COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF WASTE, AIR, RADIATION, AND REMEDIATION
BUREAU OF RADIATION PROTECTION
HARRISBURG, PA 17101

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DEP INFORMATION NOTICE 2015-02: Quality Assurance Associated with Fluoroscopically Guided Interventions

ADDRESSEES

All Pennsylvania Department of Environmental Protection (DEP) registered medical facilities performing fluoroscopically-guided interventional (FGI) procedures.

PURPOSE

The DEP is issuing this Information Notice (IN) to notify registrants of a recently released National Council on Radiation Protection and Measurements (NCRP) Statement to clarify recommendations given in the NCRP Report No.168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures.*

DISCUSSION

NCRP Statement No. 11 (attached) emphasizes that the safe performance of FGI procedures requires controlling radiation dose in order to prevent unexpected or avoidable tissue reactions and to minimize the severity of medically unavoidable injuries. It also provides guidance for controlling dose and for patient post procedure follow-up.

DESCRIPTION OF CIRCUMSTANCES

The NCRP Report No. 168 defines substantial radiation dose level (SRDL) as “an appropriately–selected reference value used to trigger additional dose-management actions.” Suggested values for a number of different dose metrics are provided in Table 1 of the NCRP Statement No. 11. The SRDL is not an indicator for tissue reactions or a predictor of the risk of stochastic effects. SRDLs are intended to alert operators and staff to the possibility of harm. The facility may adopt other values if appropriate, as stated in NCRP Report No. 168. Each interventional service that performs FGI procedures should have policies and procedures in place to ensure appropriate actions are taken when an SRDL threshold is exceeded.

A Quality Assurance – Peer Review (QA-PR) program is necessary to track and review radiation dose for all FGI procedures and not just those where the radiation dose exceeds an arbitrary threshold. The QA-PR committee should include a qualified medical physicist when radiation management issues are discussed. All available metrics that describe the total dose from a case shall be recorded in the procedure report and the patient’s medical record. The radiation dose data should be collected and tracked for all FGI procedures. It is recommended that a summary of the patient radiation dose metrics for all FGI procedures (e.g., percutaneous

intervention, embolization, stent placement, etc.) be analyzed at least annually. Patient follow-up shall be based on exceeding the SRDL.

The QA-PR process shall assess performance of FGI procedures, including justification, radiation dose optimization, the time course over which radiation doses were administered, and outcomes. Appropriate improvements should be implemented based on the assessment.

DEP recommends you review NCRP Report No. 168 and NCRP Statement No. 11 for a comprehensive understanding of the quality assurance associated with fluoroscopically guided interventions. NCRP reports can be found at http://www.ncrppublications.org.

Please be advised that the U.S. Environmental Protection Agency (EPA) has recently issued Federal Guidance Report No. 14 *Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures.* http://www.epa.gov/radiation/federal/fgr-14.html

CONTACTS

This Information Notice requires no specific registrant action or response. If you have any questions about the information in this notice, please contact the Radiation Control Division at 717-787-3720.

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