



# NRC NEWS

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## **Adequate Protection in Commission Decision- Making**

Remarks of Commissioner William C. Ostendorff

United States Nuclear Regulatory Commission

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Good morning. I want to thank the Nuclear Energy Institute for inviting me to speak today. Most of my interactions with stakeholders to date have been on the technical side of my work, so this was a great opportunity to finally engage an audience on the legal side. In my 11 months on the Commission, I have noted how much of our work is infused with legal issues. I graduated from law school in 1984, but subsequently took an unconventional route. Taking a position on the Commission gave me a great excuse to dust off a few of my old law school books.

With the wide array of legal issues confronting the Commission on a daily basis, there are numerous topics that I could have discussed with you today and some – like pending adjudicatory matters -- which I cannot. So it was a challenge to select a subject that I thought would be of interest. In that light, rather than discuss a specific legal issue, I decided that I would discuss a more high-level subject: the notion of "adequate protection." This subject is relevant because it seems to be a term that all of us in this field use frequently, yet few discuss how it is applied practically. Therefore, I thought I would offer you one perspective on the concept and try to explain how it comes into play in my own decision making through a few examples that I have dealt with since coming to the Commission.

As a Commissioner, it took me some time to appreciate the importance of the concept of "adequate protection." My goal today is to give you some sense of how I as an individual Commissioner come to a decision that I believe results in "adequate protection" of the public health and safety, while comporting with the NRC's principles of good regulation.

Before I proceed, let me take a moment to explain how the Commission operates. It is important to understand the decision-making process and how the "adequate protection" concept fits within it. The vast majority of rulemaking, adjudicatory, and policy issues that come to the Commission do so through decision documents drafted by the NRC staff. For policy making, the decision document typically identifies the policy issue for the Commission, provides a series of options, and provides a recommendation from the NRC staff. For rulemaking and adjudicatory

matters, the staff also sends a paper to the Commission, but typically that paper includes only one option in the form of a draft rule or draft adjudicatory order. Each Commissioner then votes on the matter, providing his or her own perspectives. Ultimately, direction is given back to the staff that reflects the views of the majority of the Commission.

The point here is that the process of achieving the “adequate protection” standard is in some ways a system of checks and balances in which the viewpoints of the technical staff, the Office of the General Counsel, the views of our stakeholders -- both industry and public interest groups -- and finally the Commission, are integrated and synthesized to meet the agency’s “adequate protection” standard.

One of the most important things for an agency to understand is its basic statutory mandate. As you know, agencies operate only within the limits of the authority given to them by Congress. For the NRC, this primarily lies in its organic statute, the Atomic Energy Act. One of the most important aspects of the substance of the Atomic Energy Act is the "adequate protection" charge.

Through its own interpretations and those of the courts over the decades, we now understand that the NRC is required to provide "reasonable assurance of ‘adequate protection.’ ” This interpretation was affirmed early on in the landmark 1961 Supreme Court decision Power Reactor Development Company.

The “adequate protection” mandate also permeates the Commission’s regulations. As the Commission noted in its 1988 backfit rule, “an essential point of the Commission’s having regulations is to flesh out the ‘adequate protection’ standard entrusted to the Commission by Congress.” The Commission then went on to explain that “regulations and guidance arrived at in this way do not, strictly speaking, ‘define’ adequate protection” but that “compliance with such regulations and guidance may be presumed to assure adequate protection at a minimum.”

Of course, the Act allows the NRC to impose requirements that are deemed beyond “adequate protection,” referred to by some as “safety enhancements.” But imposing a safety enhancement requires the NRC to conduct a backfit analysis to determine if there would be a substantial increase in safety, and whether the costs of that enhancement would be justified in light of that increase in safety.

Though the NRC, the courts and Congress have repeatedly refused to define "adequate protection" in concrete terms, there are four principles that I believe are generally accepted that provide appropriate guidance.

The first principle is that the NRC’s authority under the "adequate protection" mandate is extremely broad, and that the NRC has significant discretion in determining whether the “adequate protection” standard has been met. In fact, over the years, the courts have been consistent in holding that defining “adequate protection” is almost entirely left to the expert scientific judgment of the NRC, and therefore have generally deferred to our decisions.

