

NRC Backfitting and Regulatory Analysis: Practices and Perspectives in 2009

Geary Mizuno – NRC Office of the General Counsel

Brian Richter – NRC Office of Nuclear Reactor Regulation

2-19-2009 draft



What is backfitting, and why does the NRC have a Backfit Rule?

- Backfitting:
 - Change in agency position

- Backfit Rule Purpose:
 - Don't change the rules after the game has started.

2

Purpose of Backfit Rule

- Regulatory stability

- Reasoned and informed agency decisionmaking

- Transparency of agency decisionmaking

3

NRC Backfitting requirements

- 10 CFR 50.109 power reactors
- 10 CFR 70.76 Subpart H requirements
- 10 CFR 72.62 ISFSI
- 10 CFR 76.76 GDF
- Part 52 power reactors

4

Regulatory History of Backfit Rule

- 1970
 - Final Rule 35 FR 5317 (March 31, 1970)
 - Proposed Rule 34 FR 6540 (April 16, 1969)
- 1985
 - Final Rule 50 FR 38097 (September 20, 1985)
 - Proposed Rule 49 FR 47034 (November 30, 1984)
 - ANPR/Policy Statement 48 FR 44217 (September 28, 1983)
- 1988
 - Final Rule 53 FR 20603 (June 6, 1988)
 - Proposed Rule 52 FR 34223 (September 10, 1987)

5

When Must the NRC Prepare a Backfit Analysis?

- Three steps to NRC's decision:
 - Is the proposed NRC action a "backfit"?
 - Do one or more exceptions to preparation of a backfit analysis apply?
 - Does the backfit represent a substantial increase in protection to public health and safety or common defense and security whose costs are justified in light of this increased protection?

6

First Step:
Is there a backfit?

Backfitting is defined in 50.109(a)(1)

7

First Step:
Is there a backfit? (continued)

- **Modification or addition to SSC, design or procedures**
- **New or amended rule or staff position** interpreting Commission rules
- **New or different** from a previously applicable rule or staff position
- **Imposed** on licensee
- **Occurring after an NRC approval** as designated in 50.109(a)(1)(i) through (viii)

8

First Step:
Is there a backfit? (continued)

- “Imposed” means “legally binding”
- Legally binding NRC agency actions are:
 - Licenses and technical specifications (licenses are, legally speaking, “orders”
 - Rules, other than “interpretive rules”
 - Orders

9

First Step:

Is there a backfit? (*continued*)

- NRC regulatory action may raise “backfitting policy concerns” even if not constituting “backfitting” subject to the Backfit Rule
 - Corollary: NRC must be sensitive to “backfitting policy concerns” and be ready to address them when responding to external stakeholders.

10

Second Step:

Do one of the exceptions in 50.109(a)(4) apply?

- Compliance
 - 50.109(a)(4)(i)
- Necessary for adequate protection
 - 50.109(a)(4)(ii)
- Defining or redefining what is needed for adequate protection
 - 50.109(a)(4)(iii)

11

Second Step:

Do one of the exceptions in 50.109(a)(4) apply?
(*continued*)

- A “documented evaluation” must be prepared to support the reliance on one or more of the 50.109(a)(4) exceptions
- Oftentimes, the documented evaluation is combined with the justification required by 10 CFR 50.54(f) for information requests needed to assess compliance with the current licensing basis of a facility

12

Third Step, part 1:
Does the backfit provide substantial increase in protection to public health and safety or common defense and security?

- Consider factors in 50.109(c)(1) through (9)
- Qualitative consideration of benefits also permissible, to account for non-quantifiable (or difficult to quantify) benefits
 - June 30, 1993 SRM on SECY-93-086

13

Third Step, part 2:
Is the cost of the backfit justified in light of the increase in protection?

- Consider factors in 50.109(c)(1) through (9)
- Traditional cost/benefit analysis in Regulatory Analysis will satisfy requirement
- Consider non-quantifiable costs
 - Consistent with June 30, 1993 SRM on consideration of non-quantifiable benefits

14

Special Backfitting Provisions for Part 52

- Part 52 contains special issue resolution and backfitting provisions applicable to early site permits, standard design certification rules, and combined licenses.
- 3 separate, but analogous provisions on backfitting:
 - ESP - Section 52.39
 - DCR - Section 52.63
 - COL - Section 52.98
 - References 50.109 as basic backfitting protection
 - Adds reference to 52.103 for special, post-COL issuance ITAAC changes
 - Clarifies backfitting protection when COL references a ESP and/or a DCR

15

**Special Backfitting Provisions for Part 52
(continued)**

- DCRs have special backfitting aspect – all changes are “flowed” to every application and license referencing the DCR, under Section 52.63(a)(3)

16

**Special Backfitting Provisions for Part 52
(continued)**

- In the course of Part 52 update rulemaking, DCR applicants (vendors) requested additional flexibility to change the DCRs themselves without being subject to the special backfitting restrictions in Section 52.63
 - New technology, e.g. I&C
 - New methodologies
 - Correction of errors
 - Greater efficiencies, reduction of unnecessary margin

