

APPENDIX E
SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER
PROCEDURAL REQUIREMENTS

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
ASME	American Society of Mechanical Engineers
CDF	core damage frequency
CFR	<i>Code of Federal Regulations</i>
CRGR	Committee to Review Generic Requirements
EIS	environmental impact statement
NEPA	National Environmental Policy Act
NRC	U.S. Nuclear Regulatory Commission
OMB	U.S. Office of Management and Budget
SBREFA	Small Business Regulatory Enforcement Fairness Act
U.S.C.	United States Code

SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

E.1 INTRODUCTION

This appendix is designed to assist the analyst in preparing effective regulatory analyses, backfit analyses, and environmental analyses and to provide a consistent approach and methodology for preparing cost-benefit analyses. The guidance in this appendix is consistent with U.S. Nuclear Regulatory Commission (NRC) policy and, if followed, should result in an acceptable analysis. Although this document is comprehensive, it does not anticipate all conceivable possibilities. Further, the methods used in regulatory analyses, backfit analyses, and environmental analyses continue to evolve, and applicable data may change over time. This appendix is intended to provide general guidance to assist the analyst in working through such circumstances. In addition to the examples provided in this appendix, the NRC and other Federal agencies (e.g., the U.S. Office of Management and Budget (OMB), the U.S. Environmental Protection Agency, the U.S. Government Accountability Office, and the U.S. Department of Transportation) continue to undertake research and development to improve the regulatory decisionmaking process, which may provide additional help in performing these analyses.

This appendix also discusses the relationship of regulatory analyses to certain statutory procedural requirements applicable to the NRC. The documentation that the Regulatory Flexibility Act requires may be included as an appendix to the regulatory analysis or within the *Federal Register* notice. Documentation required by the Paperwork Reduction Act, though not appended to the regulatory analysis, will be developed and approved in tandem. The remaining procedural requirements addressed in this appendix involve issues closely related to those examined in the regulatory analysis.

E.2 SPECIAL CIRCUMSTANCES

E.2.1 Safety Goal Screening

The evaluation of core damage frequency (CDF) reduction helps to calibrate the significance of the proposed regulatory action. If an action results in a small change in CDF (less than 1×10^{-5} per reactor-year), the regulatory analysis should, in general, proceed only if an alternative justification for the proposed new requirement can be formulated. A class of accident sequences involving the potential for early containment failure or containment bypass should receive further consideration even if the reduction in CDF is less than 1×10^{-5} per reactor-year. However, there may be other special circumstances that should be analyzed. The NRC staff should refer such issues (and include sufficient supporting information) to the appropriate office director for review.

In comparing the estimated resulting change in CDF for the affected class of plants, the analysis should consider contributions from both internal and external events to the extent that the information is pertinent to the issue. However, the uncertainties associated with certain external event risk contributions (especially seismic and flooding) can be relatively large. Therefore, to supplement any available quantitative information, the analysis should consider additional insights for issues involving external events.

For the purpose of evaluating regulatory actions against safety goals, the analysis should consider the magnitude of the change in CDF when determining whether the substantial additional protection criterion of the backfit rule is met. Specifically, the analyst should use a single common criterion when determining whether a regulatory action involving a reduction in CDF (1) meets the substantial additional protection standard identified in the backfit rule (e.g., Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting") and (2) is appropriate, considering the subsidiary safety goal of 10^{-4} in mean CDF per reactor-year. The staff has determined that a subsidiary safety goal of 10^{-4} in mean CDF per reactor-year is a useful benchmark, but it is not a Commission-approved safety goal. For this usage, CDF is defined as "the sum of the accident sequence frequencies of those accident sequences whose end state is core damage," where core damage is defined as "sufficient damage that could lead to a release of radioactive material from the core that could affect public health" (NRC, 2013a).

