

No: S-14-009  
CONTACT: 301-415-8200

July 14, 2014

**“Regulatory Perspectives on Radiation Protection”  
Prepared Remarks of Chairman Allison Macfarlane  
Health Physics Society Annual Meeting  
July 14, 2014 – Baltimore, Maryland**

Good morning and thank you for the kind introduction. The Nuclear Regulatory Commission enjoys a fruitful working relationship with the Health Physics Society (HPS), including regular periodic meetings. We value these interactions very much, so I’m glad to be able to talk with you today about a variety of regulatory issues of mutual interest.

I particularly appreciate having an opportunity to address radiation protection issues across the regulatory landscape. For obvious reasons, the Fukushima accident has drawn substantial attention to reactor safety issues over the past few years. But, as you know, the NRC’s portfolio extends well beyond reactors and there are many other activities and areas of interest that merit discussion. HPS has a similarly broad focus – with a diverse membership spanning all 50 states and a variety of disciplines. Health physicists are represented in just about every industry regulated by the NRC. As a result, the Society is well-placed to offer important insights on the NRC’s work.

As you know, the NRC’s mission is to license and regulate civilian uses of radioactive materials in the United States to protect public health and safety, promote the common defense and security, and protect the environment. The NRC oversees commercial nuclear power plants; research, test, and training reactors; nuclear fuel cycle facilities; and other medical, academic, and industrial uses of radioactive materials.

The agency also regulates the transport, storage, and disposal of radioactive materials and wastes, decommissioning of commercial, research, and test reactors and complex materials facilities, and the export and import of radioactive materials. The NRC shares regulatory oversight of radioactive materials with 37 Agreement States, and works with other federal agencies, Tribal government organizations, and nuclear regulators around the world to maintain nuclear safety and security.

The NRC benefits greatly from public comments, including those from HPS, on our regulatory work. We currently have a number of radiation protection-related rulemakings in process. Of particular significance, the NRC is considering whether to change our standards and regulations for radiation protection and radioactive effluents. At the Commission’s direction, the NRC staff is

carefully examining our domestic radiation protection regulations under 10 CFR Part 20 and 10 CFR Part 50, Appendix I. They're using data collected from research studies, information collected as a result of public meetings, comments submitted in response to *Federal Register Notice* requests, and international experience to identify appropriate changes.

Recognizing the broad range of licensees and the correspondingly complex regulatory structure that we have in the U.S., the NRC believes it's essential that we take a careful, thoughtful approach when revising these requirements. I'd like to note that NRC staff experts will host a special session this afternoon to provide you with the latest information on the upcoming Advance Notices of Proposed Rulemaking for Part 20 and Part 50, Appendix I.

The staff is also preparing to publish a proposed rule in the Federal Register related to Part 61, which covers the licensing requirements for disposal of low-level radioactive waste.

As most of you know, the DC Circuit Court of Appeals vacated and remanded the Commission's Waste Confidence rule in 2012. In response, the Commission directed the staff to develop a generic environmental impact statement and an updated rule. Last fall, the staff published drafts of these products for public comment. We received more than 33,000 written comments and transcribed more than 1,600 pages of comments from public meetings. The NRC appreciated the comments we received from HPS as part of this process. The Waste Confidence rulemaking is still on track to be completed in the fall of 2014.

Finally, the Commission is in the process of developing a proposed rule related to the medical use of byproduct material, specifically addressing the issues of medical event definitions, training and experience, and clarifying amendments. Within the next several weeks, the proposed rule will be published in the *Federal Register* for a 120-day public comment period. I encourage you to share your insights with us through the regulatory process.

Coming from the academic community, I'm a strong proponent of continuous learning. The NRC has a variety of ongoing research activities that help us identify, explore, and resolve safety issues. Our research also informs our licensing decisions, new regulations, and guidance. To that end, I wanted to update you on several research activities that may be of interest.

First, the NRC is working with the National Academies of Science to conduct a study analyzing the cancer risk of populations living near NRC-licensed facilities. NRC regulations ensure that nuclear power plant operators monitor and control any radioactive releases to meet strict radiation dose limits, and require plants to publicly report these releases to the agency. This study will be used as an update to the 1990 National Cancer Institute (NCI) report, "Cancer in Populations Living near Nuclear Facilities," which concluded that cancer mortality rates generally are not elevated for people living near nuclear reactor facilities.

The NRC is also conducting research to inform the regulatory bases for potential changes to Part 20. These studies support our examination of the potential impacts of changing NRC's occupational dose limits and the use of dose constraints. Our staff is also collaborating with the Environmental Protection Agency to develop new biokinetic and dosimetric models and dose coefficients for occupational and public exposure. Similarly, the NRC is supporting research relevant to potential changes to Part 50, Appendix I.

