NEI Licensing Forum
Remarks By:
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Licensing Issues Topics

- Change Control Processes
- Role of the Regulator
- Establishing Standards
- Changing Standards
- Public Involvement

The program NEI prepared for this forum listed three particular issues which almost everyone would recognize as "hot topics" in the world of reactor licensing: GL 91-18 operability guidance, worker fatigue, and the interpretation of the Commission's 1996 "Perry Decision." These issues reflect different aspects of the regulatory processes which the NRC relies on to fulfill its mission, so I thought it would be useful to discuss these issues in process terms, reflecting on the processes that control changes to safety requirements for nuclear power plants. In order to properly describe how the processes are implemented, it is important to understand roles and responsibilities, the manner by which safety standards are defined and changed, and the relationship between the regulator's responsibility to define and defend safety standards and the means by which we provide our customers an opportunity for involvement in those decisions. Our customers are the public - we are, after all, public servants - and nuclear power plant owners, operators and staff are the largest public group who are affected by ... and interested in ... our regulations.

Change Control Processes

- Legislation
- Rulemaking
- Guides & Standards
- License Amendments
- Plant Procedures

The basic hierarchy of the regulatory processes is:
(1) Legislation is the means by which the Congress can direct the NRC to impose or change certain requirements on our applicants and licensees.
(2) Rulemaking is the process that federal agencies use to establish and change the specific requirements in the Code of Federal Regulations, which each agency establishes to fulfill it's statutory responsibilities - for the NRC the regulations are promulgated in Title 10. All regulations must meet the requirements of the Administrative Procedures Act.

(3) Guidance are reference materials developed in a technical process which is intended to articulate at least one acceptable way to satisfy the requirements of regulations and law - whether the NRC practice of issuing Reg Guides, the Standard Review Plan, Inspection Guidance, Branch Technical Positions, Review Standards, and Office Instructions, or the more general practice of developing and applying consensus codes and standards within particular industries.
(4) License Amendments are the means by which plant-specific safety requirements can be changed - the Atomic Energy Act provides in Section 187 that "the terms and conditions of all licenses shall be subject to amendment, revision, or modification, by reason of amendments of this Act, or by reason of rules and regulations issued in accordance with the terms of this Act."
(5) Plant Procedures are the means by which plant owners and operators exercise control over the manner by which the plant staff will perform its functions, and satisfy the plethora of laws, regulations, codes, standards, and practices which are applicable to the industry and jurisdiction that the plant serves.

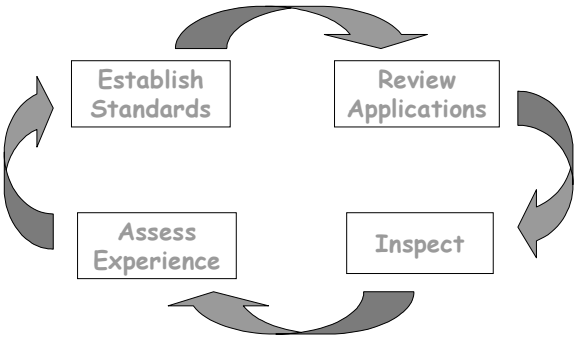
Each of these processes have controls to manage changes. NEI requested that we speak to *"the interpretation of the Commission's 1996 Perry decision*." I am not going to attempt to explain the *interpretation* of the Perry decision; only the NRC's General Counsel can interpret the regulations. I can, however, and will ... describe a licensing engineers' view of the appropriate thresholds for license amendments and regulatory approvals.

The controversies associated with the imposition of working hour limits to address fatigue involve the standards by which the NRC defines the regulatory benefits of a proposed rule, which I can discuss in terms of the ways in which the NRC can achieve it's performance goals.

The controversies associated with the operability guidance in the inspection manual involve the role of the regulator in a plant management decision process, which I can discuss in terms of the roles and responsibilities of the regulator and the plant operator.

These three issues cover the range of regulatory processes and, therefore, will be useful in illustrating the regulatory processes and objectives from the engineering practitioner's perspective.

Role of the Regulator



The regulator is responsible for defining safety requirements that will ensure that there is reasonable assurance that public health and safety are adequately protected.

The plant operator is responsible for establishing procedures and practices that will fulfill the safety requirements, consistent with the regulations, license conditions, orders, technical specifications, and licensing basis.

The regulator verifies compliance with the regulations, license conditions, orders, technical specifications, and licensing basis through a system of inspections.

The regulator assesses the experience from the inspection program, including an evaluation of operating experience and plant performance, to determine the effectiveness of the safety standards and develop changes to those standards when appropriate.

