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The Evolving Area of Radiation Protection of Patients

By

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Good afternoon. I am pleased to join you today to share my thoughts on the evolving area of radiation protection of patients. The International Conference on Patient Safety held in Malaga, Spain, this past March highlighted the importance of this topic and serves as a backdrop to my presentation.[1] In addition, the NRC has been on the "front-lines" of this evolution as a result of the recent revision of our regulations governing the medical use of byproduct material. I will call on these two activities in my remarks today.

Background

I know all of you are aware of the application of ionizing radiation in medicine, but I suspect that many of you would be surprised at the extent of this application. At the Malaga Conference, it was observed that there are 2 billion diagnostic x-ray examinations, 32 million nuclear medicine procedures, and 5.5 million radiation therapy treatments that are undertaken each year around the globe. It turns out

[1] "International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy" - The conference was held in Malaga, Spain from March 26-30, 2001.

that medical practice accounts for the vast majority of the dose arising from man-made sources of radiation. These are striking statistics to a regulator who spends much of his time minimizing "potential" exposures from extremely low concentrations of radioactive material.

Two trends provide insight into the significance of this data. First, the medical use of ionizing radiation is growing. Part of this growth is the result of the expansion of modern health care throughout the globe. Part of it arises from the expanding application of modern imaging techniques. Computed tomography (CT), for example, offers remarkable benefits in the diagnosis of disease, but involves relatively high doses. A single whole-body CT scan, for example, can involve a dose of 20-40 millisievert (2-4 rem). During a week in which the NRC has promulgated regulations to require a demonstration that the Yucca Mountain site, over a period of 10,000 years, will not cause a dose in excess of 150 microsieverts/yr (15 mrem/yr) total effective dose equivalent to the reasonably maximally exposed person, I find the dose from a CT to be quite startling. Given the trends in both the number of medical applications of radiation and the magnitude of the average dose arising from many of the most modern techniques, I think it plausibly could be predicted that the average dose arising from medical procedures might well exceed the annual dose arising from natural background within the next 20 years.

The second factor that serves to heighten the significance of medical exposures arises from changes in the practice of medicine. The use of ionizing radiation in medicine is no longer largely the exclusive province of trained radiologists. Ionizing radiation is now routinely used as a tool in diagnosis and therapy by a variety of specialists. The new applications no doubt hold the promise of increasingly effective health care, but at the risk that medical professionals with limited educational and practical experience in radiation are playing an increasing role in ensuring radiation safety.

I mention this information as a backdrop because, given the significance of the medical applications of radiation and the magnitude of the risks involved in some procedures, it would seem obvious that there is a clear regulatory role. But there are complicating factors which make the task of defining the appropriate regulatory role somewhat problematic.

Regulations: too much or not enough?

It goes without saying that exposure to ionizing radiation is intentionally administered in the course of the medical application of radiation. Moreover, no medical intervention, whether diagnostic or therapeutic, comes without at least some risk. But this, by itself, does not justify regulatory intervention. The NRC recognizes that it should not intrude in the practice of medicine or in medical judgments affecting patients. These are matters that must be left to the discretion of physicians, in consultation with their patients.

Rather, the regulator's role is to ensure that appropriate steps are taken to ensure that misadministrations of radioactive materials and involuntary exposures of medical staff and of the public are minimized -- for example, overexposures, underexposures, or exposures of wrong treatment sites in patients, or exposures of visitors of patients who have radioactive substances in their bodies. It is these unintended exposures that justify regulation. The challenge for the regulator is to establish a regulatory structure that serves to minimize these unintended risks, while also avoiding undue interference in medical judgments.

There is another aspect of regulation of medical application of radiation that must also be considered in establishing the appropriate depth of regulation. Too much regulation can result in the needless delay of medical or technological advances, higher health care costs, or ineffective patient care.

Too little regulation can lead to an increase in misadministrations[2] and increased likelihood that patients, medical staff, and the public will receive involuntary exposures. A careful balance must be attained in establishing an appropriate regulatory regime.

The U.S. Nuclear Regulatory Commission's (NRC's) role in patient protection has evolved over the years as we have wrestled with the issue of determining regulatory controls. Our experience shows that finding an appropriate balance is not easy or free from controversy. The situation is complicated in the U.S. as well by the fact that regulatory authority over ionizing radiation is divided among several government agencies at the federal and state levels. At the federal level, the NRC and the Food and Drug Administration (FDA) have primary responsibilities. The FDA has authority for approving radiopharmaceuticals and devices, while the NRC has responsibility for ensuring their safe use. I must also point out that NRC regulatory authority is limited to only specific classes of radioisotopes. Accelerator-produced materials and machine-produced radiation are outside of the scope of the NRC's authority.[3] States have regulatory authority over materials that are outside NRC jurisdiction and the States, as a general matter, regulate the practice of medicine.