17

**Special Backfitting Provisions for Part 52
(continued)**

- New criteria added to Section 52.63 for changes to DCRs
 - Unnecessary regulatory burden
 - Provides detailed design information which are directed at certification information
 - Correct material errors in the certification information
 - Substantially increases overall safety, reliability or security, and the direct and indirect costs of implementation are justified
 - Contributes to increased standardization of the certification information

18

Nexus between Backfit and Regulatory Analyses

“Certain regulatory actions are subject to the backfit rule at 10 CFR 50.109 and to the analysis and information requirements of the Committee to Review Generic Requirements (CRGR). NRC intends that, for these actions, the analysis performed in accordance with the Guidelines will satisfy the documentation requirements of the backfit rule and the provisions of the CRGR Charter without a need to prepare separate submissions.”

Source: Excerpt from footnote 3 in “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” NUREG/BR-0058, Revision 2, November 1995.

19

What is a Regulatory Analysis?

- A tool provided to decision makers which analyzes the need for and the consequences of a proposed regulatory action.
- It recommends a preferred alternative from the potential courses of action studied.
- It documents the analysis in an organized and understandable format.

20

When is a Regulatory Analysis Required?

- An RA should accompany any proposed action that establishes or communicates requirements, guidance, requests, or staff positions that would result in a change in resources by NRC licensees
- RA requirements for any given action can be modified or eliminated at the discretion of the Office Director or above
- An RA is required for all actions that involve “backfits” and impose generic requirements

21

Why is a Regulatory Analysis Needed?

- Decision Tool for Policymakers
- Rationale for Action
- Transparency of Agency Decisionmaking
- Comply with Executive Orders requiring them from Presidents Ford through Bush
- Comply with Office of Management and Budget (OMB) guidance

22

Examples of Actions Requiring RAs

- Rules
- Bulletins
- Generic Letters
- Regulatory Guides
- Orders
- Standard Review Plans
- Branch Technical Positions
- Standard Technical Specifications

23

Examples of Actions That DO NOT Require RAs

- Licensing Actions
 - NEPA EIS ordinarily involves cost/benefit analysis
- Topical Reports
- Regulatory Issue Summaries
- Information Notices
- Inspection Reports

24

Elements of a Regulatory Analysis

- Statement of the Problem and Objective
 - Explain why the action is needed
- Identification of Alternatives
 - Explain why this is the best regulatory action
- Estimation and Evaluation of Values and Impacts
 - Elucidate the benefits and costs

25

Elements of a Regulatory Analysis (cont.)

- Presentation of Results
 - Use net-benefit not benefit-cost ratio
- Decision Rationale
 - Explanation of staff's recommendation
- Implementation
 - Specify when the rule takes affect

26

Steps to Perform a Regulatory Analysis

- Review the Regulatory Basis of the proposed action
- Determine if an RA is needed
- What would the proposed regulatory action require that is different from what was required before
- Identify legitimate alternatives

27

**Steps to Perform a
Regulatory Analysis (cont.)**

- Determine if the action is a backfit
 - i.e., a change in agency position
- If it is, performing an RA will provide a good basis upon which to do the backfit analysis
- Perform a safety goal evaluation, if needed
 - Determine if the 'substantial' added protection standard is met

28

**Steps to Perform a
Regulatory Analysis (cont.)**

- Identify the attributes which would be affected by this rule and those which would not
 - Public Health (Accident)
 - Public Health (Routine)
 - Occupational Health (Accident)
 - Occupational Health (Routine)
 - Offsite Property
 - Onsite Property

29

**Steps to Perform a
Regulatory Analysis (cont.)**

- Attributes (cont.)
 - Industry Implementation
 - Industry Operation
 - NRC Implementation
 - NRC Operation
 - Other Government
 - General Population

30

**Steps to Perform a
Regulatory Analysis (cont.)**

- **Attributes (cont.)**
 - Antitrust Considerations
 - Safeguards and Security Considerations
 - Environmental Considerations
 - Other Considerations

31

**Steps to Perform a
Regulatory Analysis (cont.)**

- **Attributes (cont.)**
 - Improvements in Knowledge
 - Regulatory Efficiency
 - Antitrust Considerations
 - Safeguards and Security Considerations
 - Environmental Considerations
 - Other Considerations

32

**Steps to Perform a
Regulatory Analysis (cont.)**

- Determine the type and number of licensees affected, how, and when they'd be affected
- Identify the number and types of other entities affected, how, and when they'd be affected
- Identify:
 - the impacts or costs
 - the values or benefits

33

Steps to Perform a Regulatory Analysis (cont.)

- Calculate a discounted flow of the annual costs and benefits
 - See App. B of the RA Handbook
- Use both the 3% and 7% discount rates
 - See tables on p. B.4 of the RA Handbook

34

Steps to Perform a Regulatory Analysis (cont.)

- Include a discussion on the treatment of individual requirements, a.k.a. 'bundling'
 - Is each individual initiative a necessary requirement
 - Where bundling would tend to obscure a non-cost beneficial regulatory requirement.
- Provide results in a net-benefit format
 - i.e., benefit-costs, not benefit/costs

35

Recurring Issues

Relaxations: Are they backfits?

