NRC NEWS

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"Nature and Technology Collide"

Prepared Remarks
by the Honorable Gregory B. Jaczko
Commissioner
U.S. Nuclear Regulatory Commission

at the
48th Annual Meeting of the American Association of Physicists in Medicine
Orlando, Florida

July 31, 2006

Let me first say that I am pleased to be here today to participate in your 48th Annual Meeting. I started out as a physicist in the University of Wisconsin-Madison program where I completed my doctorate. While I was there, I thought about being a medical physicist. Instead, however, I became a particle physicist – so I worked with tiny particles to pursue the general advancement of scientific knowledge. Your work deals with some of the same particles, but for the specific purpose of the preservation of life. It is important work. So, while I missed my opportunity to directly join your profession, I am excited to be able to address you in my role as an NRC Commissioner.

The U.S. Nuclear Regulatory Commission's (NRC) mission is to ensure adequate protection of public health and safety. When it comes to regulating the work you do, that means making extra sure that we have a positive effect and do not create any impediments to the crucial medical treatments you provide. To ensure we do that, I have made it a priority to learn more about our interactions.

First time I visited a licensee's nuclear medicine program was in May 2005 at the University of Pennsylvania. While at the Children's Hospital I met Dr. John Maris who oversees nueroblastoma treatments in children, which is an iodine-131 base therapy, which I am sure most of you know already. Meeting Dr. Maris to discuss his work, in which parents serving as primary caregivers are exposed to radiation during the treatment, helped inform my understanding when I later approved a measure before the Commission allowing licensees to justify doses to caregivers on a case-by-case basis.

Approving this measure was important because evidence shows that patient response and recovery to the treatments are often much better when caregivers (or parents) are actively involved in caring for and comforting them. The opportunity to discuss this important issue demonstrated how NRC action in this area would positively impact the lives of the members of the public in the beneficial and safe use of NRC-licensed materials.

Second, I visited Johns Hopkins Outpatient Center and Johns Hopkins Hospital. Coincidentally, the folks at American Association of Physicists in Medicine (AAPM) helped to coordinate my visit to Johns Hopkins. The primary purpose of that visit was for me to get a first hand look at the facilities and operations related to the use of accelerator-produced material. This was important because the Commission, under the new authority given to it under the Energy Policy Act of 2005, was soon to begin its deliberations on a proposed rule to expand the definition of byproduct material to include certain aspects of accelerator-produced radioactive material. I will talk more about that in a moment.

Third, while reviewing the staff's proposal to expand the definition of byproduct material to include radioactive materials produced from these accelerators, I recognized that the regulations as proposed may create confusion with previous regulatory actions regarding grand-fathering or the recognition of diplomates of certifying boards in medical physics.

Before I voted on this issue, I had an opportunity to meet with representatives of the AAPM and the American Board of Radiology (ABR) during my time at the Conference of Radiation Control Program Directors annual meeting in May, where we discussed this issue in broad detail. We discussed the fact that the Authorized Medical Physicist (AMP) was a recent construct in the regulatory structure, and how in the past licensing authorities did not necessarily require that medical physicists be named on a license. Further, we talked about how there were also few, if any, requirements for qualified medical physicists to be named in connection with manual brachytherapy. Thus, these and other issues have caused some difficulty with grandfathering certain medical physicists. The solution - AAPM wanted the Commission to consider, through the Energy Policy Act proposed rulemaking, reinstating 10 CFR 35, Subpart J for an additional year - would help to ensure diplomates of the boards are able to continue practicing medical physics and serving as Radiation Safety Officers.

So where are we now? I have been working with my colleagues on the Commission to ensure this issue is expeditiously addressed. We are moving forward with a solution separate from the new rulemaking so that this issue can be resolved more quickly. As I speak to you today, the NRC staff is engaged in determining the extent of the challenge related to grandfathering, and as part of that effort conducting an outreach program with the Agreement States and appropriate Medical Boards. The NRC staff's interactions with the Agreement States and various boards are to be completed in the next month or so, and the Commission should be receiving recommendations by the end of September.

I will remain focused on finding a solution to this issue and it is a good example of the importance of communication.

There certainly is a lot going on in this area. The NRC staff issued a press release in July indicating that the proposed rule for the expansion of the definition of byproduct material will be out in the *Federal Register* shortly with a 45-day comment period. As part of this effort the NRC staff is

planning to hold a public meeting at the agency's William Olmstead High-Level Waste Hearing Facility, in Las Vegas, Nevada on August 22, 2006.

I believe it is important for AAPM and its membership to weigh in on this important rulemaking to appropriately inform the final rule that will come to the Commission. It is critical that any issues potentially impacting patient care are addressed before the rule becomes final.

I will refer to a specific technology as an example the level of cooperation we must strive for. Positron Emission Technology (PET) has become a vitally important technology in the diagnosis and treatment of patients with various types of cancers and heart disease. The importance of what you do utilizing PET/CT scans coupled with the radio pharmaceutical fluorodeoxyglucose (FDG) F18 is impressive as evidenced by the phenomenal advancements I witness during my visit to Johns Hopkins.

The ability to superimpose the PET and CT scans to get an image that is perfectly co-registered and localizes and defines tumors with amazing precision was not possible before the combination of these two elements. You - the medical physicists - help doctors use the information gathered from these diagnostic procedures to precisely target radiation therapy, accurately guide biopsies, make informed decisions on the advisability of surgery and monitor tumors to be sure treatments are eradicating the cancer cells. This clearly demonstrates your expertise in treating members of the public.

It is my job as a Commissioner to ensure the safety of the public in the use of this new technology. Thus, as the NRC embarks on regulating in this new area we need to do so in partnership with you. 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 using the nuclear materials the NRC regulates. Ultimately, we share the same goal of ensuring the continuation of high quality patient care.

This is why it is critical that you get involved in NRC's policy development process at the rulemaking stage and that we communicate effectively with each other.

Everyone wants what is best for the patient. I believe that if all interested stakeholders get involved around the intersection of public safety and good patient care we will achieve the best outcome for the public patients.

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