

Department of State Health Services
Council Work Session Agenda Memo for State Health Services Council
February 22, 2012

Agenda Item Title: Repeal and new rule concerning radiation control regulations for use of radiation machines in the healing arts

Agenda Number: 2.a

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The Radiation Control Program in the Division for Regulatory Services protects and promotes the physical and environmental health of Texas citizens. The program includes licensing, registration, inspection, enforcement, and emergency response functions for the use of radioactive material and radiation machines. The program regulates approximately 1,600 licensees and 16,000 registrants.

The program routinely monitors complaints received and resolved, number of new and renewed registrations, numbers of disciplinary actions taken, and violation trends. There are 6803 registrants that are held to certain parts of this rule depending on the type of radiation machine used. The new radiation protocol committee (RPC) requirements will affect 859 registrants using computed tomography. There are 1132 registrants that use fluoroscopy, however, only those registrants who use fluoroscopy for interventional procedures will need to implement the RPC requirements. Over the last fiscal year there were 29 x-ray related incidents or complaints and 91 x-ray related enforcement actions taken.

The program charges fees for issuing licenses and registrations in amounts that cover the costs of the program.

Summary: The purpose of the repeal and new rule is to protect the public, workers, and the environment from unnecessary exposure to radiation by ensuring that the rule is clear and specific. The rule change will:

- correct rule citation references and update terminology to be consistent with current technology;
- add definitions for fluoroscopically-guided interventional (FGI) procedures and reference levels;
- revise the kilovolt peak half-value layer table;
- change the requirements for calibration of the dosimetry system used to measure radiation output;
- require the development of a radiation protocol committee (RPC) for facilities that perform FGI and computed tomography (CT) procedures;
- require the development of a radiation safety awareness training program for the use of fluoroscopy radiation machines;
- require an equipment performance evaluation at installation and re-installation of radiation machines;
- revise equipment performance evaluation intervals; and
- revise record keeping intervals and record retention requirements.

Registrants that perform FGI procedures will incur the cost of the proposed radiation safety awareness training requirements. These costs will range from approximately \$200 to \$3,000 depending on the scope and length of the training program. Facilities using CT systems will incur costs ranging from approximately \$350 to \$640 per system to have licensed medical physicists perform radiation output measurements after initial installation or re-installation. This cost and requirement does not apply to currently installed CT systems unless they are moved and re-installed.

In addition, entities registered for possession of radiation machines will be required to pay the cost of an equipment performance evaluation at the time of installation or re-installation ranging from approximately \$95 to \$280 per machine depending on the type of x-ray machine tested. This cost and requirement does not apply to currently installed radiation machines unless they are moved and re-installed.

During the past 20 years, medical exposure to ionizing radiation has increased significantly. As a result of radiation over exposures in other states with the use of fluoroscopy and CT radiation machines, DSHS is taking a proactive approach to raise awareness among stakeholders concerning radiation safety during FGI and CT procedures. The added requirements for facilities to establish a RCP and radiation awareness training for users will assure appropriate protocols are followed and quality control is achieved thereby reducing radiation dose to the patients and workers.

Key Health Measures: The program collects and analyzes data related to the number of licensed and registered facilities meeting state and federal requirements, the number of complaint investigations conducted, and the number of violations or facilities referred for enforcement action. Program staff has evaluated the effectiveness of the current rule by collecting and reviewing these performance measures and the findings were used to identify areas where rule revisions and clarifications were needed.

DSHS will continue to monitor the number of x-ray related incidents, complaints, and enforcement actions. The effectiveness of the program and revised rule will be indicated by an increase in the number of facilities meeting state requirements; number of complaint investigations resolved; and number of violation or facilities that are not referred for enforcement action.

Summary of Input from Stakeholder Groups: The draft rule has undergone six revisions since October 2009 with stakeholder input throughout the process. The draft rule was posted on the Radiation Control website. Stakeholders and appropriate DSHS staff were notified of the draft rule and given the opportunity to comment using email, list servers, and the United States Postal Service.

In addition, DSHS conducted two stakeholder meetings in Austin. Approximately 100 stakeholders, including medical doctors, administrators, licensed medical physicists, and employees of medical organizations, attended the first public meeting. Two stakeholders requested that the requirements for a RPC and physician radiation safety awareness training be deleted; however, DSHS retained these requirements to ensure patient and operator safety during FGI and CT procedures. One stakeholder suggested that DSHS require radiation safety awareness training for all users of fluoroscopy radiation machines; however, DSHS determined that only those physicians performing FGI procedures, with the exception of radiologists and radiation oncologists, are required to complete the radiation safety awareness training. At the second meeting, one commenter inquired if several facilities could form a cooperative to meet the RPC requirement. DSHS included clarifying language to address this comment.

The Texas Radiation Advisory Board (TRAB) Medical Committee reviewed rule drafts at their April 2011, August 2011, and November 2011 meetings. TRAB suggested that a definition for "radiologist" be added and that non-radiologists performing FGI procedures should have continued education documented. TRAB also recommended that physicians performing FGI procedures have two years after the effective date of the rule to complete the radiation safety awareness training. DSHS made these suggested changes. TRAB recommended that the proposed rule be forwarded to the State Health Services Council for consideration.

Approved by Assistant Commissioner/Director:	Kathryn C. Perkins, R.N., M.B.A.	Date:	2/6/2012
Presenter:	Barbara J. Taylor Manager: Radiation Group	Program:	Policy/Standards Quality Assurance Unit
Approved by CCEA:	Carolyn Bivens	Date:	2/9/2012