

August 29, 2018

MEMORANDUM TO: New Reactor Business Line

FROM: Frederick Brown, Director /RA/
Office of New Reactors

SUBJECT: EXPECTATIONS FOR NEW REACTOR REVIEWS

I laid out my expectations for how we would execute the Office of New Reactor's mission statement¹ in January this year at an Office of New Reactors (NRO) all-hands meeting. Since that time, I've met with each branch within the office, and worked closely with a number of staff on challenging technical issues. In those interactions, I've reinforced the same expectations. Generally, I think that we are making excellent progress in executing our mission.

The purpose of this memorandum is to both more formally document my expectations for ease of reference, and also to share these expectations with staff in partner offices who perform work in the New Reactor Business Line.

My expectations for New Reactor work are:

- We will operate in a manner consistent with the U.S. Nuclear Regulatory Commission's (NRC's) Principles of Good Regulation (Independence, Clarity, Openness, Reliability, and Efficiency)².
- We will make our findings based upon the principle of "Reasonable Assurance of Adequate Protection"³, not on absolute certainty or risk avoidance.
- When we encounter process and organizational barriers that impede our ability to achieve effectiveness and efficiency (also referred to as achieving modern, risk-informed regulation), each of us needs to identify these barriers. The management team and staff must work to remove the barriers to support the success of the Office and the agency.

Understanding that these expectations can be a challenge to apply without further explanation, the NRO management team has put together the following additional description of how to apply the concepts that these expectations embody.

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¹ "The Office of New Reactors serves the public interest by enabling the safe, secure, and environmentally responsible use of nuclear power in meeting the nation's future energy needs."

² <https://www.nrc.gov/docs/ML1413/ML14135A076.pdf>

³ The slides that I used to discuss this concept at the NRO all-hands meeting in January 2018 are attached to this memorandum.

I. What we are required to address in our licensing findings (adequate protection):

The legal standard for our licensing decisions is that we have reasonable assurance of adequate protection - not the elimination of all risk. We worked with our colleagues in the Office of the General Counsel (OGC) to provide the legal perspective on the “reasonable assurance of adequate protection” standard and how that standard applies to new reactors and advanced technology. The legal discussion is provided at the end of this Memorandum.

Every regulatory review that we perform should start with ensuring that we have identified the regulations that are applicable for a given application. Normally, it is both necessary and sufficient for an application to show compliance with the specific language in the applicable regulations for us to make a finding of adequate protection. Regulatory Guides provide an acceptable way to meet a regulation (sufficiency), but they do not represent checklists for compliance, and satisfying the contents of a guidance document is not necessary.

NUREG-0800, “Standard Review Plan” (SRP) and, to a large extent, the Design Specific Review Standard (DSRS) for NuScale, provide information to reviewers evaluating license and license amendment applications. The SRP and DSRS are not a substitute for the NRC’s regulations, and compliance with them, including specifically the “acceptance criteria” (which in some cases go beyond the regulatory requirements) is not required per se. Furthermore, the SRP and DSRS do not create the need for findings beyond the finding that the underlying regulation is satisfied. Remember that if any technical issue described in the SRP and DSRS was necessary for adequate protection, it would have been addressed in a requirement (usually in an order or regulation) – not only in a guidance document. In summary, the SRP and DSRS provide structure and information on areas to consider in reaching a finding on whether the regulations will be satisfied, but they do not create the need for individual findings or assessments for every item listed in those guidance documents for each application.

It is very important to understand that we rely on your technical expertise and knowledge to help identify those unusual cases where compliance with the regulations may not be sufficient to achieve adequate protection. These cases would be associated with a new or novel design or design feature that differs significantly from designs reviewed in the past. However, just being different does not justify additional requirements. Only a case-specific, demonstrably increased likelihood or consequence of failure, is likely to justify new requirements or approaches to existing requirements. If you identify a case-specific situation where a regulation does not appear to sufficiently address a unique situation, or a novel case where previous methods of meeting a regulation might not be adequate, please start an immediate engagement with your management team and OGC to align on the best path forward. I’m heartened by the safety consciousness that I see being demonstrated in this area.