Establishing Standards

- Rulemaking
- Reliance on consensus standards
- Demonstrating safety margins
- Flexibility versus specificity
- Performance-based requirements

In the modern regulatory world, the regulatory activities strive to be risk-informed and performance-based, because we have learned that resources are more efficiently used and the public interests are more effectively served when the risk insights are applied to define safety standards and when performance criteria replace prescriptive criteria. These principles apply to all regulated activities, not just nuclear regulation.

Common safety standards - that is, generic safety requirements - are established through rulemaking. Ideally, all safety requirements should be codified and enforced through a system of rules. The National Technology Transfer and Advancement Act of 1995 requires that federal agencies place greater reliance on voluntary consensus standards to avoid unnecessarily duplication of effort. However, the federal agencies still have to determine that the use of such standards fulfills the regulatory purpose and, where appropriate, voluntary consensus standards may be augmented by regulatory requirements where necessary to achieve the regulatory purpose.

The rulemaking process includes features for performing a regulatory analysis to establish the value of the rules. This includes the means to decide which new requirements should be backfit on existing license requirements. The process has evolved in a way that provides a fairly straightforward way to measure safety - $2000 per person-rem averted - and information collection requirements in terms of the paperwork reduction requirements. However, measures for the other NRC performance goals are not so well defined, particularly public confidence.

This performance measures issue is evident in the controversy over the proposed worker fatigue rule. Clearly, rulemaking is the appropriate process to resolve whether and how requirements should be imposed on the amount of overtime that could lead to impairment of nuclear power plant workers. While rulemaking will provide an opportunity for open public comment on the need for and implementation of overtime limits for workers at nuclear power plants, in the interim, the regulator is still expected to be clear about the basis for changing technical specifications requirements for overtime through license amendments and still expected to provide guidance for the treatment of marginal cases like the employee protection issues described in RIS 2002-07.

Many safety requirements for nuclear power plants have to be established on a plant specific basis because of the complexity of the plants and the degree to which individual licensees desire flexibility in the design and operation. The process of establishing safety requirements would be much simpler if we could establish the requirements in the regulations with great specificity that could be applied readily to all plants. Such ideal safety requirements would be perfectly clear and specific regulations. If we could achieve such perfect regulations, we would not need plant-specific license requirements or license amendments or regulatory guidance. Compliance would be self-evident.

However, such perfectly clear regulatory requirements tend to be very prescriptive; thus, allowing little latitude for individual licensees to be different. Over time it has been demonstrated that performance based requirements - that is, a safety standard that described a desired outcome rather than a conditional state - is much more effective and efficient. It is

much harder to establish and measure performance-based requirements. Performance-based requirements tend to create a greater need for interpretation and implementation guidance.

Changing Standards

- Legislative mandates
- Technology improvements
- Operating experience
- Design changes
- NRC Approval versus Oversight

The processes for changing safety requirements consist of legislation, rule changes, license amendments, updating regulatory guidance that may impact the understanding of compliance, and revising the regulator's oversight practices. While we would all like a stable and predictable set of clear regulatory requirements ... *change happens*!

The most straightforward way to change regulatory requirements is through legislation. However, this approach is also more difficult to plan and predict. Moreover, legislation is probably not the best way to define safety requirements but it is a better way to establish public policies and clarify the role of the federal regulator.

We want to encourage licensees to adopt improvements in technology, but we should not necessarily require such improvements. That policy is at the heart of the need for a backfitting standard.

Similarly, operating experience identifies issues that must be resolved so that plant safety is maintained. In such cases, the regulatory requirements may need to be revised. In the majority of cases, operating experience identifies ways to improve performance at a level of detail that is reflected in plant procedures rather than license conditions or technical specifications. That explains why the NRC issues far more Regulatory Information Summaries than Bulletins and Orders.

Experience implementing and enforcing regulations and license conditions also causes the need for guidance. Guidance can take the form of the Standard Review Plan the describes the expected manner by which NRC reviewers should judge license applications, Inspection Guidance - Section 9900 of the Inspection Manual for example, or a Regulatory Information Summary. Such guidance is intended to illustrate ... "one acceptable way to satisfy the requirements." Generic Letter 91-18 was spawned from such a collection of anecdotal cases of operability questions ranging from the sublime to the bizarre. It was intended to present, in a constructive way, a collection of examples to <u>illustrate</u> how to decide whether and how continued operation is justified in the face of degraded equipment or plant conditions, the

nature and considerations of prompt and effective corrective actions under Criterion 16 of Appendix B and, finally, the administration of those pesky reporting requirements in §50.72 & 73.

