

Toward an Effective CRGR

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Agenda

- Common Goals
- Backfitting and CRGR
- Why change is needed
- What does an effective CRGR look like?
- Recommendations

We share Common Regulatory Goals

NRC Strategic Plan:

- Safety
- Security
- Openness
- Effectiveness
- Excellence

Industry would add Predictability and Stability

Stability and Predictability

- One of the most important themes I have been stressing is the need for the NRC to be a strong, credible, and consistent regulator. No less a figure than James Madison addressed this subject in the Federalist Papers — that famous series of essays which serve as a kind of “user’s manual” for the Constitution. Madison explained that stability and predictability in the law would, quote, “inspire a general prudence and industry, and give a regular course to the business of society.”

Chairman Klein at 2007 Regulatory Information Conference

NRC Backfitting Rule

- Backfitting is the:
modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position...

Backfitting Rule Exceptions

- Compliance Exception
 - Modification is necessary to bring a facility into compliance with a license or the rules and orders of the Commission or into conformance with written commitments of the licensee;
- Adequate Protection Exception
 - Regulatory action is necessary to ensure that the facility provides adequate protection to the public health and safety; and
- Cost-Justified With Substantial Safety Increase Exception
 - Regulatory action involves defining or redefining the level of adequate protection for the public health and safety

From the 10 CFR 50.109 Statements of Consideration:

"The compliance exemption is intended to address situations in which the licensee has failed to meet known and established standards of the Commission because of omission or mistake of fact. It should be noted that new or modified interpretations of what constitutes compliance would not fall within the exception and would require a backfit analysis and application of the standard."

50FR38097 9/20/1985



Regulatory Analysis is Key to Good Decisionmaking

- “The regulatory analysis process is intended to be an integral part of the NRC’s decisionmaking that systematically provides complete disclosure of the relevant information supporting a regulatory decision.”
- “NRC intends to ensure that its decisions that impose regulatory burdens on licensees are based on adequate information regarding values and impacts associated with a reasonable set of alternatives, and to follow a systematic and disciplined process that is also open and transparent in arriving at decisions.”

NUREG/BR-0058 Rev 4, Regulatory Analysis Guidelines



CRGR Charter

“The [CRGR] **will ensure** that proposed generic backfits to be imposed on the NRC-licensed power reactor and selected materials licensees are appropriately justified based on backfit provisions of applicable regulations and the Commission’s backfit policy. The CRGR’s **primary responsibilities** are **to recommend** to the [NRC EDO] **either approval or disapproval** of the staff proposals and **to provide guidance and assistance** to the NRC program offices to help them implement the Commission's backfit policy.”

CRGR Charter also requires:

- Ensuring licensees are informed of the existence and structure of the generic backfit management program, and that substantive changes are communicated to all licensees and certificates.
- Reviewing all new and revised regulatory requirements, generic correspondence, regulatory guidance, and selected staff guidance related to licensing, inspection, and enforcement, which could impose a backfit.

CRGR Charter also requires:

- Focusing on administrative controls for generic backfit practices (in particular, office and regional directives, procedures, and staff guidance and technical staff training in NRR, NMSS, and the Regions). Ensures guidance on backfits is clear and comprehensive.
- As part of its regulatory effectiveness responsibility for monitoring effectiveness of the NRC's generic backfit management process, CRGR will periodically visit licensed facilities, and hold periodic meetings with stakeholders, as appropriate, and perform special tasks at the EDO's request.

Why Change is Needed


- CRGR is critically important to NRC regulatory decision making, but its role has diminished
- Many new people are entering the NRC and industry and do not understand the requirements for backfitting and regulatory analysis
- Loss of “regulator historians” (initial policy makers)
- Informal backfitting occurs outside CRGR purview
- Desire to improve regulatory positions trumps backfit requirements

Why Change is Needed

- Staff often has a broad interpretation of exceptions – especially compliance
- New interpretations and positions are imposed on individual licensees in inspections, license amendments, license renewal
- Some proposals brought before CRGR do not pass the backfit test, but are approved anyway
- Industry has lost confidence in the NRC's ability to implement the backfitting rule correctly

What Does an effective CRGR look like?

- CRGR is recognized as the Regulator of the Regulator
- Appropriate scope of review
- Credible, robust reviews
- Clear expectations the staff is following
- Demanding review of exceptions
- Demanding review of regulatory analyses
- Stakeholders actively engaged
- Documented, publicly-available information that supports regulatory decisionmaking

 Transparent and consistent decisions

Recommendations

- Self Assessment
- CRGR should set expectations for NRC staff
- A more open process
- When does the backfit rule apply?
- Plant specific backfits

Self Assessment

- Critical to improvement
- Consider third party to conduct, e.g., former CRGR members, retired senior NRC managers, consultant
- Review history, SOC of backfitting rule, etc.
- Select recent packages to assess
- Engage stakeholders; assess frequency and significance of backfitting outside CRGR purview
- Solicit stakeholder comments in Federal Register
- Develop recommendations for improvement and implement

CRGR Should Set Expectations for NRC Staff

- Insist on quality packages and presentations
- Inadequate backfitting and regulatory analysis should not be accepted
- Can the regulatory analysis process be improved?
- Could risk analysis inform generic communications or other regulatory processes?
- Workshop and training on expectations
- Accountability and consequences
- Expectations also need to be set and actions sampled for other staff guidance related to licensing actions and inspections which could impose a backfit.

A More Open Process: Engagement and Transparency

- Allow greater stakeholder involvement
- ACRS model (open and closed sessions)
- How are public comments represented?
- Basis documents made available; consider dedicated web page
- Opportunity for licensees to appeal to CRGR reviewer/inspector interpretation of generic issues
- Annual public meeting/workshop
- Visit plants and obtain first hand input

When Does the Backfit Rule Apply?

- Many new people in NRC and industry
- Common understanding lacking
- Regulation – Review -- CLB
- Must address inappropriate use of backfit analysis avoidance techniques
- Conduct an NRC/stakeholder workshop
- Follow-up with training
- Routine assessment of performance

CRGR Role in Plant Specific Cases

- Licensees are reluctant to challenge individual reviewers and inspectors
- Not a current responsibility for CRGR
- Expand role to act as ombudsman/ FAQ process
- Enhance monitoring of staff training and implementation of requirements regarding plant specific backfitting

In Conclusion

- Licensees and NRC are both focused on safety
- Regulator expects licensees to rigorously follow requirements; we expect the same from the NRC
- CRGR must take a strong leadership role and be the champion for the integrity of the backfitting rule
- Need to engage stakeholders to work together to meet common goals