In addition, the NRC is developing a framework to coordinate and share experiences and resources through our radiation protection computer code analysis and maintenance program, or RAMP. As many of you know, RAMP is a computer code management program that will support the development and maintenance of radiation protection, dose assessment, and emergency preparedness codes. Specifically, we're working to ensure that state-of-the-art models and data are incorporated into the codes.

Earlier this year, the Commission further directed staff to re-assess the basis for dose calculations related to the release from medical facilities of patients who have received radiation treatment and to collect limited empirical potential release data to fill in regulatory gaps. This research will be conducted over the next several years. I will discuss this issue in more detail later in my presentation.

Before I move on, let me emphasize that the NRC carefully considers each potential new or revised requirement based on a variety of factors. As part of our processes, we conduct rigorous analyses to determine which actions may be necessary for safety or security. This chart shows which regulatory requirements materials licensees and Agreement States must implement within a specified period of time. We seek to ensure that our licensees can implement regulatory requirements effectively. Our efforts in this regard depend on receiving accurate feedback from those we regulate, particularly about estimated implementation costs.

While many of the rulemakings I've just discussed focuses on safety, the NRC's mission is dually focused on safety and security. We recognize that, in a post-9/11 world, our licensees must address day-to-day safety and security priorities. The NRC maintains a robust security regulatory framework to protect against potential terrorist threats, including acts of sabotage, theft, or use of radioactive sources in a radiological dispersal device or a radiation exposure device.

Ensuring the security of radioactive materials is a high-profile issue with domestic and international implications. On the public engagement front, we must address security a bit differently than we do other aspects of our work. While I feel that, in general, the NRC has an obligation to be as open and transparent as possible about our regulatory activities, there are also considerations associated with the need to protect sensitive information. The NRC strives to achieve this balance effectively, and we welcome input on how we're doing.

From an international perspective, we've actively participated in International Atomic Energy Agency (IAEA) security guidance development activities. Last fall, we hosted an International Physical Protection Advisory Service (IPPAS) mission. During the mission, a team of international experts reviewed both our physical security regulations and how our licensees implement them. The IPPAS team determined that civilian nuclear materials and facility security in the United States is robust.

There are approximately 20,000 radioactive materials licensees in the United States; the Agreement States regulate 87 percent of these. NRC materials licensees with Category 1 and 2 quantities of radioactive material are subject to the new physical protection regulations under Part 37. The Agreement State licensees must be fully compliant with Part 37 by March 2016 – States are responsible for changing their regulations in the intervening period.

The NRC's Integrated Source Management Portfolio (ISMP) is an important aspect of our radioactive material security program. The ISMP is a set of information technology tools to facilitate effective materials licensing and tracking activities and protect the materials most likely to be used in a terrorist attack. The Portfolio has three components.

First, the National Source Tracking System tracks the most risk-significant sources each time they are manufactured, transferred, exported, disposed, or disassembled. The system tracks the movements of more than 80,000 sources, mostly Cobalt 60, with an average of 200 transactions per day. I should note that we have had productive international collaboration, most notably with the Canadians, on source tracking activities.

Second, the Web-Based Licensing System is a database of issued NRC and Agreement State licenses for Category 1 and 2 sources. We use this system to track licensing and inspection activities. Finally, the License Verification System enables users to electronically verify that licensees are legitimate before shipping radioactive materials to them.

We appreciate licensees' cooperation in fulfilling their requirement to use these systems. We believe that the ISMP has added an essential information technology component to complement our security requirements, which enhances our ability to keep radioactive material out of the wrong hands. As always, we valued public input throughout the course of our effort to develop our physical protection requirements for Category 1 and 2 sources under Part 37. We thank HPS for its comments related to this effort during the public comment period.

The NRC also supports a variety of international radiation protection initiatives both technically and financially. These include efforts to advance the underlying science through the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). We're actively involved in the recommendation-setting work of the International Commission on Radiological Protection (ICRP), as well as complementary domestic activities with the National Council on Radiation Protection and Measurements (NCRP). We also support the IAEA's work to develop appropriate regulatory standards.

As I mentioned earlier, the 2011 Fukushima accident has been at the forefront of many people's minds for the past three years. As the NRC has worked to address lessons learned from the accident and implement appropriate safety enhancements, our international engagement has increased. We've learned a great deal from our foreign regulatory counterparts and shared insights and information about changes we've been making.

These efforts have also underscored the need to approach potential international harmonization with the unique attributes of our own oversight responsibilities in mind. Simply put, our regulations have to fit our program. This is an important consideration as our staff continues its work to revise Part 20, and other parts of our regulatory framework, to increase alignment with international recommendations.