Despite the NRC's constrained role, our regulations do have an important impact both in direct application and as guidance for other regulators, such as the States. In general, NRC's regulations are designed to foster good practices and consistency in application. Our regulations include requirements for confirming patient identity and verifying doses (§35.41), taking dose measurements (§35.63), surveying patients (§35.404), and making safety checks on equipment (§35.615). Other provisions include requirements for having a radiation safety officer (§35.24 (b)), establishing a radiation safety committee (§35.24(f)), and notification and reporting of medical events (§35.3045). Perhaps most importantly, we also have specific training and experience requirements (§§35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, and 35.690).

I believe that the framework established by NRC's regulations has helped to ensure that the frequency of unintended or involuntary exposures associated with medical procedures involving radiation is low. Although it is difficult to quantify the frequency of unintended or involuntary exposures because of the limited NRC jurisdiction and the possibility of under reporting of events, it has been estimated that a misapplication involving radioactive material occurs at a rate of less than 1% for both diagnostic and therapeutic procedures in the U.S.[4] Although the frequency of medical misapplications may be small, this does not mean that efforts to maintain, or even reduce the frequency are unwarranted, particularly when the absolute number of exposures is large and the consequences of a misapplication can be severe. The challenge, as I have indicated, is to ensure the right balance in the regulations so as to assure the realization of the medical benefits.

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[2]Under the revised 10 CFR Part 35, the term "medical events" replaces the nomenclature for "misadministrations." For the purposes of this presentation, I have used the older terminology.

[3]As a result, one of the emerging technologies, Positron Emission Tomography (PET), is currently not covered under the NRC regulatory authority. PET is a diagnostic procedures that involves the injection of the patient with an accelerator-produced radioisotope and then scanning the patient.

[4]National Academy of Sciences - Institute of Medicine, Radiation in Medicine - A Need for Regulatory Reform, 306 (National Academy Press, 1996).

In 1993, the NRC undertook an in-depth examination of the issues surrounding its medical-use program. As a result of that examination, we concluded that changes were needed. We decided to revise our regulations to make them more risk-informed and performance-based.

Making the regulations more risk-informed has involved the use of risk-insights to guide the process. That is, the revised regulations are intended to focus regulatory oversight on those procedures that pose the highest risk, while reducing the burden for procedures, such as many diagnostic procedures, which involve a lesser degree of risk. The goal of this process is to reduce unnecessary burdens while maintaining safety.

We also sought to make the regulations more performance-based. By this I mean that the emphasis in the revised regulations is on performance outcomes. The revised regulations substantially reduce prescriptive requirements,[5] while retaining provisions for training and education and for reporting misadministrations. Provisions for written directives from the physician to prevent significant errors in radiation delivered to the patient also were retained. The revised regulations also include new provisions that allow for an easier and more timely licensing of new technologies. Overall, the revised regulations are significantly less burdensome than our former regulations.

I must add, however, that even our revised regulations have proven controversial. Some members of the medical community do not believe that the revisions go far enough. For example, some would advocate that the NRC remove all requirements for diagnostic nuclear medicine because of the low risks involved. We concluded, however, that although the risks associated with diagnostic medicine are generally low, they cannot be dismissed entirely. Moreover, some newer diagnostic medical techniques use high doses of radiation,[6] and consequently result in meaningful risk.

The NRC's revised regulations have been held in abeyance while the matter of whether the NRC should be allowed to use appropriated funds to implement them is considered by the Congress. I am hopeful that the Congress will agree that the risk-informed and performance-based regulatory framework we have established provides the appropriate vehicle for reducing radiation risks, while also minimizing interference with the beneficial uses of medicine.

The role of the health care community

Although it is clear that we as regulators have an important role in minimizing the risks to patients, the medical community has an even more important role. Obviously, the medical community must take the necessary steps to minimize human errors. Moreover, I believe that the medical community needs to help shape the regulatory framework because it has unique insights. In fact, our goal is to build on the expertise in the medical profession. I believe the NRC has found effective ways to include the medical profession in our processes that may be of interest to you.

First, we have gained the benefit of the insights of the medical profession through the use of industry and professional standards. As a general matter, we encourage industry to develop codes, standards, and guides that can be incorporated into our regulatory system. This strategy increases the involvement of our licensees, as well as others, in regulatory development and fulfills a national

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[5]The revised medical-use regulations reduces requirements for radiation safety committees, instrument calibration, and prescriptive safety procedures.

