rem (5 mSv)
- Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1mSv)
- Individuals entering a high radiation area or a very high radiation area.

When does an x-ray facility have to provide dosimetry badges to employees?

These employees are required to wear dosimetry badges unless an employer has **demonstrated and documented** that annual occupational exposure to radiation is less than 500 mrem (5mSv) which is 10% of the allowable annual limit.

- Adult employees
- Declared pregnant workers -The annual limits and monitoring threshold for declared pregnant workers is lower than the dose limits for adult. The x-ray facility must keep documentation of monitoring of a declared pregnant employee and records of dose to the embryo/fetus. Declared pregnant employees will wear two (2) dosimetry badges, one whole body badge at chest level and one fetal badge over the abdomen. This documentation must include the declaration of pregnancy date and estimated date of conception. Declared pregnant employees likely to receive 100 mrem (1mSv) deep dose equivalent during the entire pregnancy shall be monitored.
- Minor employees - The annual limits and monitoring threshold for minor workers is lower than the dose limits for adults. Employees who are minors typically do not work directly with radiation per the Colorado Youth Employment Opportunity Act (C.R.S. 8-12-101 et seq.) and the Fair Labor Standards Act (FLSA). In the event, your facility employs a minor who is likely to receive, in one (1) year, a dose in excess of 0.1 rem (100 mrem), the facility shall monitor the minor employee with a radiation badge.
- Individuals who enter high or very high radiation areas.

The Department has evaluated the following scenarios and determined them to have a likelihood of exceeding the limits for requiring occupational monitoring. As a result, employees engaging in these activities would require dosimetry as well.

- Personnel who receive, or are likely to receive, a whole body dose in excess of 25 millroentgens (mR) per week.
- Individuals who operate mobile x-ray equipment.
- Individuals consistently holding patients, animals, or objects for radiographic imaging
- Individuals who operate fluoroscopic units, therapeutic x-ray units, or traditional CT scanners.
- Individuals who service operable x-ray producing machines.
- Individuals performing industrial radiography.

How do I determine if my x-ray facility can discontinue monitoring of employees?

X-ray registrants may stop using dosimetry badges by demonstrating through a written evaluation that employees will not exceed the applicable monitoring thresholds in 4.18.1. Below are two of the most common evaluation methods your facility can use to demonstrate that employees are not likely to exceed the thresholds, which would require monitoring.

1. **Monitor the occupational exposure of employees for at least six (6) months using dosimetry badges.**

   - Provide badges to every machine operator and any ancillary staff that are regularly present in areas where radiation exposure occurs.
   - Perform the monitoring under conditions that represent a normal, routine workload. New facilities should consider whether their operations at the time of the review represent a normal, routine workload.
   - Registrants must ensure employees are using dosimeters properly and follow all requirements of the facility Radiation Protection Program during the monitoring period.
   - At the completion of the monitoring period, the registrant must evaluate the dosimetry data to verify that the thresholds of 4.18.1 will not be exceeded. Remember that if you choose to monitor for a period of six months, dosimetry monitoring data (badge results) must be doubled for comparison to the annual exposure thresholds.

   For example, if monitoring data for an adult worker represents the employee who received the highest dose and indicates they received 150 mrem (1.5 mSv) over a 6 month monitoring period, the dose would be multiplied by two (2), resulting in an estimated annual dose of 300 mrem (3 mSv) for the year (150 mrem x 2 = 300 mrem). Since the threshold for monitoring adult workers is 500 mrem per year, dosimetry would not be required in this instance and may be discontinued.

   - The evaluation of the dose data must include sufficient details and facility condition information to make an accurate assessment. The report must also include the number and locations of machines and workload estimates to help with future assessments and changes in radiological conditions.
   - Registrants must maintain a copy of the dosimetry monitoring records, facility conditions at time of monitoring, written evaluation of the monitoring results, and written determination to continue or discontinue monitoring based on the dosimetry evaluation for inspection as specified in Part 4, section 4.18.3.**

     (A worksheet to help assist with the facility evaluation process is included at the end of this guidance.)**

2. **Obtain a radiation survey assessment completed by a registered Qualified Expert (QE)[**].**

   - The assessment must take into account the facility design configuration, routine workload, radiation-producing machine output, and applicable survey data or measurements.
   - The evaluation must include sufficient details and information including the number and locations of machines to help with future assessments and changes in radiological conditions.