If it is not possible to develop adequate, quantitative supporting information for the proposed new requirement, then the analysis should provide a bounding, quantitative analysis to the extent practical. Points and insights should be related to the safety goal screening criteria. For example, the quantitative analysis should indicate how the proposed regulatory action affects the CDF and to what extent. It should address how risk and the expected improvement is measured or estimated. If important factors cannot be quantified, they may be discussed qualitatively. Appendix A, "Qualitative Factors Assessment Tools," provides additional guidance for performing qualitative analyses.

The safety goal screening criteria are in terms of a mean for the class of plants. However, the range within the class of the risk reduction is also important. Consequently, when performing safety goal evaluations, if specific plants are identified as "outliers," then the situation should be noted for specific regulatory followup (e.g., for evaluations about potential facility-specific backfittings).

The NRC recognizes that, in certain instances, the screening criteria may not adequately address certain accident scenarios of unique safety or risk interest. One example is an event in which certain challenges could lead to containment failure after the time period adopted in the safety goal screening criteria, yet early enough that the contribution of these challenges to total risk would be nonnegligible (particularly if the failure occurred before effective implementation of accident management measures). Another example is an event involving the spent fuel pool. In these circumstances, the analyst should make the case that the screening criteria do not apply and that the decision to pursue the issue should be subject to further management decision.

E.2.2 Sunk Costs

Sunk costs are costs incurred before the start of the analysis period and for which there is no value to the resources in some alternative use. Common examples include the costs of policy development, feasibility studies, or voluntary actions undertaken at an earlier date. The cost-benefit analysis does not include sunk costs because there is no opportunity cost involved and because including such costs may distort the analysis by requiring a very high return on the investment. In other words, sunk costs are irrelevant because they are the outcome of past decisions and should therefore be excluded from future decisions.

E.2.3 Criteria for the Treatment of Individual Requirements

In evaluating a proposed regulatory action, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is cost justified. However, aggregating or bundling different requirements in a single analysis could potentially mask the inclusion of an unnecessary individual requirement. If a rule provides a voluntary alternative to current requirements, the net benefit from relaxing one requirement could potentially support a second, unnecessary requirement that is not cost justified. Similarly, in the case of other types of rules, including those subject to a backfit analysis,¹ the net benefit from one requirement could potentially support another requirement that is not cost justified. This discussion does not apply to backfittings that the Commission determines to qualify under one of the exceptions in 10 CFR 50.109(a)(4)(ii) and (iii), ensuring adequate protection, or defining or redefining what constitutes adequate protection. Those types of backfitting actions require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether the exceptions are justified (although costs may be considered in determining how to achieve a certain level of protection).²

Therefore, when analyzing and making decisions about regulatory actions that are composed of individual requirements, the NRC should determine whether it is appropriate to include each individual requirement. Clearly, in certain instances, the inclusion of an individual requirement is necessary. This would be the case, for example, when the individual requirement is needed for

¹ These cost-benefit guidelines were developed so that a regulatory analysis that conforms to this guidance should meet the requirements of the Backfit Rule (i.e., 10 CFR 50.109) and the provisions of the Committee to Review Generic Requirements (CRGR) Charter.

² In a December 2016 memorandum, the NRC Solicitor provided guidance stating that some consideration of costs must be performed when the staff is invoking the compliance exception provided in 10 CFR 50.109(a)(4)(i) (NRC, 2016).

the regulatory action to resolve the problems and concerns and meet the stated objectives³ that are the focus of the regulatory action. Even though inclusion of individual requirements is necessary in this case, the analyst should obtain separate cost estimates for each requirement, to the extent practical, in deriving the total cost estimate presented for the aggregated requirements.

However, in some cases the individual requirement is not a necessary component of the regulatory action, and thus the NRC will have some discretion about its inclusion. In these circumstances, the NRC should consider that, if the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory action, it should be included only if its overall effect is to make the bundled regulatory requirement more cost beneficial. This would involve a quantitative or qualitative (or both) evaluation of the costs and benefits of the regulatory action, with and without the individual requirement included, and a direct comparison of those results.

