

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Environmental Health

Radiation Control Program

Schrafft Center, Suite 1M2A

529 Main Street, Charlestown, MA 02129

Phone: 617-242-3035 Fax: 617-242-3457

www.mass.gov/dph

DEVAL L. PATRICK
GOVERNOR

JOHN W. POLANOWICZ
SECRETARY

CHERYL BARTLETT, RN
COMMISSIONER

RCP INFORMATION NOTICE 2014-01:

**WRITTEN REPORTS OF MEDICAL
EVENTS**

ADDRESSEES

All medical licensees and registrants.

INTENT

The Massachusetts Department of Public Health, Radiation Control Program (RCP) is issuing this information notice (IN) to clarify information to be submitted when reporting a medical event (ME) as required under 105 CMR 120.435 and 105 CMR 120.594, particularly as they relate to describing the event, and why the event occurred. It is expected that recipients will review the information for applicability to their facility and consider appropriate actions to avoid or correct similar problems. Since information contained in this notice does not constitute new requirements, no specific action or written response is required.

BACKGROUND

Medical Event written reports are required to be submitted to the RCP within 15 days following the discovery of a medical event involving radioactive material or a machine (e.g., accelerator). These reporting requirements are found in 105 CMR 120.594(A)(4)(a) and 120.435(E)(4)(a) respectively. In part, these regulations require the following report details:

- 1) the licensee or registrant's name,
- 2) the name of the prescribing physician,
- 3) a brief description of the event,
- 4) why the event occurred,
- 5) the effect, if any, on the individual(s) who received the administration,
- 6) actions, if any, that have been taken, or are planned, to prevent recurrence, and,
- 7) certification that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

SUMMARY OF THE ISSUE

Information supplied to the RCP must be complete, understandable, and accurate in all material aspects. Medical Event written reports, particularly the “brief description of the event”, and “why the event occurred,” are expected to contain specific details of the event, and be free of jargons and acronyms used only at your facility. In short, the language used to describe a ME should be understandable to an expert at another healthcare facility. Missing and unintelligible information delays the RCP’s investigation that may result in an onsite investigation to acquire the requisite information, and potential further enforcement action.

A timeline with accurate dates and times shall be included in the description. Important dates include, at a minimum, the treatment, ME, discovery, RSO notification, and state notification dates. Note, that along with the discovery date, the report must include who discovered the ME (e.g., dosimetrist, physicist, physician, etc.), and how it was discovered (e.g., chart check, equipment QC, external audit, etc).

All parameters used to calculate the prescribed and delivered radiation doses must be submitted and support the quantities and percentage differences used to demonstrate which section(s) of 105 CMR 120.435(E) and 120.594(A) were exceeded. Such parameters should include the prescribed and delivered number of fields per fraction, radiation dose per field, the number of fractions and radiation dose per day and per week, and the total number of fractions and radiation dose to the treatment site; number of fractions delivered correctly and incorrectly; the radiation type and energies (e.g., 6 Mev Photons, Ir-192, etc.); and when applicable, the field size(s) prescribed and used for treatment delivery.

Many MEs involve excess radiation dose to a non-treatment site(s). In these cases, pursuant to 105 CMR 120.594(A)(1)(c) and 120.435(E)(1)(c), the brief description must demonstrate that the total dose(s) delivered to the tissues, organs, or skin other than the treatment site did or did not exceed by 50 cSv (50 rem) and by more than 50% of the total dose expected from the administration defined in the written directive. Again, all parameters used to demonstrate the doses to the unintended tissues must be included in the brief description.

The description of the event must also include information regarding the involved machine (i.e., machine type, manufacturer, model, and serial number), radiation technique (e.g., IMRT, IGRT, Tomotherapy, SRS, IVB, etc.), radiation type and radiation energy (e.g., 6 Mev photons, Co-60 photons) used, and if applicable, the software (manufacturer, model, version and/or release number) involved in the ME.

The root cause and contributing factors detailing “why the event occurred” should clearly identify the ME as a human, process, and/or equipment/software error. Examples of ME causes and contributing factors include, but not limited to:

Process Error

- policies/procedures
- quality assurance
- training
- documentation (e.g., records, staff, hardware/software data flow)
- communication

Human Error

- therapist error
- medical physics/dosimetry error
- physician error

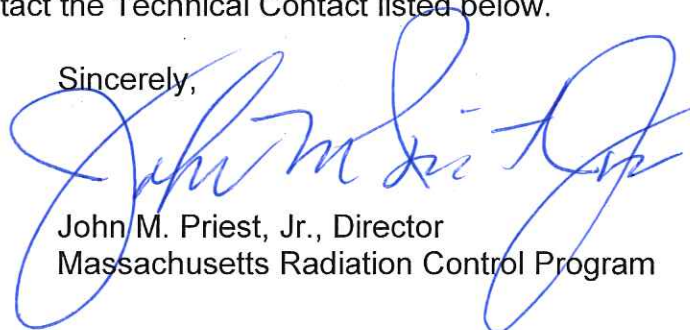
Equipment Error

- equipment malfunction
- software malfunction

When equipment and/or software malfunctions are the part of the root cause, the written report must include that the relevant national agency (e.g., FDA, NRC), manufacturer, and/or distributor have been notified.

This IN requires no specific action or written response. If you have questions about the information in this notice, please contact the Technical Contact listed below.

Sincerely,

A handwritten signature in blue ink, appearing to read "John M. Priest, Jr.", is written over the typed name and title.

John M. Priest, Jr., Director
Massachusetts Radiation Control Program

Technical Contact: Michael P. Whalen Jr.,
(617) 242-3035 x2020
Michael.whelen@state.ma.us