A: It depends.

- *Voluntary* relaxations, where licensee continues to be in compliance with after backfit is applied, are not backfits.
 - Example: Original requirement is for inspection every 6 months. Revised requirement to be backfit is for inspection every 12 months. Licensee can continue to inspect every 6 months and will still be in compliance with revised requirement. The revised requirement is not a backfit.
- *Mandatory* relaxations, where licensee must implement some change (to SSCs, procedure, organization), are backfits.
 - Example: Original requirement is for inspection with technique A costing \$1,000. Revised requirement is for inspection with technique B costing \$500.00. Licensee cannot comply with revised requirement with technique A. The revised requirement is a backfit.

36

Recurring Issues
(continued)

Tacit Acceptance: Does silence constitute agency acceptance (and therefore establish an agency position) for purposes of backfitting?

A: In most cases, silence does NOT constitute agency acceptance.

- Example: Licensee submits a letter indicating that it intends to make a change to its emergency plan because it has concluded that the change does not "decrease the effectiveness" of the EP, unless the licensee hears otherwise from the NRC within 60 days. NRC's failure to respond within 60 days does NOT constitute tacit acceptance of the change.
- Exception: 50.54(a)(4)(iv) provides for approval (*i.e.*, tacit acceptance) where agency is silent after a stated period of time

37

Recurring Issues
(continued)

Tacit Acceptance: Does the issuance of an SER constitute a NRC staff position for every matter in either: (i) the area of review discussed in the SER, or (ii) in the subject matter of the application?

A: It depends, based upon the words of the SER, and the context of the approval given in the SER.

Explicit conclusion on discrete matters specifically called out represent positions which may be the basis for backfitting claim

General conclusion may represent positions which may be the basis for backfitting claim, but only at a general level

Matter not actually examined by the NRC or discussed would not ordinarily represent position which may be the basis for backfitting claim

If SER represented complete approval and could form a basis for a backfitting claim, then most inspection findings on those aspects of SSCs or plant procedures which have not changed since initial licensing (or approval in subsequent amendment) may have to be considered backfitting

38

Recurring Issues
(continued)

Bundling: Why does the agency bundle ("aggregate") requirements?

- Reduce NRC workload in developing regulatory action
- Allow backfits whose costs are difficult to quantify to be subsumed within a total package.
- Some individual requirements are part of an integrated concept, or are interdependent.
- Guidance on Aggregation/Disaggregation
 - NRC Regulatory Analysis Guidelines, NUREG/BR-0058, Revision 4.
 - SECY-04-0045 (March 17, 2004)

39

Recurring Issues
(continued)

Information Requests: Are such requests, e.g., generic letters issued under 50.54(f), considered backfitting?

A: No.

- Information requests, by themselves, cannot result in substantial increases in protection to public health/safety or common defense/security.
- Information requests are subject to 50.54(f) test: “the burden to be imposed on respondents is justified in vies of the potential safety significance of the issue to be addressed in the requested information.”
- However, generic letters which include recommended actions are to be treated similar to guidance documents (see next slide)
- Information requests are subject to Paperwork Reduction Act requirements (OMB review)

40

Recurring Issues
(continued)

Voluntary actions: how should the NRC credit such actions when evaluating costs and benefits?

A: Two-part analysis:

- (1) Full costs and benefits without consideration of voluntary action.
- (2) Reduced costs and benefits accounting for industry voluntary action.

NRC decision whether to rely on voluntary action may consider:

- (1) Incremental increase in risk/safety if voluntary action is discontinued
- (2) Increased NRC resources to impose discontinued voluntary action
- (3) Failure to achieve NRC-desired level of risk/safety if voluntary action is discontinued

Industry concerns over “regulatory footprint” over voluntary actions

- (1) Loss of flexibility
- (2) Enforcement exposure

41

Recurring Issues
(continued)

Guidance Documents: Are new or revised guidance, e.g., regulatory guides, information notices, considered backfitting?

A: No.

- Guidance documents, by themselves, are not legally binding requirements and therefore are not considered to be “imposed,” which is an essential element of the backfitting definition in 50.109(a)(1).
- CRGR has required, in response to complaints from external stakeholders, that revisions to guidance documents should be evaluated as if they are imposed, unless it is clear that they are to be forward-fit only.
- Issuance of guidance may be subject to other requirements that effectively substitute for backfit analysis, e.g., Regulatory Analysis, Paperwork Reduction Act clearance.

42

**NRC Resources on Backfitting and
Regulatory Analysis**

- Backfitting Guidelines, NUREG-1409 (1990)

- Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058, Revision 4 (2004)

- “Regulatory Analysis Technical Evaluation Handbook,” NUREG/BR-0184, January 1997.

43

**NRC Online Resources on Backfitting and
Regulatory Analysis**

- NRC webpage on CRGR
 - <http://www.nrc.gov/about-nrc/regulatory/crgr.html>

- NRC webpage on Backfitting and Regulatory Analysis
 - <http://www.nrc.gov/about-nrc/regulatory/crgr/related-info.html>

44