In some circumstances, the analyst might consider including an individual requirement that is unrelated to the overall regulatory action. For example, an analyst may consider combining certain unrelated requirements as a way to eliminate duplicative rulemaking costs to the NRC and increase regulatory efficiency. Under these circumstances, it would be appropriate to combine these discrete individual requirements if the overall effect is to make the regulatory action more cost beneficial. Otherwise, the analysis must analyze this individual requirement separately to determine whether the effect of this change is cost-beneficial.

In general, the analyst should consider reasonableness and practicality when making a decision on the level of disaggregation. For example, more detailed disaggregation is appropriate only if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. Alternatively, individual elements that contribute little to the overall costs and benefits and are noncontroversial may not warrant much, if any, consideration. In general, it will not be necessary to provide additional documentation or analysis to explain how this determination is made, although such a finding can certainly be challenged at the public comment stage.⁴

A special case involves the NRC's periodic review and endorsement of consensus standards, such as new versions of the American Society of Mechanical Engineers (ASME) codes. Appendix D, "Guidance on Regulatory Analysis Related to ASME Code Changes," provides guidance for addressing consensus standards.

E.2.4 Intergenerational Cost-Benefit Assessments

For certain regulatory actions, such as those involving decommissioning and waste disposal issues, the regulatory analysis may have to consider consequences that can occur over hundreds, or even thousands, of years. The OMB recognizes that special considerations arise when comparing benefits and costs across generations. Under these circumstances, the OMB continues to see value in applying discount rates of 3 and 7 percent. However, ethical and

³ The stated objectives of the rule are those stated in the preamble (also known as the Statements of Consideration) of the rule.

⁴ NUREG/BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook," issued September 2005 (NRC Regulations Handbook), discusses the treatment of comments.

technical arguments can also support the use of lower discount rates. Thus, if a rule will have important intergenerational consequences, the analyst should consider supplementing the analysis with an explicit discussion of the intergenerational concerns, such as how the regulatory decision will affect future generations. Additionally, supplemental information could include a presentation of the costs and benefits at the time in which they are incurred with no present-worth conversion (e.g., no discounting). In this case, the resulting net cost should not be calculated. Also, the analyst should consider a sensitivity analysis using a lower, but positive, discount rate.

E.3 PROCEDURAL REQUIREMENTS

E.3.1 Committee to Review Generic Requirements

The Committee to Review Generic Requirements (CRGR) has the responsibility to review and recommend to the NRC Executive Director for Operations whether to approve or disapprove requirements or staff positions to be imposed on one or more classes of power reactors and, in some cases, on nuclear materials licensees. The CRGR reviews proposed requirements or positions that would reduce existing requirements or positions and also reviews proposals that would increase or change requirements. The CRGR Charter sets out the CRGR's purpose, membership, scope, operating procedures, and reporting requirements.

The CRGR Charter lists the information that is required to be submitted to the CRGR for review of proposed actions within its scope. One item is a regulatory analysis conforming to the direction in this guidance.⁵

When a regulatory analysis has been prepared in accordance with this guidance document, it will not be necessary to prepare a separate document to address the information required for CRGR review, except to address the CRGR requirement relating to the concurrence of affected program offices or an explanation of any nonconcurrences. However, the NRC staff can address this exception in the transmittal memorandum forwarding the matter to the CRGR for review.

Preparation of a regulatory analysis, including an evaluation of cost and benefits, is necessary for all proposed facility-specific and generic backfitting to facilities regulated under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," except when one of the following three conditions, identified in 10 CFR 50.109(a)(4), applies:

- (1) a modification is necessary to bring a facility into compliance with a license, a Commission requirement, or a written commitment by the licensee
- (2) a regulatory action is necessary to ensure that the facility provides adequate protection to public health and safety and is in accord with the common defense and security
- (3) the regulatory action involves defining or redefining what level of protection to public health and safety or the common defense and security is regarded as necessary for adequate protection

If a backfit meets either of the second or third exception criterion above, costs are not to be considered in justifying the proposed action. For compliance exception backfitting (i.e., the first exception criterion above), costs must be considered under 10 CFR 50.109. The analyst should prepare a documented evaluation that includes the objectives of and reasons for the backfitting action as well as the reasons for invoking the particular exception (under 10 CFR Part 50). Procedural requirements for preparing and processing the documented evaluation are in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information

⁵ Appendix C, item (ix), of the CRGR Charter states that, for adequate protection or compliance backfits affecting power reactors, new reactors, or materials licensees, documented evaluations are required instead of backfit analyses.