Regulatory guidance constantly suffers from a mistaken role - it attempts to describe one acceptable way to satisfy the regulatory requirements as a means of illustrating the regulator's expectations, but it is often mistaken for the only way. As such, the guidance is criticized because it does not have all the answers. I suppose that I should not be surprised that - a dozen years after the tech spec folks developed GL 91-18 to describe how operability decisions should be made - there is still a demand for more operability guidance. The plant operator has to make operability and compliance decisions constantly and there will always be a demand for more guidance because those are hard decisions to make. The regulator doesn't make those decisions - the regulator is required to pass a judgement on whether those decisions are right or wrong. Some industrious entrepreneur could make a fortune with a website that would charge a small fee to search operability case studies, enforcement actions, event reports, §50.59 decisions, inspection follow-up issues, and responses to inspection questions. Some less ambitious entrepreneurs provide some of this capability and make very comfortable incomes.

In my view, the greatest cause of changes in safety requirements is the licensees' need to change the licensing basis because the design is changed, corrective actions have been taken, the technology has advanced, or the license conditions are unnecessarily burdensome. As I described at the beginning of this presentation, Section 187 of the Atomic Energy Act anticipated that licenses would need to be amended, and Section 189 of the Act describes the provisions for hearings and judicial review which are part of the process by which the public can be involved in the licensing process and licensing decisions could be challenged in a formal and predictable way. Ironically, plant operators do everything they can to avoid license amendments that offer an opportunity for public intervention because the time and cost of hearings are so unpredictable.

The manner by which the regulatory requirements should evolve - even in risk-informed and performance-based enlightened regulatory environment - depends on a clear understanding of whether the regulator needs to establish safety requirements and verify compliance - which applies to either prescriptive or performance criteria - or whether the regulator can better serve the public interest in an oversight capacity and react to performance results, so that the regulatory requirements can be simplified.

Public Involvement

- Legislation
- Rulemaking

- License Amendments §50.90
  - §50.59 Threshold
- §2.206 Petitions

The regulator's role is defined primarily by the legislative mandate rather than by process attributes and objectives. Congress and the Administration have much higher expectations for those agencies that protect against risks that have broad public impact and interest. It should not surprise you that the Congress and the Administration consider nuclear power to be a topic of broad public impact and interest.

As I previously explained, the most effective means to establish regulatory requirements is through the rulemaking process. That is also the most effective way to involve the public interests because they can comment directly on the proposed requirements and their interests can be explained in the record developed in the rulemaking process. However, I also explained that even in the best attempts to define safety requirements in rules, much of the implementation detail is left to plant specific applications.

Regardless of whether you favor or oppose public involvement through formal hearings, the appropriate threshold for deciding whether a license amendment is warranted is fairly simple - any change to the safety requirements in a license that warrant NRC review and approval, may be an appropriate circumstance to invoke §50.90 and offer the public an opportunity to intervene if their interests fulfill the requirements for intervention. Having said that, it is also appropriate to ask whether the regulator needs to be involved in approving the change. The Commission's 1996 Perry decision related to the capsule withdrawal schedule is only one example of a decision related to the need for regulatory approval of a change in the licensing basis. There are many more - and many better - examples in the development of the improved standard technical specifications and the guidance for implementing §50.59. In fact, the requirements of §50.59 are specifically designed to explain the appropriate threshold for a license amendment and, given the substantial investment in the recent changes to §50.59 and the industry efforts to develop much more detailed implementation guidance, it's not clear whether the standard for license amendments is really that unclear or whether the Perry case is that germane to the threshold debate - a debate that will likely continue.

Ideally, the regulations should define safety requirements so that they can be fulfilled without the need for plant-specific regulatory decisions. It is clear in the regulations that a change to the license conditions or the technical specifications warrant a license amendment under §50.90. Congress dictated in the Atomic Energy Act that technical specifications are part of the license and changes to the technical specifications would be accomplished by license amendments. The threshold described in §50.59 defines other changes to the licensing basis that would warrant a license amendment under §50.90. That concept was used to develop the

administrative control for changes to the technical specification bases, so that certain details in the technical specifications could be relocated to the bases.

The public interest would probably be better served if more regulatory requirements were established through rulemaking. However, the public and industry seem to avoid that process because of the time and effort involved. The rulemaking process can be substantially improved by separating the developmental work - rulemaking should be limited to whether a safety requirement is justified and how it should be codified, not research work to figure out how fuel should be designed.

Like licensees, the public interests seem to be more involved in plant-specific actions, as served by §2.206 process which provides that anyone can petition the NRC to take a plant specific action if they can demonstrate that a need exists for public health and safety, common defense and security or protection of the environment. The public doesn't seem too happy with the §2.206 process, but they may be using the same performance requirements for §2.206 that plant operators use to judge the operability guidance.

That completes my reflections on processes and regulatory values. Are there any questions?