In my view, the Fukushima experience also highlighted the need for continued collaboration between the scientific and regulatory communities on effectively communicating with the public about radiation risk. I won't debate the issue of multiple units of measurement here – that could take us well

beyond my assigned time slot! But as you know, units of measurement notwithstanding, the public has many valid questions about radiation exposure, and conflicting or unclear answers may cause concerns. For this reason, the Commission, and I personally, value the emphasis HPS places on public outreach and education.

One area in which clear, consistent information is especially important is in nuclear medicine. When a patient is treated with unsealed radioactive material, he or she remains radioactive for several hours to several days. As such, precautions are needed to limit doses to other people, in particular caregivers, medical staff, and the public. Under NRC regulations, a patient who has undergone radiation therapy can be released from a licensee's control only if the total effective dose equivalent is not likely to exceed 5 millisieverts to any other individual who may be exposed to the patient. This practice is often referred to as "patient release."

This issue has been of particular interest to me personally. Earlier this year, I and one of my Commission colleagues co-authored a voting paper in which we stated that the NRC should be doing more to ensure that our licensees are able to provide clear guidance to patients on the potential treatment risks and precautions to take prior to treatment and after being discharged from a hospital or treatment facility following radioiodine therapies.

As a result, the Commission directed the staff to develop a standard set of guidelines that licensees can use to provide instructions to patients who will be treated with therapeutic radioiodine. The Commission also directed staff to revise NRC guidance documents related to patient release, develop a website that provides information to patients about radioiodine treatment, and evaluate whether significant regulatory changes to the patient release program are warranted. As our staff works to complete these newly-assigned activities, information from the Health Physics Society, our Agreement States, and other groups will be extremely valuable.

The NRC continues to promote a strong safety culture across the industries we regulate, as well as within our own agency. In 2011, the agency published a Safety Culture Policy Statement that applies to all of our licensees. The Policy Statement includes a list of traits for a positive safety culture, including personal accountability, a questioning attitude, a respectful work environment, and continuous learning. In fact, a questioning attitude – asking ourselves how and where we can improve – is also the foundation of ALARA (as low as (is) reasonable achievable), which, in my opinion, is the cornerstone of effective radiation protection.

Many of you are radioactive materials users – as you are aware, it is important to ensure that the radiation protection community continues to exhibit positive safety culture traits. The NRC has developed a training webinar and customizable training material for our Agreement State partners, and we continue to collaborate with them in this area.

After a few challenging years, the NRC is looking to the future. While we'd recently anticipated significant new reactor licensing activity, we now find ourselves revisiting nuclear power plant decommissioning. The appeals court rulings on Waste Confidence and Yucca Mountain, along with the Fukushima accident, also put a substantial amount of unanticipated work on our plate. At the same time, like the rest of the government, we faced fiscal uncertainty in the form of multiple continuing resolutions and sequestration.

I've been extremely impressed with how the NRC staff has handled the challenges that have come our way. But we've also recognized that we need a focused effort to best position the agency to succeed in the coming years. Under the direction of our Executive Director for Operations, a team of senior managers and staff are working on projections of agency workload and critical skill needs through 2020. Their work will involve extensive consultations, both internal and external, and we value the views of the many groups that contribute to our activities.

With an increased focus on decommissioning, both domestically in a traditional sense and at Fukushima in post-accident conditions, it appears to me that there will be a host of new lessons to learn on radiation protection in a decommissioning context. Sharing information, insights, and experiences from these activities will be beneficial for all of us.

As we consider future workload projections, the NRC also recognizes the importance of continuing to support students seeking careers in health physics and radiation protection. Under the Nuclear Education Grant Program, the NRC has provided funding to university programs in nuclear safety and security and environmental protection. Other fields that the Commission determines to be critical to the regulatory mission of the NRC have also received grants.

From fiscal years 2009 to 2013, the NRC awarded 98 projects, totaling approximately \$28 million, to health physics and radiochemistry programs across the nation. We're proud to have been able to offer this important support to the academic community. Given the current fiscal environment, future program funding remains somewhat uncertain. However, I believe it's important for the NRC to continue contributing to these efforts.

With radiation protection responsibilities and interests across a broad variety of industries and issue areas, the missions of the NRC and the Health Physics Society remain connected. I hope that the information I've provided this morning was helpful in giving you a sense of where your continued support, and our continued cooperation, will be beneficial. I'm also pleased that so many of the NRC's talented staff are participating in this conference – they will provide additional, detailed insights about our current activities.

I greatly appreciate the opportunity to be here this morning, and I'd be pleased to answer your questions. Thank you.