RELEVANCE OF RADIOLOGICAL PROTECTION

Nils J. Diaz, Chairman
U.S. Nuclear Regulatory Commission

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Regulators and practitioners of the health physics profession play significant roles in radiological protection in its three interconnected phases: assessment, regulation, and implementation. Protection is an encompassing, integral action that needs a defined purpose and boundaries. Radiological protection is a mature area of endeavor and, with the proper assessment, regulation, and implementation, we can reduce uncertainty and keep interpretation to a minimum. In this context, assessment is everything that needs to be known, weighed, and harmonized before you can regulate and/or implement. Regulation and implementation follow the assessment phase ... or do they?

Radiological protection needs to be exercised in a manner that provides the most benefit to society. It should not be too little or too much; it has to be prudent, well-based, equitable, and open. And it must be relevant. Radiological protection per se is a practical undertaking that fulfills a special social responsibility. In the following, I focus on how we can make it more relevant. These are my personal views, which do not necessarily represent the views of the U.S. Nuclear Regulatory Commission (NRC).

Let me start with an overall picture, work into regulation and then step right into relevancy. In society, we end up with regulated and non-regulated activities. Both are usable and useful. The perennial question is, what should and should not be regulated? In the United States, that decision has mostly been made in favor of regulating radioactive risks, and especially those covered by the United States Atomic Energy Act of 1954. However, across the risk range, from naturally occurring and accelerator-produced radioactive materials to everything else, is the regulation or lack of regulation prudent, well-based, equitable and open, and is it done as efficiently and effectively as it should be? This is where the present debate should be focused.

As established by the Atomic Energy Act and other statutes, the mission of the NRC is to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment by the licensing and regulation of radiation sources and nuclear energy. The NRC mandate is centered on radiological protection, not on the mere existence of a broken pump or a leaky line.

The NRC's Commission must ensure that the radiological protection mission of the agency is being fulfilled in its policy decisions, regulations, and other actions, using all the information at our disposal. Regulation is an important component of society's infrastructure; it is a tool of society to implement what society needs, in an orderly,

equitable and fair manner. Regulation is done for the people, with their best interests as the essential objective; it is done for the common good, with full consideration of the national interest.

Although all regulations restrict, regulations should not deter beneficial activities, but should frame them and guide them. In fact, the NRC's "enabling" role is specifically addressed in our strategic objective to "enable the use and management of radioactive materials and nuclear fuels for beneficial civilian purposes in a manner that protects public health and safety and the environment, promotes the security of our nation, and provides for regulatory actions that are open, effective, efficient, realistic, and timely." I believe that the role of regulation of the peaceful uses of nuclear energy and radiation is to provide a meaningful and useful framework for the protection of rights, health, safety, and the environment from radiological risks. Regulations for radiological health and safety need to be based on facts and supported by the best available knowledge, which must be used within the boundaries defined by risks and benefits to society. Regulations need to be technically, socially, and economically sound, but not necessarily in equal proportions. Regulation of the use of radiation must result in a benefit or it will result in a loss. There are no benefit-neutral regulations. Regulation has to be relevant to the people it protects.

While there is significant agreement among practitioners on what is meant by "radiation protection," we do need an increasingly better understanding and explanation of the basis for either regulating or not regulating, as well as the basis for the activities that provide for radiological protection of the workers and the public. The guiding legal principle of the Atomic Energy Act for the regulation of nuclear energy and radiation in the United States is the envelope established for reasonable assurance of adequate protection. The principle is sound, it has worked, and is being implemented increasingly well, with balance and reasonableness. The regulation and the implementation of radiological protection must be a practical undertaking that fulfills a special social applicability; they have to make a difference.

As regulators, radiological protection practitioners, and users, we are responsible for assuring that radiation risk is understood, that it is managed, that it is low, and that it is effectively communicated. Please note that the emphasis is on low, not zero. Let me restate the established legal requirements for the NRC's radiological protection mission and its relationship to zero risk. It is clear that the courts, interpreting the law, have ruled: "The level of adequate protection need not, and almost certainly will not, be the level of 'zero risk.'" Furthermore, "the courts have long accepted the Commission's definition of its statutory mandate to 'provide adequate protection of public health and safety' as requiring not a risk-free environment, but a 'reasonable assurance'. . . ." NRC is not in the business of zero risk. I oppose the arbitrary imposition of a zero factor to narrowly selected radiological risks not only because it is contrary to the law governing the NRC, but also because it hampers debate on radiological protection, and gets in the way of good radiation protection. I believe that the zero factor needs to be eliminated and subsumed into reasonable assurance; this is relevant to society.

One of the fundamental reasons to have regulation is to decrease uncertainty in the implementation of a nation's interests, without undue burden to society. This is, of course, applicable to the use of nuclear energy and radiation in the United States; however, it should be applicable everywhere.