- The assessment must demonstrate that the monitoring thresholds of 4.18.1 will not be met.
- Registrants must maintain a copy of the written assessment for inspection as specified in Part 4, section 4.18.3.

If either of these evaluations demonstrate that occupational doses are likely to exceed the monitoring thresholds of 4.18.1, then monitoring is required. The facility shall initiate or continue monitoring for occupational exposure. When monitoring is required, then the requirements of Part 4, Section 4.46 and Part 10, Section 10.4 must be followed. This includes providing dose information to occupational workers and maintaining records of exposures.

(A list of Qualified Experts is available on the Department website at: https://cdphe.colorado.gov/hm/xray-registration-verifications.)**

How often must I review the evaluation and determination regarding dosimetry monitoring at my facility?

If the radiation exposure conditions change at any time, the need to provide individual monitoring shall be re-evaluated. Changes that could affect radiologic conditions include:

- Facility remodeling
- Relocating a machine
- Changing the orientation of the machine
- Adding x-ray machines
- Increases in workload
- Similar activities

Additionally, every year, each x-ray facility, as part of the Radiation Protection Program, must review changes that could affect radiation safety at the facility. The annual review of the Radiation Protection Program required by Part 4, section 4.5 shall include a review of changes that could impact occupational exposure.

What do I do if my facility has a previously issued dosimetry waiver?

Any dosimetry waiver issued prior to December 15, 2023 (the effective date of the Part 4 regulation that amended section 4.18.3) will remain in effect. Facilities must retain a copy of the waiver issued by the X-ray Certification Unit and have it available at the time of inspection. Each waiver is conditional upon radiological conditions remaining relatively consistent from the time when the waiver application was submitted and approved. Changes to the number of x-ray machines or types, locations or orientations of x-ray machines, may change radiological conditions and invalidate an existing waiver. To determine if changes to the monitoring program are needed, registrants must review their Radiation Protection Program annually. A worksheet to help assist with the facility evaluation process is included at the end of this guidance. (Part 4, section 4.5)

Can my x-ray facility choose to "voluntarily" monitor employees, even if they are not likely to exceed monitoring thresholds?

Yes. Some registrants may choose to monitor workers for reasons other than meeting the requirements of section 4.18.1. Facilities choosing this option are performing "voluntary monitoring." Facilities may choose to provide "voluntary monitoring" for numerous reasons including documenting that occupational exposures are within the legal limits, to provide comfort or reassurance to employees, monitoring is included as part of the facility Radiation Protection Program, or to provide a level of liability protection for the facility. A facility that provides voluntary monitoring devices should develop and retain documentation demonstrating that the monitoring is for purposes other than to meet the requirements in 4.18.1. When a facility has developed and maintained documentation demonstrating that monitoring is not required by 4.18.1, but is providing dosimetry for other purposes as discussed above, then the requirements for records of individual monitoring results in Part 4, section 4.46 do not apply.

Can a facility receive a citation (violation) if they do not maintain documentation supporting their dosimetry monitoring decision?

Yes. As with other regulatory requirements, an inspector can issue a citation when a facility does not maintain documentation regarding its decision to monitor or not monitor. The requirement to maintain documentation applies regardless of whether dosimetry monitoring is used to meet 4.18.1 or where the monitoring threshold is not met and monitoring is being performed voluntarily. Dosimetry reports or a Qualified Expert assessment along with documentation of the facility conditions at time of monitoring, written evaluation of the monitoring results, and a written determination to continue or discontinue monitoring will meet the documentation requirement in Part 4, section 4.18.3.

Definitions

Applicant - an entity that is in the process of applying to become a registrant.

Department - a term used to indicate the Colorado Department of Public Health and Environment.