I will mention three significant cases that you’re probably familiar with to elaborate on this point. First, perhaps one of the strongest endorsements of deferential review of the NRC’s

“adequate protection” determinations comes in the 1989 Union of Concerned Scientists decision in the DC Circuit Court of Appeals. As you may recall, this decision involved the court’s review of the NRC’s revised backfit rule, which the court had struck down in an earlier decision. On review and upon affirming the revised rule, the court noted that “the determination of what constitutes ‘adequate protection’ under the Act, absent specific guidance from Congress, is just such a situation where the Commission should be permitted to have discretion to make case-by-case judgments based on its technical expertise and on all the relevant information.”

Several other cases on this point bear mentioning. The First Circuit noted in the 1989 case Massachusetts v. NRC that its appellate review of NRC actions was “at its most deferential when it involves scientific or technical issues.” Likewise, the Second Circuit in the recent 2004 Riverkeeper decision endorsed a deferential approach to the NRC’s decision-making under the Act. And the Supreme Court, though not in an “adequate protection” decision per se, notably observed in the 1983 Baltimore Gas and Electric decision that “a reviewing court must remember that the Commission is making predictions, within its specific expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.”

The second principle that can be gleaned is that the NRC's authority over “adequate protection” is bound to matters that have a reasonable nexus to radiological health and safety. In other words, just a mere nexus to health and safety is not enough if there is no radiological aspect to the concern. A case on point here is the 1969 First Circuit decision, New Hampshire v. Atomic Energy Commission, where the court considered whether the AEC had authority over thermal discharges from the Vermont Yankee facility into the Connecticut River. The court concluded that the AEC did not have such authority, holding that “the responsibility of the Commission [is] confined to scrutiny of and protection against hazards associated with radiation.”

In practice, this interpretation has shown itself through the Commission’s work in two recent rulemakings: the Limited Work Authorization rulemaking, in which the NRC revised the definition of construction for nuclear power plants to confine it to the NRC’s statutory authority over radiological health and safety, as well as the current ongoing rulemaking to make similar revisions for construction of materials facilities.

The third principle is that the NRC has the ability to determine if “adequate protection” has been achieved on a case-by-case basis. I will not repeat all of the cases, but many of the decisions I mentioned earlier emphasize this point. The 1989 Union of Concerned Scientists case, for example, refused to require the NRC to employ “a set of objective criteria for determining what level of protection is adequate.” Thus, in practice there are no set criteria or checklists or quantitative data that a Commissioner uses to decide this question across the board. And rightfully so. Aside from being nearly impossible to come up with such a thing generically, it would significantly diminish the responsibilities of the Commission to make such decision making so automated. It would not allow us, as individual Commissioners, to use our own significant experiences to help guide our decisions if such a process were already so rigidly decided based on a set of pre-established criteria.

And finally, and perhaps the most important principle: “adequate protection” does not mean “zero risk.” Let me focus on the concept of zero risk for a moment. Many, if not all, of the

issues that come before the Commission boil down to how much risk we are willing to accept. The risk can be from a safety, security, or even from a legal perspective. In all of these situations, the “adequate protection” standard puts the responsibility on us as Commissioners to decide how much risk is acceptable. Another way to look at this is “how much regulation is enough.” These are simply two different ways of looking at the same issue. I will discuss the concept of risk in more detail shortly.

From a legal perspective, the “no risk” issue is also well settled. The 1987 Union of Concerned Scientists decision, for instance, noted that “‘Adequate protection’ is not absolute protection.” This view is also endorsed by the Second and Ninth Circuits.

With that review of the legal landscape, let us take a look at some of the more significant factors that I consider while evaluating the matters that come before me and how these tie back to an ultimate “adequate protection” determination. The main factor that I find critical to decision making related to “adequate protection” is the consideration of risk. In short, this requires an assessment of the probabilities and consequences of a particular risk, as well as a hard look at whether concerns raised in a proposal are based on realistic assumptions, or real world safety, security, or legal issues.

To accomplish this, it is essential that the Commission have a clear understanding of the problem that is being addressed, as well as of any risks associated with not addressing the problem. Identification and acceptance of these risks is critical to making a final decision on “adequate protection.” As previously stated, it is well established that the “adequate protection” standard does not mean “zero risk.” I do not believe that the NRC has a technical or legal basis to ever try and achieve zero risk in a given area. Therefore, determining how much risk is acceptable is part of the critical function of this agency and one that I take very seriously as a Commissioner.