With respect to removing barriers, we are launching a review and restructuring of the SRP in the coming months, including verifying that any identified “findings” or “acceptance criteria” are specifically tied to the applicable regulatory requirements.⁴ The entire management team of NRO and your colleagues in OGC are ready and willing to help evaluate any concerns that you may find with respect to the adequacy of guidance/precedent in satisfying the regulations or the sufficiency of the regulations themselves.

⁴ See the Enclosure to SECY-11-0024 for illustration of the philosophical approach to this revision.

II. What we spend time and effort on (reasonable assurance):

As described above, the SRP, and to some extent the DSRS for NuScale, act as a repository for knowledge and experience gained through previous reviews and operating experience, and serve as our roadmap in conducting reviews. Because the SRP is written to apply to a broad array of applications, it necessarily includes information that may not be applicable to each individual application. We should continue to look to the SRP or DSRS to provide structure for our reviews, but we need to be judicious in determining the particular aspects of the SRP to utilize for a particular application. For instance, the SRP states: "Because the staff's review constitutes an independent audit of the applicant's analysis, the staff may emphasize or de-emphasize particular aspects of an SRP section, as appropriate, for the application being reviewed." As each application presents new and unique issues, the scope and depth of NRC's review should also be customized to reflect the specifics of the particular application. It would not be consistent with the Clarity, Reliability, and Efficiency principles if we did an in-depth review of every aspect of the SRP/DSRS for every license application. Staff should use pre-application engagement to scope the necessary reviews for each application, and should work with their management to define and document the appropriate review scope. That scope may be adjusted during the review as appropriate to the circumstances, and the review scope and its bases should be documented in the safety evaluation.

You should consider the following in establishing the scope of your review, and should expect that your peers and managers will use the same evaluation criteria in engaging with you:

- Did you start your review familiarization and scope evaluation by verifying the purpose and objective of the regulatory requirement(s) (as documented in the Statements of Consideration for the applicable rules(s)) that apply to the design or design features you are reviewing? New and unique designs may have characteristics that require, in coordination with management, OGC, and potentially the Commission, special handling to fit within the Commission's regulatory framework.
- Have you ensured that your review area has been coordinated with other review disciplines to ensure a holistic look at safety? An aspect of a design can be more or less risk significant than "normal," justifying more or less scrutiny than "normal." This should be considered in setting the review-specific scope. See the SRP Review Matrix (ML17306A134) for assistance in coordinating your scoping activities.
- Is your review appropriate for the stage of the licensing process? Doing in-depth reviews of parts of a Design Certification application that require site-specific parameters or values may not be necessary or efficient where there is no concurrent review of a combined license or early site permit application that references the design. New and unique design features that have significant risk worth should, as a minimum, be evaluated for reasonable proof of concept at the Design Certification stage and have Inspections, Tests, Analysis, and Acceptance Criteria and operational test and inspection requirements identified to ensure reasonable assurance that they will function as described if called upon.
- Is the information in the application sufficient to make the necessary regulatory finding? Cases where you are unsure should be discussed with your management team. If so, requests for additional information (RAIs) are not necessary. Clarifications and validation of your understanding can be obtained through phone contacts, public meetings, or audits, and can be documented in meeting summaries, audit reports, and the safety evaluation, consistent with Management Directive 3.53, "NRC Records and Document Management Program."