Dose - a generic term that means absorbed dose, dose equivalent, effective dose, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

Dosimetry badge - a device that measures the absorbed dose of ionizing radiation for personnel that are in occupational contact with radiation.

mrem - units for dose equivalent are the roentgen equivalent man (rem), biological dose equivalents are commonly measured in 1/1000th of a rem (known as a millirem or mrem).

mSv - units for dose equivalent are the sievert (Sv), and biological dose equivalents are commonly measured in 1/1000th of a SV (known as a millisievert or mSv).

Registrant - an entity that is registered with the Department to use, service, or provide services for x-ray machines in the state of Colorado.

If you have any questions or comments regarding this document, please contact the X-Ray Certification Unit at 303-692-3448, or email: cdphe.hmxraycomments@state.co.us

Authorized by: Katherine Liberman Digitally signed by Katherine Liberman Date: 2023.12.14 11:22:35 -07'00' Date: December 14, 2023

EVALUATION OF X-RAY FACILITY OCCUPATIONAL MONITORING DATA TO DETERMINE IF THRESHOLDS OF 4.18.1 ARE LIKELY TO BE MET

1. FACILITY AND REGISTRATION INFORMATION

Facility name:	
Facility address:	
Facility registration number:	
Date of review:	
Reviewer:	
Radiation Safety Officer:	
Dosimetry monitoring period* (start and end dates):	
Dosimetry provider	NVLAP#

* Monitoring period must be at least 6 months.

2. OCCUPATIONAL MONITORING INFORMATION

Employee category (e.g., physician, dentist, operator, hygienist, etc.)	**Number of employees monitored for each category**
TOTAL NUMBER OF EMPLOYEES MONITORED:	

3. X-RAY MACHINES AND TYPES IN USE DURING MONITORING PERIOD.

Machine type (Intraoral, CBCT, podiatry, hand-held XRF, etc.)	**Location of machine within facility (exam 1 - west wall; etc.)**
TOTAL NUMBER OF X-RAY MACHINES:	

4. FACILITY WORKLOAD

Machine type (e.g., intraoral, CBCT, podiatry, etc.)	**Average number of patients per week per machine**	**Average # of x-ray images per week per machine**

5. FACILITY DESIGN

Please attach a shielding design or facility blueprint showing machine type and location and adjacent offices, and working and visitor locations

6. COMMENTS / NOTABLE CHANGES AND DATES

DOSIMETRY REVIEW AND ATTESTATION STATEMENT

I am an authorized radiation safety officer, representative, or registered provider of services for the above listed facility, and hereby **attest** that I have reviewed the personnel monitoring dosimetry data for the period specified above and have determined that all of the following are true and correct:

1. Employees properly wore radiation badges routinely during the monitoring period; and
2. Radiation producing (x-ray) machine use is representative of typical and normal levels of use and workload; and
3. When normalized to an annual exposure period, no individual occupational worker (including minors or declared pregnant workers) is likely to exceed the thresholds for occupational monitoring listed in 4.18.1.

Additional information:

_____
_____
_____
_____
_____
_____

_____

Printed name Title

_____

Signature Date

Attach all dosimetry data to this evaluation and maintain on file, at your facility, for future inspection as required by Part 4, section 4.18.3. Failure to maintain documentation may result in a notice of apparent violation.

This guidance document provides information and describes methods that are acceptable to the Department to meet this specific requirement pertaining to the use of dosimetry badges for external radiation monitoring of employees at facilities using only x-ray machines*.

*This document does not apply to occupational monitoring for internal exposure from radioactive materials. Internal dose monitoring is evaluated on a case-by-case basis during the radioactive material licensing process.

Guidance documents are not regulations**. The intent of the information in this guidance is to assist in compliance with Colorado Radiation rules and regulations. This guidance provides methods acceptable to the Colorado X-Ray Certification Unit (XRCU) to meet the regulatory requirements and represents the minimum acceptable standard. The methods described in this document are for information only.

**This guidance is not a substitute for state or federal regulations, commitments made by an applicant or registrant on a registration application or form, requirements specified in formal communications from us, or other legally binding requirements.