



The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Environmental Health

Radiation Control Program

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January 21, 2015

RCP INFORMATION NOTICE 2015-01:

**TITLE: MEDICAL EVENTS TO
NON-TREATMENT SITE(S)**

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 the identification and reporting of medical events (MEs) to the skin, an organ or tissue other than the treatment site ["non-treatment site"]. It is expected that recipients will review the information for applicability to their facility, or including past required notifications with respect to medical events, 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 events occurring to the skin or an organ or tissue other than the treatment site involving radioactive material or a machine (i.e., accelerator) are defined in 105 CMR 120.594(A)(1)(c) and 120.435(E)(1)(c) respectively. Specifically, these regulations require reporting and notification when a "dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the written directive". For radioactive material, this excludes, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site.

SUMMARY OF THE ISSUE

Recent Agency investigations have disclosed that MEs due to over-dosing of a non-treatment site(s) are not being consistently identified and reported. There appears to be a misunderstanding by medical licensees and registrants of what the treatment site encompasses; difference between an intended versus expected radiation dose to the non-treatment site(s); and, difference between published dose constraints versus the Agency definition of an overexposure (i.e., ME) to a non-treatment site. MEs to non-treatment site(s) are to be assessed and included in written reports to the Agency pursuant to 105 CMR 120.594(A)(4) and 120.435(E)(4).

Pursuant to 105 CMR 120.502, the treatment site is “the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive [WD].” (The same definition holds true for machine based radiation treatments under 120.400.) More specifically, the treatment site includes the volume of tissues falling within the planning target volume (PTV), or clinical target volume (CTV) when appropriate, as identified by the pre-procedure, intra-operative or portal images, treatment plan, etc., within which the authorized user (AU) prescribes the radiation dose to be delivered. The treatment site does not include the skin, tissue, or organs located adjacent to, or in front/behind the treatment site, unless it falls within the PTV or CTV as prescribed in a WD.

All medical facilities have established radiation dose constraints to the non-treatment site - many, for example, can be found in a radiation therapy oncology group (RTOG) protocol or in a quantitative analysis of normal tissue effects in the clinic (QUANTEC) paper. These dose constraints are generally based on the radiotoxicity of nearby non-treatment site critical structures. The *intent* of all radiation treatments prescribed by an AU in a WD is, in part, to spare the healthy critical structures as much as possible and below the medical facility’s established radiation dose constraints.

However, the above *intended* radiation dose(s) to a non-treatment site(s) is different than the Agency’s ME regulatory language “of the dose **expected** from the administration” to a non-treatment site found in 120.435(E)(1)(c) and 120.594(A)(1)(c). The dose **expected** to a non-treatment site is relative to the prescribed dose to the treatment site; it is based on the dosimetric parameters of each unique WD. Specifically, non-treatment site(s) are expected to receive radiation dose for each correctly administered radiation treatment; it is this expected non-treatment site radiation dose that becomes the baseline for determining whether a ME to “other than the treatment site” has occurred. **A non-treatment site receiving a radiation dose that is more than 0.5 Sv above the expected dose and is also more than 50% above expected from an administration is a Medical Event.** Note, the Agency expects licensee and registrant procedures, developed in accordance with 105 CMR 120.522 and 120.435(D), to be robust enough to evaluate the radiation dose to a non-treatment site(s) when performing an assessment of whether an ME may have occurred.

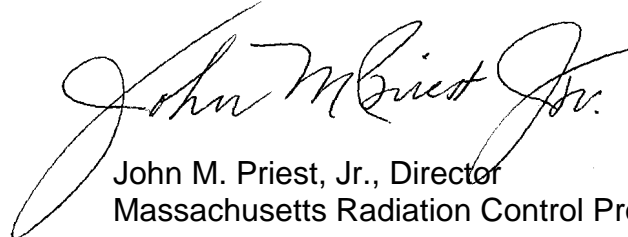
Furthermore, nationally published dose constraints (e.g., RTOG, QUANTEC, etc.) are used by AUs to ensure nearby critical structures radiotoxicity thresholds are not exceeded and to ensure positive clinical outcomes, while the regulatory limit of a ME to a non-treatment site is designed to capture quality assurance problems that have potential, though not the

certainty, to result in harm to the involved patient or human research subject. Hence, dose constraints are generally always higher than the dose expected to any non-treatment site for any WD. It should be noted that Agency ME investigations, in part, assess whether the root cause is systemic (i.e., QA issue) or a one-time-only isolated incident, and the severity of enforcement action, if any, are partly based on whether the patient was adversely affected (e.g., dose constraint exceeded).

Written reports to the Agency, pursuant to 105 CMR 120.594(A)(1)(c) and 120.435(E)(1)(c) must explicitly demonstrate that the dose(s) to a non-treatment site(s) did or did not exceed by 0.5 Sv (50 rem) to an organ or tissue and 50% of the dose expected from the administration defined in the WD. Describing this type of ME as causing 'no adverse effects are expected' or 'the dose was within acceptable clinical limits', fulfills the requirement to describe "the effect, if any, on the individual(s) who received the administration", but this does not fulfill the requirement to describe the radiation dose(s) to the non-treatment site(s). When a ME to a non-treatment site has occurred, at a minimum, the intended and delivered radiation dose to each non-treatment tissue, organ, and/or skin per fraction, per week, and in total, the field size(s) intended and delivered, and the radiation type (e.g., electrons, photons) must be included in the ME written report description. Lastly, for MEs due to other issues (e.g., overdose to the treatment site) the written report must include an assessment that the radiation dose to the non-treatment site did or did not occur.

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 black ink that reads "John M. Priest, Jr." with a stylized, cursive script.

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

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