



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 15, 2019

MEMORANDUM TO: Office of Nuclear Material Safety
and Safeguards Staff

FROM: Marc L. Dapas, Director /RA/
Office of Nuclear Material Safety
and Safeguards

SUBJECT: KEY PRINCIPLES FOR NUCLEAR MATERIAL SAFETY AND
SAFEGUARDS REVIEWS

On May 23, 2018, the Executive Director for Operations signed a Commission paper titled "Achieving Modern Risk-Informed Regulation,"¹ that seeks Commission approval of several transformation initiatives, including actions to enhance and sustain a culture that embraces transformation at the NRC. One of the overarching themes discussed in the paper is the need for systematic and expanded use of risk and safety insights in decision making, including the need to appropriately scale the scope of staff review and level of detail needed from an applicant for licensing decisions, consistent with NRC regulations and the overall standard of reasonable assurance of adequate protection. Consistent with observations identified in that paper, I believe that the scope of staff reviews should be adjusted in the following ways:

- focus staff resources and expertise on the most safety-significant portions of a licensing decision;
- focus staff effort on reaching "adequate protection" or other regulatory conclusions based on reasonable assurance with respect to system performance, rather than an individual component; and
- enable the staff to acknowledge that a new technology may be safer than an existing technology, although operating experience with that new technology may be lacking and the new technology may not meet the regulatory review standards developed for the existing technology.

These concepts address the question of "how much information is enough" to make a finding of reasonable assurance. In line with this discussion of our optimal review approach to licensing actions, I have asked the division directors to engage you in discussions on the need for continued innovation and transformation in our work, including enhancing our use of risk insights in making a finding of reasonable assurance.

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¹ SECY-18-0060, ADAMS Accession No. [ML18110A186](#)

The purpose of this memorandum is to reiterate some of the key principles that guide the manner in which we conduct our work and make decisions, particularly with respect to the concept of “reasonable assurance of adequate protection.”

These key principles are:

- **We operate in a manner consistent with the Principles of Good Regulation (i.e., independence, clarity, openness, reliability, and efficiency).²**
- **We make our findings based upon reasonable assurance of adequate protection of safety and security, as implemented in NRC requirements, and not on absolute certainty or total risk avoidance.**
- **We identify, elevate, and resolve process and organizational barriers that impede our ability to achieve effective and efficient licensing reviews and make decisions through a graded or risk-informed, performance-based approach where appropriate.**

The enclosure to this memorandum provides additional information to support a shared understanding of expectations on what constitutes “reasonable assurance of adequate protection.”³

This memorandum is also intended to foster an ongoing conversation on the principles, concepts, and approaches to becoming more risk-informed in our decision-making. As such, I encourage you to reach out to your division management and senior level advisors to further engage in discussions on these important topics. We will also be continuing with our series of related workshops and seminars, such as Tim McCartin’s recent seminar on risk-informing the high-level waste program (for which a video link will soon be available). These are opportunities to engage agency experts and your management. Furthermore, we need formal guidance to incorporate risk-informed decision making more fully and consistently into our work and achieve the cultural change necessary to become a modern, risk-informed regulator. I expect this to be achieved as we update, on a priority basis, our guidance for each type of licensing activity in the materials and waste business lines. In the interim, we need to leverage ongoing engagement by the Office of Nuclear Material Safety and Safeguards (NMSS) management team and discussions, through the above-mentioned workshops and seminars, to make progress in becoming a more modern and risk-informed regulator. Finally, I am asking the division directors to share this memorandum and its enclosure with our partner offices to ensure the vision and expectations for how we perform our work and make our decisions are consistent and fully integrated.

Thank you for your commitment to our mission and to achieving it through safety-focused, effective, and efficient approaches.

Enclosure: As stated

² ADAMS Accession No. [ML14135A076](#)

³ Another helpful perspective on adequate protection from a Commissioner’s perspective is captured in a March 2011 speech by former Commissioner Ostendorff, ADAMS Accession No. [ML110670377](#)

SUBJECT: KEY PRINCIPLES FOR NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
REVIEWS

DATE: January 15, 2019

ADAMS Accession Number: ML19015A290

***Via email**

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Additional Information on Reasonable Assurance of Adequate Protection

I. Background

The Atomic Energy Act of 1954, as amended (AEA), which authorizes and governs our work, neither specifies the precise level of safety the Commission must assure nor defines the factors the Commission may or should consider in defining the appropriate level of safety. Instead, the AEA gives the Commission broad discretion to weigh and balance factors, such as the state of the art of nuclear safety, accident risk, operating experience, and other factors, in reaching licensing decisions. Similarly, the AEA does not define “reasonable” or “adequate.” It does contain terms such as “adequate protection,” “unreasonable risk,” “minimize danger,” and “inimical.” Adequate protection generally focuses on radiological risk, with some exceptions.¹ The U.S. Nuclear Regulatory Commission (NRC) has historically inferred from these terms in the AEA that some level of risk is expected when it comes to activities involving the use of a radioactive source, and absolute protection is not required.