In my view, the NRC has done an excellent job of factoring risk evaluation into its regulatory decisions, and in understanding that the NRC does not regulate to a “zero risk” standard. As an individual Commissioner, I try to contribute to this success by looking critically at the basis for a proposal from a risk perspective, and try to focus on the likelihood of the event and its potential consequences. I closely examine the underlying safety or security basis for the proposal and the process through which it was developed. I ask whether we accounted for all reasonable risks. I also evaluate whether the proposal is based on identification of a real problem, or is it a “solution looking for a problem?” I think these questions are often very difficult to answer, particularly in areas where we have very little real world experience in commercial nuclear power or radioactive materials.

There are several recent examples where realistic assumptions of risk have factored heavily into my deliberations. First is the NRC’s handling of security issues associated with the use of cesium chloride in blood irradiators. Personally, I believe that the current security measures imposed by the NRC and Agreement States are adequate to protect the public health and safety. I was not convinced that an increase in security measures for these materials beyond what is currently being required of them in the “Increased Controls” orders issued by the NRC was consistent with the postulated threat or the consequences of misuse. Therefore, I believe that the draft policy statement on the use of cesium chloride sources that was published for comment

last year is a success story in the use of risk information to achieve the right “adequate protection” result.

Second, the Commission recently dealt with the issue of limiting the amount of radioactive materials in generally licensed devices. The primary issue that the rule appeared to address was the potential for aggregation of sources for malevolent purposes. As I indicated in my vote on that matter, our regulations should be based on the best available knowledge. However, I was not convinced that there was enough concrete information to indicate that such an aggregation scenario was likely or that the rule was based on specific information other than the notion that such aggregation is possible. In other words, I concluded that “adequate protection” was provided under the current requirements without additional measures.

A final example I find relevant to the idea of incorporating risk into the Commission’s deliberative process is “GSI-191,” or Generic Safety Issue 191 – Assessment of Debris Accumulation on Pressurized Water Reactor Sump Performance. This subject is for you “wanna be engineers” in the audience! In short, the concern here is with the response of certain emergency systems in pressurized water reactors if there is a pipe break that causes a loss of coolant flow to the reactor. In particular, there is a concern with the clogging of sump screens from dislodged pipe insulation that would impair the ability of the emergency systems to recirculate water through the core and thereby remove core decay heat.

This is a technically complex issue. In my evaluation of this problem, I looked at the likelihood of occurrence as well as the expected consequences in order to reach my own conclusion. I would describe the outcome here as another success story in the NRC being ultimately focused on “adequate protection.” In its December direction to the staff, the Commission observed that “While they have not fully resolved this issue, the measures taken thus far in response to the sump-clogging issue have contributed greatly to the safety of U.S. nuclear power plants. Given the vastly enlarged advanced strainers installed, compensatory measures already taken, and the low probability of challenging pipe breaks, adequate defense-in-depth is currently being maintained.”

Closely related to risk evaluation is the notion of something that I will coin “contextual evaluation.” Assessing regulatory proposals in this sense could require looking at a particular proposal as part of the framework of the existing regulatory measures in place for a given class of facilities. In other words, in the universe of regulatory requirements applicable to a given class of NRC licensees, how does a particular proposal fit into that universe? By imposing a new measure, do we get that universe back into balance, or would we throw it out of balance?

This contextual evaluation might also ask whether the concerns are addressed or mitigated by existing requirements or by other measures such as voluntary initiatives, commitments or guidance. I also examine whether implementation of the rule could actually somehow adversely impact safety or security overall. For example, would licensees have to shift resources to address an issue of minor safety significance at the expense of addressing issues with a potentially more significant safety impact?

Many of the decisions rendered by the Commission since I joined have adequately taken this consideration into account, and have thus achieved “adequate protection.” For instance, the

Commission recently approved a proposed rule for comment that would require an integrated safety analysis at large source material licensees. The concern that the Commission sought to address was that there are chemical hazards which could, and have, caused significant radiological accidents at these facilities. Had we focused our regulatory microscope solely on the safety of the radiological materials, we might not have appreciated how those non-radiological materials might have a safety impact.

