

Radiology Compliance Branch
RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

MEDICAL REPORTING

This guidance is provided to assist X-ray registrants in reporting of X-ray incidents involving the use of electronic X-ray equipment. This guidance does not apply to the use of radioactive materials or licensed therapy equipment. Guidance for reporting incidents/medical events for licensed facilities is available at <http://www.ncradiation.net/rms/rmsforms2.htm>.

The following X-ray incidents involving radiation workers or members of the public are required by NC Rules 10A NCAC 15 to be reported to the Radiation Protection Section:

Each registrant must provide the Radiation Protection Section a written report of the following X-ray over-exposures **within 30 days** of the occurrence:

- Employee exceeded the occupational dose limits for adults¹
- Employee exceeded the occupational dose limits for a minor²
- Employee exceeded the dose limits for an embryo/fetus of a declared pregnant worker³
- Dose limits have been exceeded for an individual member of the public⁴

Each registrant must provide the Radiation Protection Section a written report of the following X-ray incidents **within 30 days** of the occurrence:

- Failure of a critical safety component (industrial machines only)

Each registrant must provide the Radiation Protection Section an **immediate** written report of an X-ray incident that may have caused an exposure to an individual of at least:

- Total effective dose equivalent of 25 rems
- Eye dose equivalent of 75 rems
- Shallow-dose equivalent to skin or extremity of 250 rads

Each registrant must provide the Radiation Protection Section a written report within 24 hours of:

- A loss of X-ray equipment

The Radiation Protection Section would also like to collect reports of erroneous X-ray exposures on patients from diagnostic exams. This information will be provided to the Conference of Radiation Control Program Directors (CRCPD). The CRCPD analyzes this information to attempt to identify problems in equipment use or manufacturing.

Registrants are not obligated by Regulations to report this information to RPS but providing this information could be beneficial in identifying safety issues.

The following patient exposures may be reported voluntarily to the Radiation Protection Section:

- Unintended dose to the skin of 200 rads
- Unintended dose 5 times ordinary protocol and exceeds 50 rads to an organ or 5 rads total effective dose
- Expose wrong patient or wrong site and exceeds 50 rads to an organ or 5 rads total effective dose
- Any equipment or personnel error that causes a dose in excess of 5 rads total effective dose

Malfunctioning medical equipment

Any patient or operator death that may have been caused by malfunctioning medical equipment (including X-ray equipment) must be reported to the FDA and the manufacturer of the equipment. Malfunctioning medical equipment that may have caused a serious injury must be reported to the manufacturer of the equipment.

Any concerns about the quality, authenticity, performance, or safety of any medical device should also be reported to the FDA.

Required or voluntary reports to the FDA can be made through the FDA's Medwatch program at <http://www.fda.gov/Safety/MedWatch/default.htm> or by calling 1-800-FDA-1088.

¹Annual occupational limits for adults

- Total effective dose equivalent = five rems (0.05Sv)
- The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye = 50 rems (0.5 Sv)
- Eye dose = 15 rems (0.15 Sv)
- Shallow-dose = 50 rems (0.50 Sv) to the skin of the whole body or to the skin of any extremity.

²Annual occupational limits for minors

- Total effective dose equivalent = 0.5 rems (0.005Sv)
- The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye = 5 rems (0.05 Sv)
- Eye dose = 1.5 rems (0.015 Sv)
- Shallow-dose = 5 rems (0.05 Sv) to the skin of the whole body or to the skin of any extremity.

³Dose limits for an embryo/fetus of a declared pregnant worker

- Deep dose equivalent = 0.5 rems (5 mSv)

⁴Dose limits for an individual member of the public

- Total effective dose equivalent = 0.1 rem (1 mSv)

*Annual occupational dose is the combined dose received by a worker from all employers in a calendar year. It does not include radiation received from medical exams or background radiation.

This form may be used to report X-ray incidents to the Section. If your facility has an incident that is required to be reported the following information if applicable must be provided in the report.

Facility Name	Registration Number
Exposed Individuals Name	Social Security Number
Date of Birth	Dates of Exposure

Estimate of individual's dose

Level of radiation involved (Type of equipment, kVp, mAs, exposure time etc.)

Cause of elevated exposure or description of incident

Details of lost equipment

Corrective action