The NRC implements the relevant provisions of the AEA through regulations, and in legal cases challenging the agency’s application and interpretation of its regulations, the courts have agreed that absolute safety or zero risk is not required. Throughout our history, as technology has advanced, the courts have recognized the Commission’s broad discretion to balance the factors it deems relevant to determine what constitutes adequate protection in reaching licensing decisions. In addition, the courts have recognized that nuclear technology continues to change and advance and what constitutes “reasonable assurance of adequate protection” will also change as the state of the art of nuclear safety advances. The Commission retains the authority to establish the level of protection that it considers adequate and reasonable.

II. What reviewers are required to address in their licensing findings (adequate protection)

The legal standard for our licensing decisions is that we have reasonable assurance of adequate protection, as implemented in NRC regulations; not that all risk will be eliminated. Every regulatory review that we perform should start by ensuring that we have identified the regulations that are applicable to the specific application. Normally, it is necessary and sufficient for the licensee or applicant to show compliance with the specific language in the applicable regulations for us to make a finding of adequate protection. Guidance documents, such as Consolidated Guidance, Standard Review Plans, and Regulatory Guides, provide an acceptable way to meet a regulation (i.e., sufficiency), but they do not simply represent checklists for compliance, and conformance with guidance is not always necessary to demonstrate adequate protection or regulatory compliance. These guidance documents are not a substitute for the NRC’s regulations, and complete conformance with them, including any “acceptance criteria” that may be referenced in the subject documents, is not required to reach a finding that an applicable regulation is satisfied, or that ultimately, adequate protection has been demonstrated with reasonable assurance. Any finding or acceptance criterion discussed in a guidance document as being “necessary” to ensure adequate protection should be associated with a specific regulatory requirement. In summary, guidance documents provide structure and information on items to consider in reaching a finding of whether there is

¹ In the nuclear materials arena, the NRC does regulate chemical hazards under specified conditions, such as those conditions reflected in 10 CFR 70.62(c)(ii) and the associated performance requirements of 10 CFR 70.61. This arrangement is supported by a memorandum of understanding with the Occupational Safety and Health Administration. In addition, the NRC regulates certain non-radiological hazards associated with uranium milling.

reasonable assurance of adequate protection—that is, whether the approach described by the licensee or applicant in its licensing submittal will meet our regulations. They do not require a license reviewer to affirmatively find that the application satisfies each and every acceptance criterion.

In addition to guidance, a reviewer's technical expertise, knowledge, and judgment is critical to performing sufficient licensing reviews. If the staff identifies a situation where a regulation is not sufficient, a previous approach is no longer considered adequate to demonstrate that a regulation is met, or "acceptance criteria" in a guidance document are not properly linked to an applicable regulatory requirement, the staff should promptly engage their management to determine how best to resolve the matter. A backfitting evaluation or other structured approach may be appropriate to consider in these situations. The entire management team of NMSS is ready and willing to listen and help evaluate any concerns that the staff may identify with respect to the sufficiency of the regulations, adequacy of the guidance, or precedents relied upon in demonstrating the regulations are satisfied.

III. What reviewers spend time and effort on (reasonable assurance)

As described above, guidance documents are based on knowledge and experience gained through previous licensing reviews and operating experience and serve as a roadmap for conducting reviews. Because these documents are written to apply to a broad range of applications, they necessarily include information that may not be applicable to each individual application. The staff should continue to use guidance documents to provide structure for their reviews while being judicious in determining the relevant aspects of these documents to apply to a particular application. As each license application or amendment has the potential to present new and unique issues, the scope and depth of the staff's review should also be customized to reflect the specifics of the application. Furthermore, the scope and depth of review should be consistent with the principles of good regulation, specifically clarity, reliability, and efficiency. The staff should take advantage of pre-application meetings to determine the appropriate scope of review and should work with their management to define and document the appropriate review scope. Of course, the review scope may need to be adjusted during the review. The staff review scope and its bases are important aspects to document in the final staff evaluation.

