



Maryland

Department of
the Environment

Larry Hogan
Governor

Boyd Rutherford
Lieutenant Governor

Ben Crumbles
Secretary

DATE: October 19, 2016

TO: All State Licensed Private Inspectors and Medical Radiation Machine Facilities

FROM: Roland G. Fletcher, Program Manager IV, Radiological Health Program (RHP)

SUBJECT: Changes in Diagnostic "Misadministration" Requirements

RGF 10/19/16

Effective November 1, 2016, the requirements outlined in the memorandum dated April 2015 entitled "Misadministration Reporting Requirements" are superseded for diagnostic reporting requirements only. The reporting requirements for therapeutic alleged misadministration's remain unaffected and is denoted in the Code of Maryland Regulations (COMAR) 26.12.01.01 entitled "Regulations for the Control on Ionizing Radiation (1994)." To avoid further confusion with therapeutic misadministrations, the Maryland Department of the Environment (the Department) will rename "diagnostic misadministration" and refer to such incidents as "diagnostic medical radiation event" which will be referenced in Section F of the COMAR 26.12.01.01 via a future regulation change.

Diagnostic medical radiation events will be defined as the following:

1. irradiation of the wrong individual, or
2. irradiation of the wrong part of the individual's body, or
3. use of the wrong mode of diagnostic x-ray examination, or
4. a diagnostic radiation exposure of a type other than the one intended.

All alleged diagnostic medical radiation events must be reported to the RHP no later than the next business day after discovery of the event. The registrant must submit within 15 days after discovery of the event the Diagnostic Medical Event Occurrence Log, the RX38, which is enclosed. The registrant must maintain an occurrence log book of events at their physical location and make it accessible to state licensed private inspectors during their certification inspection. The diagnostic medical radiation event occurrence log will allow all radiation facilities to be uniform and consistent with reporting and documenting diagnostic medical event(s). The RX38 is available via the following link and in fillable PDF format:

http://www.mde.state.md.us/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx under Guidance Documents.

The completed form can be submitted to mdexray.submission@maryland.gov. For the next two years, the Department will conduct a study to evaluate facility reporting trends and effectiveness of procedural changes made by facilities to prevent diagnostic medical radiation events. The Department will cease issuance of penalties for "diagnostic medical radiation event(s)" reported from November 1, 2016 through October 31, 2018, except in circumstances where the event warrants immediate action, such as gross negligence. The Department continues to foster practices that control the use of radiation and protect the environment as well as the safety and health of the public.

If you have any questions about diagnostic medical radiation event reporting regulations, please contact Ms. Eva Nair, Ms. Talya Langbaum, or Ms. Shannon Page at 410-537-3193.

Enclosure: Diagnostic Medical Event Occurrence Log RX38