



American Association of Physicists in Medicine

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November 19, 2014

The Honorable Mike Simpson
Chairman, Subcommittee on Energy
and Water Development Appropriations
United States House of Representatives
Washington, DC 20515

Dear Chairman Simpson:

The American Association of Physicists in Medicine (AAPM) would like to express its serious concerns regarding legislative language included in the Senate Energy and Water Development Subcommittee draft appropriations legislation for Fiscal Year (FY) 2015. Specifically, AAPM does not support Section 402 of the Subcommittee approved draft FY 2015 Energy and Water appropriations bill, which establishes new “mandatory security standards for all equipment located within the United States using High Risk Radiological Material (HRRM).”

AAPM is a scientific and professional organization composed of more than 8,000 scientists whose clinical practice is dedicated to ensuring the accuracy, safety and quality of medical procedures involving the use of radiation or radioactive materials, such as medical imaging and radiation therapy. We are generally known as medical physicists and are uniquely positioned across medical specialties due to our responsibility to connect the physician to the patient through the use of radiation producing technology. The role of the medical physicist in our healthcare delivery system is to assure that the radiation prescribed in imaging and radiation therapy is delivered accurately and safely.

If adopted, we believe Section 402 would impose many undue and unnecessary burdens on medical facilities that use radiation in their treatment of their patients. Equally important, we see minimal, if any, added security benefits were these new standards to be adopted.

Mr. Chairman, the legislative language in section 402 would have a profoundly negative effect on patient access to medical care on a broad level, with little or no improvement in national security or community safety. Section 402 would impose burdensome security standards on medical devices that use radioactive materials and would significantly increase the cost and resources needed to maintain and use the equipment.

Numerous radiation oncology facilities employ HDR systems (high-dose-rate remote afterloaders) in the treatment of disease, particularly for gynecological, prostate, and breast cancers. The additional security, beyond that currently in force through U.S. Nuclear Regulatory Commission (NRC) regulations (10 CFR Part 37), would impose additional costs on these treatment facilities; costs which would result in significant increases in the cost of medical care for these patients. Many of these cancer care facilities are freestanding and it is likely that a significant number of these institutions would be forced to halt HDR treatments, denying care to many patients.

Hospitals and health systems are already experiencing financial hardship due to changes in the way healthcare is delivered and paid for in this country. Adoption of Section 402 will make it more difficult for facilities to maintain their existing equipment and could potentially require them to purchase newer machines despite the fact that their current equipment has not outlived its usefulness. "Most of the nominally equivalent replacement equipment fails to provide the quality treatments of the current equipment, and in some cases can pose a safety

hazard for patients." In the end, we fear that patients will have less access to the latest treatment options or they will pay dramatically more to obtain the benefits of those treatment options.

Even if one presumes that third party payers (government and commercial) will adjust their reimbursement rates to reflect these higher costs, historically it can take two years or longer for these payment adjustments to make their way through the system. In the meantime, facilities will have incurred the costs to perform the upgrade and have to wait two or more years to obtain reimbursement rates that reflect those added costs. This alone could create a significant cash-flow problem for many institutions.

Often times, Mr. Chairman, these devices and equipment are the only option for treatment of certain cancers or tumors. Imposing barriers to facilities for housing this type of diagnostic and treatment equipment will significantly reduce the physical number of these pieces of equipment which gives patients fewer options at a higher cost.

The Subcommittee-approved language requires the mandatory adoption of the Department of Energy's National Nuclear Security Administration (NNSA) Global Threat Reduction Initiative (GTRI) security standards for all devices using HRRM. THE NNSA/GTRI defines HRRM as the 14 radionuclides identified by the Interagency Task Force on Radiation Source Protection and Security in its 2010 Radiation Source Protection and Security Task Force Report.

Many of these sources are used in clinical procedures such as blood irradiators and gamma stereotactic surgery. The rationale for mandating these higher security standards appears to be to protect this equipment from theft or sabotage, which could potentially result in the use of the radioactive material in the commission of an act of violence or terror.

As you may know, two Government Accountability Office (GAO) reports, one from 2008 and another from 2012, recommended that the U.S. Nuclear Regulatory Commission (NRC) take steps towards securing these radiologic devices. However, after considering the GAO's findings and recommendations and after conferring with industry experts, the NRC opted to not adopt the GAO's recommendations. The NRC in a letter dated September 10, 2014 to the House Appropriations Committee most recently communicated this view. A similar letter of opposition was sent to the Senate Energy and Water Subcommittee Chair from the Organization of Agreement States (OAS). The 37 OAS member states regulate the safety and security of radioactive materials in their states.

AAPM strongly urges the committee to reject Section 402 from the Senate's draft version of the bill, as it is overly burdensome and unnecessary to the goal it is trying to accomplish.

We appreciate the opportunity to submit our comments and are available to discuss them should you have any questions or require any additional information. Please contact Lynne Fairbent, AAPM's Senior Manager of Government Relations at 301-209-3364 or via email: lynne@aapm.org.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Boone', with a horizontal line underneath.

John M. Boone, Ph.D., FAAPM