In the vast majority of matters that have been brought to the Commission, I believe that the staff has struck the right balance. Yet occasionally, the checks and balances system requires the Commission to take a hard look at a proposal to ensure that the proper balance is being achieved. At times, the agency might become concerned with the need to address a very discrete area of safety or security without evaluating the concern in a larger context. As a Commissioner, I attempt to evaluate the concern in the context of the "big picture;" of how a particular concern that may seem significant when examined out of context seems less significant when viewed in context.

Security at nuclear power plants is a notable example of the NRC assessing "adequate protection" in context. As an aside, I would like to note that, based on my observations of security at the nuclear plants I have visited, as well as a Force-on-Force exercise I observed at the Millstone plant last month, and my past experiences both in the military and in government, my view is that security at nuclear power plants is very robust. I believe that we have currently achieved "adequate protection."

Since the events of September 11th, the NRC has completed substantial work in the security area, issuing a series of security orders to licensees in 2002-2003, and completing comprehensive rulemakings on the Design Basis Threat in 2007 and the Part 73 requirements in 2009. There is also an ongoing effort to implement the NRC's cyber security requirements. I also remark that I have been highly impressed with the professionalism and expertise of the NRC staff in this regard. I am satisfied with the current level of security at our regulated facilities especially when you compare them to other critical infrastructure facilities in hazardous industries.

The Design Basis Threat is in my view a good example of where the Commission took a contextual approach in achieving a proper outcome. This rule was, of course, before my time on the Commission. But looking back at the record, it is clear that amongst other factors, the Commission looked closely at the entire context of security at nuclear power plants, and factored this into their "adequate protection" formula. The Commission, for instance, ultimately decided not to incorporate aircraft threats into the DBT, finding that such threats were the responsibility of the Federal government and were in fact being adequately addressed by the government as a whole.

As I am sure you know, the Ninth Circuit Court of Appeals affirmed this approach in their 2009 decision on that rulemaking in Public Citizen v. Nuclear Regulatory Commission. In addition to affirming long-standing principles about the "adequate protection" concept and deference to the NRC's technical judgment, the court also agreed in the reasonableness of the NRC's approach with regard to a contextual approach to dealing with threats. The court held that the NRC did not abdicate its "adequate protection" responsibilities by not protecting against the threat of air-based attacks through individual regulatory decisions. Rather, the court agreed that

the NRC could take into account “its knowledge of actions that other Federal agencies have taken since 2001 and its active coordination with many of those agencies” in determining that “adequate protection” had been achieved.

Though the case was decided prior to the final DBT rule, the Second Circuit also affirmed this approach to “adequate protection” in the 2004 Riverkeeper decision. There, the court observed that the NRC’s decision to address aircraft attacks through a comprehensive, government-wide approach was consistent with the NRC’s obligation to ensure “adequate protection.” The court stated that “relying on other governmental bodies to address a risk is not equivalent to ignoring the risk.”

I believe in the principle of regulatory stability. Thus, if the NRC has determined that “adequate protection” has already been achieved, I believe that we have a duty as a reliable and consistent regulator to ensure that we make this perfectly clear to our licensees and stakeholders. We must set the bar for future changes at the appropriate height.

Of course, to be clear, this does not mean that I would not consider the need to impose additional security measures sometime in the future. As a regulator in a dynamic threat environment, the NRC must always remain vigilant in ensuring that “adequate protection” is being achieved as the threat basis evolves.

In addition to risk consideration and looking at matters in context, there are other aspects that I think about when considering whether we have achieved “adequate protection.” For instance, when I evaluate the basis for a particular proposal, I rely heavily on my own real world experiences over the course of my 34-year career to take a common sense approach to the issue. I have tried to keep informed and situationally aware by getting out to licensee sites as frequently as possible.

This takes me to another key point: the importance of the NRC engaging with its affected stakeholders and doing its homework before making a regulatory decision that would result in new requirements. While undertaking any regulatory effort, the NRC – staff and Commissioners alike - should be getting out into the field and looking at the issues first hand. We must give serious consideration to questions such as "how will this be implemented," "what will be the impact of regulation," and "are our basic assumptions about the issue based on accurate and up to date information"? The NRC cannot make its decisions in a vacuum. Insulated or isolated regulatory decision-making is both ineffective and inefficient.