[6]An example is the use of radiation in cardiology to visualize arterial blockages.

mandate to use technical standards developed by voluntary consensus bodies to the extent possible. In developing our revised medical-use regulations, we have referenced appropriate industry guidance and standards in the regulations where possible, such as standards from nationally recognized bodies.[7]

Second, we obtained input from the medical community through a formal advisory community. Our Advisory Committee on Medical Uses of Isotopes (ACMUI) consists of highly qualified physicians, scientists, and representatives of patient advocacy groups. They provide advice on matters relating to the medical use of radioactive material, inform staff of emerging technologies, and provide guidance on the impacts of our regulations on the medical community. Again, this helps the NRC identify areas where we may be unnecessarily intruding into the medical field.

Finally, we involve the medical community directly in the regulatory development process. The promulgation of regulations at the NRC has always been a participatory process involving those being regulated, as well as other stakeholders. Over the last several years, the NRC's activities have greatly benefited from encouraging strong stakeholder involvement early in the process. In the past we sought comments from stakeholders on a proposed regulation only after it was formulated. Now we have an outreach program to engage interested stakeholders while the regulation is being developed. This approach helps in the identification of critical issues early in the process, fosters a clearer understanding of positions and concerns, and serves to allow identification of areas of agreement or disagreement. This approach not only helps ensure more effective regulation, but also reinforces the reality that nuclear regulation is the public's business and is being transacted openly.

Despite these efforts to engage the affected community, we recognize the inevitability that not all stakeholders can be satisfied with the substance of our decisions. Nonetheless, the NRC seeks to ensure that every stakeholder has concrete evidence that his or her concerns has been heard, analyzed, and carefully considered.

Importance of Education and Training

Before concluding, I want to touch upon what I believe is a central finding of the Malaga conference - - the importance of education and training. As I have already stated, the medical community has the main obligation to minimize the risk to patients, medical staff, and the public. However, strong and effective regulations, particularly those involving education and training, should be viewed as providing an additional level of protection to patients -- really, to borrow a reactor term, providing defense-in-depth against unintended exposures. Although some level of error is probably unavoidable in any human endeavor, effective training of health care workers will help to reduce the likelihood of error. This effort is important because the consequences of error can be significant. Take, for example, the case of the overexposure of patients at the National Oncology Institute in Panama earlier this year -- an incident that has been traced in part to human error. At least five deaths have been

[7] See, e.g., 10 C.F.R. §§ 35.432(a)(3) (use of published protocols currently accepted by nationally recognized bodies to determine the source output or activity in calibrating brachytherapy sources); 35.632(d) (use of published protocols accepted by nationally recognized bodies in calibrating teletherapy units).

attributed to this overexposure.[8] This incident highlights the need for education, for an appropriate quality assurance program, and for appropriate staffing and credentialing standards.[9]

Notwithstanding the fact that medical personnel are highly trained professionals who are deeply concerned about the welfare of patients, it is nonetheless important that they receive training on occupational safety procedures and the overall management of radioactive materials. The NRC's regulations are predicated on the assumption that properly trained and adequately informed medical professionals will provide for effective radiological protection of patients. As a result, our regulations focus on the need for such training.

In addition, we have adapted our training and experience requirements to conform to the risk posed by the procedure. We concluded that, in some cases, the existing requirements did not provide an adequate level of assurance that physicians and other users would have adequate training in the safe use of radioactive material.[10] On the other hand, we saw a need to reduce some of our training and experience requirements for diagnostic procedures because of the lower risk associated with their use.

The participants at the Malaga conference concluded that training should be established for specific medical modalities. Again, this is consistent with the position taken by the NRC. We recognize that there is a certain degree of basic radiation safety knowledge that is common among all types of radiation uses.[11] However, we also believe that the different uses of radiation by the various medical disciplines dictate that there be different training and education requirements among the disciplines. Thus, the training and experience requirements in our revised regulations are designed to target individual medical modalities.

Conclusion

Let me note in conclusion that effective, balanced regulatory controls are needed to provide protection arising from the medical application of ionizing radiation. The approach taken by the NRC has been to establish a risk-informed and performance-based regulatory regime that has been fully informed by insights from the medical community and our other stakeholders. We believe that the revisions to our medical-use regulations provide for radiation safety without being overly intrusive on medical practice.

I recommend that this conference similarly consider encouraging the development of a risk-informed and performance-based regulatory framework for medical uses of radiation. The IAEA effort to develop an Action Plan in this area is an important first step.

Thank you.

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[8] NRC Information Notice 2001-08, Supplement 1: "Update on the Investigation of Patient Deaths in Panama, Following Radiation Therapy Overexposures."

[9] ACR, ASTRO, AAPM Comment on Panama Radiation Overdose Incidents, http://www.acr.org/announce/062201.html

[10] An example is 10 C.F.R. 35.390 (therapeutic use of unsealed material).

[11] Examples include the use of decay formula and decontamination techniques.