NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

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"A Regulator's Perspective on Safety"
Prepared Remarks for
The Honorable Gregory B. Jaczko
Chairman
U.S. Nuclear Regulatory Commission
at
American Society for Radiation Oncology (ASTRO)
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Thank you for the introduction. I'm honored to speak before this esteemed organization. Throughout my time with the Nuclear Regulatory Commission (NRC), I have always been impressed by the expertise that you bring to bear on the medical issues that fall under the NRC's regulatory jurisdiction.

I am sure many of you are familiar with the NRC, and have interacted with the agency in the course of your professional practices. For those of you not familiar with who we are and what we do, I'll provide just a bit of background. The NRC is an independent federal regulatory Commission, responsible for regulating the safety and security of the nation's nuclear power plants and nuclear materials. Although we are most well-known for our role in regulating nuclear power, we have an important role in regulating the medical uses of nuclear materials. And in this area, our work has a direct impact on people's lives. Specifically, our authority covers uses of byproduct materials and, therefore, exposures for medical treatment by these materials. I also should note that 37 states—through our Agreement State Program—have taken on certain responsibilities in this area, subject to the NRC's general oversight.

As a Commissioner and now as Chairman of the NRC, I have made a point of developing a strong understanding of both the benefits and risks of the medical use of the radiological materials that the agency regulates. I have visited hospitals throughout the country and met with medical experts on many occasions to better understand cutting-edge developments in this ever-evolving field. Remarkably to me, about one-third of all patients admitted to hospitals today are diagnosed or treated using radiation or radioactive materials. Thirty years ago, these sources accounted for approximately 15 percent of the public's total radiation exposure. Today, that figure has more than tripled, so that nearly 50 percent of public's overall radiation exposure can be attributed to medical sources. That reflects in part significant advancements by the research and medical communities in developing more and more effective ways to use this technology to improve patient care.

We also, however, have seen examples of what can go wrong when nuclear materials are improperly used. For example, in the 1990s a brachytherapy patient died from complications associated with the mishandling of the radiation sources. More recently, in 2008, the NRC discovered a difficult situation at the Veterans Affairs (VA) hospital in Philadelphia, where 97 medical events occurred out of 116 permanent implant brachytherapy procedures to treat prostate cancer. Although many of these procedures resulted in underdoses, a number resulted in overdoses to unintended organs. The sheer number of these instances reflected a fundamental breakdown in the Philadelphia VA therapy program. This was a systemic problem, in which the administrators, doctors, medical physicists, and radiation safety staff all contributed to the situation. These issues resulted in one of the largest fines ever levied by the NRC against a medical facility. I don't believe that these types of problems are widespread, but they do continue to occur. It's with these types of issues in mind that the NRC fulfills its statutory requirement to regulate radiological materials.

Because of the broad range of our regulatory activities, the NRC has always strived to be a nimble, flexible regulator—one that responds to the unique issues and challenges raised by different uses of nuclear technology. For example, in regulating nuclear power, our safety objective is to prevent the public's exposure to radiation. In the medical area, we have a very different aim—to ensure that the intentional exposure of large numbers of the public is done safely and securely from a radiological perspective. Likewise, the regulation of a relatively small number of large nuclear facilities may call for certain approaches, while different approaches may be needed for ensuring that effective programs are in place for overseeing thousands of medical licensees throughout the country.

In light of these considerations, we have developed a regulatory framework for medical uses that sets general requirements for radiation safety and is overseen through licensing, reporting requirements, and periodic inspections—all the usual tools of a regulator. The type of continuous, onsite oversight that we apply in the reactor sphere with full-time, onsite resident inspectors is neither feasible nor desirable in the medical context. Our approach enables us to meet our safety and security responsibilities while at the same time allowing you the space to practice medicine and fulfill your important responsibilities to your patients.

In regulating radiation safety, the NRC's primary focus is on ensuring that the physician's directions are followed safely. We have expertise in health physics and are the authority on radiation protection, but you are the medical practice experts and the authority when it comes to treating patients. Our regulatory efforts are, therefore, predicated on the assumption that properly trained and adequately informed physicians make decisions that are in the best interests of their patients.

You can see this principle reflected in one of our most important regulatory tools for ensuring patient safety—medical event reporting. Under this rule, the NRC requires that a medical practitioner notify the agency when a patient receives an unintended dose, explain how it happened, and describe what steps will be taken to keep it from happening again. An unintended dose could result from an error in calculating or delivering the radiation dose, or administering the wrong material or the incorrect amount of the right material. Our role is certainly not to question medical judgments regarding the best course of treatment for the patient. Our responsibility is to ensure that the radiological treatment intended for the patient is the treatment that the patient receives. The reporting of unintended doses furthers important radiation safety goals. It will help prevent those

issues from recurring at the facility. It may help bring potentially broader issues to the attention of other medical facilities. And it may help patients and their physicians take the needed next steps.