- During the course of your review, consider how much margin exists in the design. If the application reasonably demonstrates that there is significant margin from regulatory limits, then it should not be necessary to ask for or review detailed information that would have only a small impact on the available margin. If there is very little margin, it will be important to carefully consider the key parameters and more review and some independent confirmatory analysis will likely be appropriate.
- Regulatory limits are the requirement, and already include the margin (before a consequence such as failure) that was considered necessary by the Commission for adequate protection. There is no regulatory requirement for additional margin beyond regulatory limits, even if referenced in SRP “acceptance criteria.” The applicant/licensee will be accepting the risk of non-compliance or operational restrictions if they provide too little “operational margin” in their design.
- Every finding associated with issuing a license, permit, or design certification is predicated on compliant construction and operation. This compliance is associated with both the provisions of the license and the applicable regulations. Your review should give credit for the expected compliance with operational phase programs (Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, 10 CFR 20.1101(b)) that are required by conditions of the license or the regulations.

One area where we can continue to improve efficiency, and remove burden from reviewers in the process, is in making our safety evaluations more succinct. Evaluations should only include the information necessary to support our safety findings. This includes identifying the relevant regulations and acceptance criteria and providing a concise basis for your conclusion that the applicable requirement(s) is(are) met. Recounting activities, including the back and forth of RAIs, is not necessary. Recent training on Backfit and Finality also provided insight into the importance of clearly stating the basis for our findings. Streamlining our safety evaluation reports so they focus on why we reached our conclusion keeps us focused on the most safety significant issues while being timely.

With respect to removing barriers, part of the upcoming review and restructuring of the SRP will be to address each of the above items, providing additional clarification where possible. In addition, further work is anticipated on providing examples of high quality, succinct safety evaluations.

III. Legal Analysis:

The Atomic Energy Act of 1954, as amended, which authorizes and governs our work, does not specify the precise level of safety the Commission must assure or define 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, the risk of accidents, the record of past performance, and the need for further improvement in nuclear safety, along with other matters, in reaching licensing decisions.

Similarly, the AEA does not define “reasonable” or “adequate.” It does, however, contain language such as “adequate protection,” “unreasonable risk,” “minimize danger,” and “inimical.” “Adequate protection” focuses rather narrowly on radiological risk, and not on something broader. Looking at these terms to try to determine what “reasonable assurance” means, the NRC has historically inferred from these words that some risks may be tolerated and something less than absolute protection is required.

The NRC implements the AEA through its regulations, and in cases challenging the agency's application and interpretation of its regulations, courts have agreed that absolute safety or zero risk is not required. Throughout our history, as technology has advanced, courts have recognized the Commission's broad discretion to balance the factors it deems relevant to determine what level of protection is adequate and reasonable in reaching licensing decisions. In addition, courts, including the U.S. Supreme Court, 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 is adequate and reasonable.

Adequate Protection (AEA of 1954 as Amended)

- **Sec. 182. License Applications**

The content of a license application shall contain such information as the “Commission may, **by rule or regulation**, deem necessary in order to enable it to find that the utilization or production of special nuclear material will be in accord with the common defense and security and will provide **adequate protection** to the health and safety of the public.”

Reasonable Assurance (AEA of 1954 as Amended)

- **Sec. 185b Construction Permits and Op. Lic.**

the Commission shall issue to the applicant a combined construction and operating license if the application contains sufficient information to support the issuance of a combined license and the Commission determines

that there is **reasonable assurance** that the facility will be constructed and will operate in conformity with the license, the provisions of this Act, and the Commission’s rules and regulations.

Reasonable Assurance of Adequate Protection (10 CFR Part 52)

- Section 52.97(a)(1)(iii) provides that:
...after the hearing and the report by the ACRS, the Commission may issue a combined license if it finds that “[t]here is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission’s regulations.”

Reasonable Assurance of Adequate Protection (Fred’s thoughts)

- Adequate Protection – generally established by conformance to NRC Regulations
 - The history of Part 20’s Radiation Protection Standards provides interesting insight into how the Commission can go about establishing Adequate Protection
- Reasonable Assurance – confidence based on a reasonable review.
 - Not an absolute assurance or guarantee

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