Radiological protection activities have the same prerequisites as its regulation: they need to be based on facts and figures that are placed carefully in the proper context and supported by the best available knowledge and experience. As we all know, the best efforts can produce misleading results if not placed in the proper context, balanced and checked by the body of knowledge and experience. Users of radiation, regulators, and health physicists, therefore, must be mindful of the need to make decisions based on unbiased, substantiated and fully-informed state-of-the-art information. Moreover, the need for action in radiological protection often requires decisions based on justifiable conclusions at particular points in time. In that regard, we have the responsibility to put into practice what is sufficiently known. In particular, the basis and practice of radiation protection for low doses in the U.S., and hopefully globally, should become an asset for decision-making and not fuel for controversy. The need is to have a working and functional framework that ensures an adequate level of protection from low-level radiation, whatever the radiation's origin or reason for existence.

Today, it is more important to establish and implement a radiological protection framework for low doses than to resolve, to the last decimal place, every controversy and every effect. In the U.S., I believe that most radiological protection practitioners are doing a very good job understanding, managing, and making risks low. However, we could do a better job of communicating. Even when the work and studies are done well, and we communicate the conclusions well, the full significance of the results might not be realized when discussions are trapped at opposite ends of the spectrum. Regardless of our individual opinions, we need to focus on being relevant, on achieving solutions that benefit society, even as the search for knowledge continues. We should be able to communicate our knowledge, as well as factual assessments, in a manner that benefits society.

For example, I have seen a radiation dose of much less than 0.0001 millisievert (0.01 millirem) described as "not posing a significant health and safety hazard." I believe it would be correct to say "it is an insignificant health and safety hazard." Maybe someone could even dare to say "0.0001 millisievert (mSv) is not a health hazard." Another recurring issue is the use of caveats. Caveats, which we all find the need to use, should not detract from drawing useful and applicable conclusions. For example, we would not be surprised to hear that studies reveal no detectable effects from ionizing radiation below 5 mSv per year <u>but</u> more studies are needed . . . . This could be good science, but, apart from the caveat, we may be required to find a more immediate benefit to society.

In the realm of low-level radiation, say below 5 mSv per year (500 millirem per year):

-- Do we understand, and can we quantify, every effect of ionizing radiation on the human body? No, but the same can be said about the effects of the water we drink, the air we breathe, the food we eat, etc.

-- Can it be stated that there is or there is not some minimal radiation effect at 5 mSv above average background, or that there could even be some small, difficult to ascertain benefits? No, but the same can be said about the effects of hundreds of other environmental factors.

Regardless of the debate over the validity of the linear non-threshold or threshold models for predicting health effects from low-level doses, we have the responsibility to establish now those levels of radiological protection that can be openly defended for society's benefit. To this end, a few years ago I drafted one of the major conclusions that came out of a conference on Bridging Radiation Policy and Science:

> The effects of low-level radiation below 1 mSv (100 mrem) per year above background radiation cannot currently be distinguished from those of everyday natural health hazards.

This conclusion remains valid today. It is supported by state-of-the-art science and technology, and takes into account dose levels at which there is confidence that health effects from radiation are indistinguishable from existing everyday health effects. I believe that an overwhelming majority of health physicists, radiation biologists, epidemiologists, and informed citizens would agree with that statement. There is no way to distinguish the effect of 1 mSv per year from the effects of your hot shower or hot food or . . . whatever you do everyday. That does not mean that there is no effect; it means the effect is just one of the myriad of everyday biological and chemical responses that are assimilated by the human body. But, what if science improves, and the effect can be isolated at a particular instant? What if low-level radiation-induced genomic instability can be measured, however small? Like many other cellular responses, I believe that it will likely be assimilated and become indistinguishable the next instant.

The conclusion quoted above is clear, it is usable, it can be communicated, and it is relevant. How relevant? It is relevant to radiological protection of the general public, site termination limits, exposures from medical diagnostics, and many other issues. Furthermore, this conclusion can be very helpful for the global debate on the consideration of the scope of regulatory controls over very low-level radiation, because regulation needs to be implemented within a defendable, reasonable, and usable framework to benefit society. Regulation needs to be well-founded in science, and must use science to make decisions.

Therefore, I offer a practical definition for the practice, and specially, the regulatory practice, of radiological protection:

> Radiological protection is the practice that ensures radiation risks are understood, managed, maintained acceptably low, and well-communicated to the people. It allows for the safe use of radiation sources and nuclear energy for the benefit of society.

Therein lies the relevance of radiological protection, and it is essential that regulators and practitioners continue to identify and implement practical methods and limits to guide the conduct of this critically important activity.