

Regulatory and Backfit Analysis

Regulatory Analysis

A regulatory analysis is an analytical tool used by NRC decisionmakers to assist in determining whether the NRC should implement a proposed regulatory action. A regulatory analysis contains estimates of benefits and costs, which are quantified when possible, together with a conclusion as to whether the proposed regulatory action is cost-beneficial. "Cost-beneficial" means that the benefits of the proposed action are equal to, or exceed, the costs of the proposed action.¹

The regulatory analysis process should begin when it becomes apparent that some type of NRC regulatory action to address an identified problem may be needed. A regulatory analysis is intended to be an integral part of the NRC's decisionmaking, and should not be used to produce after-the-fact rationalizations to justify decisions already made, nor should it unnecessarily delay regulatory actions.² A regulatory analysis is prepared for, and normally accompanies, any proposed NRC action that establishes or communicates requirements, guidance, requests, or staff positions that results in a change in licensee resources.³

There is no statute or NRC regulation that requires the performance of a regulatory analysis for NRC-initiated actions. However, the NRC has been voluntarily performing them since 1976. The regulatory analyses prepared by the NRC before 1983 were termed value-impact analyses.

In February 1981, President Reagan issued Executive Order (E.O.) 12291 that directed executive agencies to prepare a regulatory impact analysis for all major rules and stated that regulatory actions should be based on adequate information concerning the need for and consequences of any proposed actions. Moreover, E.O. 12291 directed that actions were not to be undertaken unless they resulted in a positive net value to society. As an independent agency, the NRC was not required to comply with E.O. 12291. However, the Commission noted that its established regulatory review procedures included an evaluation of proposed and existing rules in a manner consistent with the regulatory impact analysis provisions of E.O. 12291. The Commission determined that clarifying and formalizing the existing NRC value-impact procedures for the analysis of regulatory actions would enhance the effectiveness of NRC regulatory actions and further meet the spirit of E.O. 12291. Thus, the NRC issued NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," in January 1983 (Guidelines). The NRC has updated the Guidelines several times, and the current version is Revision 4, issued in 2004.

The Office of Management and Budget (OMB) has published regulatory analysis guidance in its Circular A-4, last issued on September 17, 2003. Although the NRC, as an independent agency, is not required to follow Circular A-4, the Guidelines have consistently followed it.

¹ The decision criterion for a regulatory analysis, viz., that the benefits of the proposed action are equal to, or exceed, the costs of the proposed action, are different from the decision criterion in a backfit analysis under 10 CFR 50.109. Under 10 CFR 50.109(a)(3), the backfit analysis must address whether the proposed backfit represents a "substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection." The differences between these decision criteria are addressed in this Enclosure in the discussion of backfit analysis.

² See NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004.

³ If there is a change in licensee resources, the regulatory analysis will analyze societal costs and benefits of the proposed NRC action. *Id.*

Circular A-4 establishes a discount rate of 3 percent as the expected return on a government investment, and a discount rate of 7 percent as the expected return on a private investment. The discount rate provides a means for a fair presentation, expressed in present day dollars, of future costs and benefits.

The Guidelines identifies “averted offsite property damage” as one of the values to be assessed in a regulatory analysis. Additional detailed guidance on how to perform a regulatory analysis is described in “Regulatory Analysis Technical Evaluation Handbook,” NUREG/BR-0184, January 1997 (Handbook). The Handbook states on page 5.11 that the averted offsite property damage (which it describes as the offsite impacts attribute):

...measures the expected total monetary effects on offsite property resulting from the proposed action. Changes to offsite property can take various forms, both direct (e.g., land, food, and water) and indirect (e.g., tourism). This attribute is typically the product of the change in accident frequency and the property consequences resulting from the occurrence of an accident (e.g., costs of interdiction measures, such as decontamination, cleanup, and evacuation). A reduction in offsite property damage is taken as positive; an increase in offsite property damage is considered negative.

Further, the Handbook indicates that in the case of nuclear power plants, changes in public health and safety from radiation exposure and offsite property impacts should be examined over a 50-mile distance from the plant site which go well beyond the NRC emergency planning zone.

As noted in the following Backfit Analysis Section, a regulatory analysis is required for all actions that involve “backfits” and impose generic requirements. The “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” NUREG/BR-0058, Revision 2, November 1995, was the first edition to state that,

Certain regulatory actions are subject to the backfit rule at 10 CFR 50.109 . . .
NRC intends that, for these actions, the analysis performed in accordance with
the Guidelines will satisfy the documentation requirements of the backfit rule. . .

In other words, a complete regulatory analysis will provide all the information necessary to address the nine factors of the backfit analysis.⁴ However, as noted in footnote 1, the decision criterion for a regulatory analysis differs from a backfit analysis.

Backfit Analysis

A backfit analysis is a regulatory requirement that is an analytical tool used by NRC decisionmakers to assist in determining whether a proposed regulatory action applicable to nuclear power plants or materials facilities, identified as a backfit, is a cost-justified substantial safety enhancement and should be adopted. The decision criterion in a backfit analysis is whether the proposed backfit is a “substantial increase” in protection to public health and safety or common defense and security and that the costs are justified by the benefit. Thus, the

⁴ Although 10 CFR 50.109(c) specifically cites nine (9) factors that must be considered in a backfit analysis, the introductory sentence of that paragraph also states that the NRC should consider any other information relevant and material to the proposed backfit.

backfitting decision criterion differs from the regulatory analysis decision criterion in that a “substantial increase” is needed to justify backfitting. The Commission has indicated that “substantial” effectively means “large,”⁵ but the Commission has not indicated whether this is an absolute or relative measure, nor has the Commission set thresholds for a substantial increase if it is an absolute measure.