The staff should consider the following principles in establishing the scope of its review, as well as performing and documenting the results of its licensing review. Likewise, all staff and managers should consider these principles in engaging with one another to ensure the licensing reviews are consistent with the NRC's principles of good regulation:

- Reviewers should interact with one another and the project manager when initially establishing the scope of their review and subsequently on a regular basis to ensure the review reflects a holistic, integrated approach to safety. Such a holistic, integrated approach may reveal aspects of the review that may be more or less significant than in a normal circumstance, justifying more or less scrutiny and effort, as appropriate. The level of detail required by the licensee or applicant and subsequently documented in the associated safety evaluation report for each item should depend on that item's significance in meeting applicable requirements, and its relative risk significance in informing the staff's determination of whether there is reasonable assurance of adequate protection.
- Reviewers should adjust the scope and depth of their review to reflect the stage of the licensing process. For example, in the review of a license renewal application, if the

staff concisely documents why its prior reasoning remains applicable to the renewal period, a detailed review of unchanged design features or of programs that were previously reviewed and approved, would typically not be needed. Instead, the staff should focus on the programs used to monitor and maintain these design features over the renewed license term, such as a program to address the impacts of aging on equipment. Likewise, new or unique aspects of an application that propose to prevent or mitigate a potentially significant hazard or risk should, at a minimum, be evaluated for reasonable proof of concept, and measures, such as operational testing and inspection requirements, should be identified that provide reasonable assurance that controls or programs will function as described and credited by the licensee or applicant.

- Reviewers should start their review by ensuring they are familiar with the objective and purpose of the applicable regulations. The Statement of Considerations for the applicable rule may provide valuable information on its overarching objective and purpose that may help further scope the licensing review.
- Reviewers should identify as early as possible if there are unique or complex aspects to the licensing review. Unique or complex aspects of a design or activity referenced in an application may require, in coordination with management, the Office of General Counsel, and potentially the Commission, special consideration about the best application of the existing regulatory framework.
- Reviewers should determine as early as possible if the information in the application is sufficient to make the necessary regulatory finding. Clarifications and validation of staff understanding can be obtained through multiple means, such as phone contacts, public meetings, or audits, and can be documented in meeting summaries, audit reports, and the safety evaluation report, consistent with Management Directive 3.53, "NRC Records and Document Management Program." Requests for additional information should be pursued if the submitted and docketed information is not sufficient for the staff to make a finding, and such requests should provide a clear regulatory basis for why the information is needed. Further, the project manager should work with the licensing reviewers in determining and communicating the NRC's expectations of an applicant in responding to a request for additional information.
- Reviewers should consider the relative margin to any applicable regulatory limits pertaining to the item under review. If the licensee or applicant has reasonably demonstrated that there is significant margin from the regulatory limits, then a detailed review of the item may not be warranted beyond confirming the adequacy of the licensee's or applicant's models, codes, and/or approach, including any key parameters and assumptions, used to demonstrate that significant margin exists. If there is little margin, a more detailed review may be justified to carefully consider the key parameters and assumptions, and independent confirmatory analyses will likely be appropriate. In each case, the reviewer's focus should be on the applicant's demonstration of meeting (or not meeting) the applicable requirements.
- Regulatory standards should already include the appropriate margin the Commission previously deemed necessary to provide for adequate protection. There is no requirement or expectation for additional margin beyond these regulatory standards, even if additional margin is reflected in any "acceptance criteria" contained within guidance documents. The licensee or applicant incurs operational risks if it does not

provide sufficient operational margin. If on the other hand, the reviewer determines that the licensee's or applicant's proposed method for demonstrating compliance with a standard, as described in its application, does not adequately demonstrate such compliance, or does not provide for reasonable assurance of adequate protection, then the reviewer should promptly engage the project manager to determine the most appropriate approach for resolving the issue.

- Many review findings are associated with, or predicated on, the licensee or applicant properly implementing various management controls or programs that are identified as license conditions or are separately required by the regulations (e.g., Title 10 of the *Code of Federal Regulations* (10 CFR) 61.25, 10 CFR 70.72, 10 CFR 72.48, 10 CFR 20.1101(b)). After determining that the licensee's or applicant's program meets the regulatory requirement(s), the staff should give appropriate credit to the implementation of these programs as part of their review. Reviewers should also use existing information, for example from operating experience or other Federal government reviews, to support their independent findings on the sufficiency of the application.
- Reviewers should continue to improve the clarity and efficiency of their evaluations by making them more succinct and more focused on the information necessary to support the regulatory findings and conclusions. The evaluation should identify the relevant regulations, the appropriate acceptance criteria, and the basis for the staff's conclusion that the relevant requirements are or are not met. Recounting review activities, such as the back and forth of requests for additional information, is not necessary.