As mentioned earlier, the NRC has stated that “adequate protection” is presumptively provided through compliance with the NRC’s regulations. It is therefore important for the NRC to demonstrate its strength and credibility as a regulator by imposing clear and well-thought-out regulations that are consistent with this presumption. However, not all matters within the NRC’s purview have “adequate protection” implications. I would suggest, therefore, that we look to other approaches when dealing with matters where maintaining “adequate protection” is not the issue. For instance, the NRC should consider whether we can satisfy our regulatory objectives through other approaches, such as voluntary initiatives, licensee commitments, or agency guidance.

Along these lines, the NRC should not lose sight of the fact that the nuclear power industry is also subject to its own system of peer oversight. I note that the Institute of Nuclear Power Operations has proven itself to be remarkably strong over the years. I think we strengthen our position as a credible regulator by recognizing these other efforts during our decision making, and factoring this into deciding what the best way to achieve success would be without having to resort to more formal regulatory action.

The need to impose binding legal requirements also goes to the issue of whether or not a given proposal is capable of inspection and enforcement. That is, would the agency be capable of sending out an inspector to check licensee performance using a meaningful standard, and can we reasonably expect licensees to understand the expectation?

A recent example of this is the Commission's safety culture policy statement currently under development. Though I believe strongly in the need for the NRC to have such a policy statement, I do not necessarily believe that "safety culture" is something that is capable of being inspected, and therefore do not support codifying requirements.

Being in an audience of lawyers, I am sure you might all be wondering how "adequate protection" plays into some of the legal functions I perform. As you know, the Commission has both a supervisory role over adjudications conducted by the Atomic Safety and Licensing Board as well as an appellate function over the ASLB's proceedings. In both of these functions, my approach to decision-making is similar to how I approach policy formulation and rulemaking.

As a supervisor, the Commission has a responsibility to ensure that hearings are conducted efficiently and fairly. The Commission also should ensure that the Boards stay "on track" with Commission policy in managing their cases. These expectations are reflected in the NRC's rules of procedure as well as the Commission's policy statement on adjudications. During my brief time on the Commission, my impression is that the Boards have met those expectations. Generally speaking, my philosophy has been to minimize Commission supervisory interference with the Board's adjudicatory role as much as possible.

Regarding the Commission's appellate role, "adequate protection" in this context means several things. First, the Commission has an obligation to make sure its review of issues on appeal is thorough, and should be issued without undue delay. Second, I think it is critical that the Commission strictly adhere to our standards of appellate review so that the Commission is consistent in its decision making. Third, it is also important that the Commission adhere to its precedent as much as possible. Finally, the Commission should focus on the issues presented to it and minimize the amount of judicial dicta in its decisions.

On a related matter, I should note that the Commission recently made public its direction on the conduct of mandatory hearings. This matter also implicates "adequate protection" as it goes to the question of "how much is enough" from the perspective of the review of license applications for new nuclear power plants. I know that the NRC's Office of the General Counsel is addressing this matter more fully later today, but I will add a few of my own thoughts. The Commission expects to be conducting the first two mandatory hearings sometime later this year, possibly during the summer. As the Commission made clear in the Staff Requirements Memorandum on this subject, the Commission's role in the matter is a "sufficiency review" of the



NRC staff's work that focuses on non-routine matters. In other words, the Commission is not redoing all of the work that has been done, but merely performing a supervisory function to make sure that the NRC staff and the applicant properly observed our procedures, or adequately justified their departures.

I will now close.

In its seminal D.C. Circuit case, Siegel v. Atomic Energy Commission, the court remarked that the regulatory scheme in the Atomic Energy Act is "virtually unique in the degree to which broad responsibility is reposed in the administering agency, free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives."

The Commission has an important responsibility to diligently ensure that the public is adequately protected against the risks associated with the activities that we regulate. This is an iterative process that involves a near constant re-evaluation of our regulatory program to make sure we have achieved the proper balance. However, I believe that the Commission has an equally important duty to use its "broad responsibility" judiciously with appropriate reverence for the significant trust emplaced in it by Congress and the American public. We do this in part by taking our statutory mandate of "adequate protection" seriously, and by taking a hard look to ensure that the obligations we impose are truly necessary to achieve this goal.

I thank you for your attention and the opportunity to be here today. I look forward to your questions.