The requirements governing backfitting for nuclear power reactors are set forth in 10 CFR 50.109⁶. Backfit regulatory provisions for other facilities are included in 10 CFR Part 70, 10 CFR Part 72, and 10 CFR Part 76.

The NRC’s backfitting and issue finality requirements were adopted by the Commission as self-imposed restrictions on agency action – that is, there is no statutory requirement for these backfitting and issue finality requirements. In 1970, the Backfit Rule was first adopted in response to complaints of nuclear power plant applicants and licensees over the evolution of AEC safety requirements as the agency processed the first generation of nuclear power plant construction permits and operating licenses. In 1985, the Commission adopted major revisions to the rule in response to complaints of nuclear power applicants and licensees about the numerous post-Three Mile Island orders and regulations. The 1985 rule was subsequently modified in 1988 to add the “exceptions” to preparing backfit analysis for those backfits which involve adequate protection.⁷ Thereafter, the Commission has extended backfitting protection to new nuclear power plants by adopting “issue finality” provisions in 10 CFR Part 52, and extended backfitting protection to certain non-power reactor entities, as identified above. The NRC issued guidance on the Backfit Rule in 1990,⁸ but, as with other guidance discussed in this SECY, it would be appropriate to update this guidance, possibly on an expedited basis to reflect the Commission’s decision on this SECY.

The relationship between backfit analyses and regulatory analyses was first reflected in Revision 2 of NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” in November 1995. Footnote 3 of NUREG/BR-0058 stated that traditional cost/benefit analysis as performed in the NRC’s Regulatory Analyses will satisfy the backfitting requirement that actions be shown to be cost-beneficial. The guidance in footnote 3 of the Guidelines continues to be provided in footnote 2 of Revision 4 of the Guidelines.

NUREG-1409, “Backfitting Guidelines”, dated July 1990, states that, averted offsite costs that result from an estimated decrease in accident frequency or severity that are tied directly to the public health and safety are considered benefits (safety enhancement), citing to NUREG/BR-0058, the NRC’s Regulatory Analysis Guidelines. The NRC’s intent was that only averted offsite deaths and adverse health effects, resulting from an estimated decrease in accident frequency or severity attributable to the proposed backfitting, be considered as a benefit.

⁵ SRM to James M. Taylor and William C. Parler from Samuel J. Chilk, “SECY-93-086 – Backfit Considerations,” June 30, 1993. This position is also reflected in footnote 3 of the Guidelines, Revision 4.

⁶ Analogous backfitting provisions applicable to nuclear power licenses and regulatory approvals, differing in some regards from those in 10 CFR 50.109, are set forth in 10 CFR Part 52 (“issue finality” provisions). Backfit provisions in 10 CFR 70 have limited applicability (backfit provisions apply only to Subpart H) and have not yet been applied by the NRC.

⁷ The 1988 rulemaking was the result of the D.C. Circuit Court of Appeal’s decision in *UCS v. NRC*, in which the D.C. Circuit held that the 1985 Backfit Rule was defective because it allowed the NRC to consider costs in determining adequate protection.

⁸ NUREG-1409, “Backfitting Guidelines,” dated July 1990.

However, at that time, the Regulatory Analysis Guidelines used a dollar per person-rem amount of \$1,000 as a surrogate for *all* averted offsite losses, health as well as property. Thus, a simple reading of NUREG-1409 could lead to the erroneous conclusion that averted offsite costs not directly resulting from the estimated decrease in accident frequency or severity attributable to the proposed backfitting should be regarded as a public health and safety benefit (the correct conclusion is that such averted offsite costs should be regarded as a cost offset).

Prior to preparing a backfit analysis, the staff determines whether the proposed NRC action is a "backfit," as defined in 50.109(a)(1)⁹. If the proposal constitutes a backfit, the staff must determine whether one or more exceptions to preparation of a backfit analysis apply. Section 50.109(a)(4) allows exemptions to the analysis requirement if the action is necessary for compliance, adequate protection, or involved with defining or redefining what is needed for adequate protection. Unless one of these exemptions in 50.109(a)(4) applies, the staff proceeds with determining whether the backfit represents a cost-justified substantial safety enhancement. To make this determination, the staff must develop a backfit analysis of the type discussed in 10 CFR 50.109(a)(3) and 10 CFR 50.109(c) and a finding is made that there is (1) a substantial increase in the overall protection of the public health and safety or the common defense and security and (2) the direct and indirect costs of implementation are justified by the benefit.

The staff can consider several factors (among which are those identified in 50.109(c)(1) through (9)) to determine whether the backfit would provide a substantial increase in protection to public health and safety or common defense. For backfits associated with nuclear reactors, the staff typically uses, if applicable, a safety goal screening evaluation as a surrogate for this question. NUREG/BR-0058 states that "[i]f the proposed safety goal screening criteria are satisfied, the NRC considers that the substantial additional protection standard is met for the proposed new requirement." Once the staff determines that the potential backfit would result in a substantial increase in protection, they determine whether it is cost-justified in light of this increased protection.

As stated in the previous section, a regulatory analysis is used to help determine (1) whether a proposed action is subject to the backfit rule (e.g., 10 CFR 50.109), (2) whether that action is within the rule's exceptions (e.g., 10 CFR 50.109(a)(4)), (3) whether it provides a substantial increase in the overall protection of the public health and safety or the common defense and security, and (4) whether the direct and indirect costs of implementation are justified in view of this substantial increase in protection. Therefore, the offsite property damage can be taken into account at this stage in the cost-benefit analysis of the backfit analysis.

⁹ Backfitting is defined as: (1) a 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; and (2) may result from: a new or amended provision in Commission rules; or the imposition of a regulatory staff position that is either new or different, from a previously applicable staff position.