The question of how to define a "medical event" is one in which American Society for Radiation Oncology (ASTRO) has taken a very strong interest, specifically with regard to brachytherapy treatments. In general, we use a dose-based criteria, in which a medical event is considered to have occurred when the total dose delivered differs from the prescribed dose by 20 percent or more. A medical event is not a violation; it is a reporting requirement. Right now, the NRC is considering potential changes to the criteria for defining a medical event. This effort has benefited from ASTRO's expertise and perspectives on this issue. In fact, ASTRO participated in a Commission meeting last year and our rulemaking workshops earlier this summer. And I have met personally with representatives from ASTRO today on other occasions. This type of sustained dialogue helps the NRC reach the best radiological safety decisions.

The NRC is open to potential changes to the criteria if they help us to more effectively meet our radiation safety goals. For medical event reporting, that means having criteria in place, which effectively identify medical events that indicate safety and quality assurance problems and have the potential to result in radiological harm to the patient. The NRC does not believe that it is adequate, as some have suggested, that the definition of medical events be limited only to instances that result in actual harm to the patient. But harm is what we want to prevent, and we can do so by trying to identify poor practices that could lead to impacts. By detecting and correcting deviations from physician's orders early, we can directly enhance safety and potentially avoid more egregious events that actually cause radiological harm to patients, physicians, other medical staff, family members, or members of the public. But if there are better criteria that will help us more effectively meet our safety goals, that is something we would certainly consider. Whatever decision we ultimately reach on the "medical event" definition, I believe we can best move forward if ASTRO and the medical community stay actively engaged in this process, and we continue our discussions.

One area where I have seen positive steps because of that type of engagement is on the training and experience requirements for medical personnel who handle nuclear materials. Our concern here is not, and has never been, the medical competence of the medical professionals who diagnose and treat patients. Our focus instead is on ensuring that these practitioners have the necessary training and experience on radiation safety and the handling of radioactive materials.

Under our current approach, the NRC requires individuals to have an already licensed authorized user attest that the new individual has received the necessary training and experience. We've heard concerns from members of the medical community about the specific terminology used in the written statement that the already licensed user must provide. Specifically, they take issue with the use of the word "competency" because it may create a concern about personal liability that may make licensed users reluctant to attest for prospective applicants.

The Commission has asked the agency staff to develop a proposed rule that would eliminate the use of the word "competency," but that would still allow us to reach the same outcome. This specific proposal has been incorporated into a broader effort to revise our Medical Uses Program. I think this is an example where the agency and its stakeholders have worked well together.

Before closing my remarks, I'd like to touch on one final important issue—security. Looking back over the past decade, it's clear that September 11th was a paradigm-shifting event for the NRC as a nuclear security regulator. It led to dramatic changes—both in the short- and long-term—in how we approach nuclear security. Historically, the NRC's security efforts had focused on the potential sabotage of large nuclear facilities, as well as nonproliferation issues related to the potential diversion of dual use technologies and theft of nuclear materials. Those issues most directly concern nuclear power plants and fuel cycle facilities. But in the years since September 11th, we've had to increasingly focus on the security of nuclear sources, which then involves medical users and other licensees.

In thinking about your responsibilities as users of these materials, it's important that you recognize that you have an important security role. I understand that this has been a big change for the medical community, just as it has been for other users of nuclear materials. To a much greater extent than we did before September 11th, we have to consider the possibility that someone would seek to use those materials for malevolent purposes, and that they may be willing to lose their lives in obtaining and using the material.

As we move forward with our security efforts, the NRC will continue to engage the medical community to understand your perspectives, and ultimately to develop the most effective approaches to security for nuclear sources.

In closing, I'd like to thank ASTRO for the opportunity to speak with you. As I've said, this type of open dialogue plays an important role in helping the NRC make the best decisions for nuclear safety and security. Within the agency, we have taken steps to ensure the voices of medical experts and patients are always heard when we consider significant changes to our medical regulations. We have an external advisory committee of medical experts and patient advocates—known as the Advisory Committee on the Medical Uses of Isotopes—that provides valuable insights. I would encourage all of you who have an interest in these issues to stay engaged with the NRC. We will continue to benefit in the future by the diverse expertise and perspectives of the medical community. Thank you.