Collection,” for facility-specific backfitting and in Appendix C, item (ix) of the CRGR Charter for generic backfitting.

A regulatory analysis incorporating the documented evaluation may also be prepared in these instances for use as a management decisionmaking tool. In particular, if there is more than one way to achieve compliance or reach a level of adequate protection and the Commission finds it necessary or appropriate to specify the way, costs may be a factor in that decision. A regulatory analysis that explores the cost effectiveness of the various alternatives under consideration could therefore be valuable to a decisionmaker.

E.3.2 Paperwork Reduction Act

The Paperwork Reduction Act contains procedural requirements designed to minimize and control the burdens associated with collections of information by Federal agencies from individuals, businesses, and other private entities, as well as State and local governments. The NRC provides its internal procedures for complying with the Paperwork Reduction Act and preparing justifications for OMB approval of information collections in the NRC Regulations Handbook and in Office of the Chief Information Officer guidance (NRC, 2014).

Whenever a proposed regulatory action will probably involve information collections subject to OMB approval, the NRC will prepare an OMB clearance package for the rulemaking. While the OMB clearance package need not be included as part of the rulemaking package that is submitted to the Office of the Executive Director for Operations or Commission for approval, the Office of the Chief Information Officer should approve the clearance package for its submittal to the OMB before the rule can be submitted to the Office of the *Federal Register* for publication.

Under the Paperwork Reduction Act, agencies are required to obtain OMB approval for collections of information if (1) the information collection involves 10 or more persons by means of identical questions or reporting or recordkeeping requirements, (2) the information collection is contained in a rule of general applicability, or (3) the collection is addressed to all or a substantial majority of an industry, even if that majority involves fewer than 10 persons (5 CFR 1320.3(c) and 5 CFR 1320.5, “General Requirements”).

The OMB’s criteria for approving information collections are contained in 5 CFR 1320.5(d)(1). To obtain OMB approval for information collections, an agency must demonstrate that the collection of information (1) is the least burdensome necessary for the proper performance of the agency’s functions, (2) is not duplicative of information otherwise available to the agency, and (3) has practical utility. The agency should minimize its cost of collecting, processing, and using the information, but not by shifting disproportionate costs or burdens onto the public. Agencies should consult with interested agencies and members of the public in an effort to minimize the burden of the information collection to the public. OMB clearance packages identify any significant burdens placed on a substantial number of small businesses or entities (5 CFR 1320.9(c)).

If the OMB disapproves an information collection, independent regulatory agencies, such as the NRC, may override the disapproval or stay of effectiveness of approval of a collection of information by a majority vote of the Commissioners (5 CFR 1320.15, “Independent Regulatory Agency Override Authority”).

E.3.3 Regulatory Flexibility Act

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis if a proposed rule will have a significant economic impact on a substantial number of small entities. The initial regulatory flexibility analysis is to describe the impact of the proposed rule on small entities (5 U.S.C. 603). The NRC uses the following size standards, codified at 10 CFR 2.810, "NRC Size Standards," to qualify a licensee as a small entity:

- A small business is a for-profit concern providing a service with average gross receipts of \$7 million or less over its last 3 completed fiscal years, or a manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.
- A small organization is a not-for-profit organization that is independently owned and operated and has annual gross receipts of \$7 million or less.
- A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000 people.
- A small educational institution is one that (1) is supported by a qualifying small governmental jurisdiction or (2) is not State or publicly supported and has 500 or fewer employees.

The NRC Regulations Handbook sets out procedural requirements for preparing regulatory flexibility analyses. The NRC public Web site provides a summary of these procedures (NRC, 2017). If a proposed rule would likely have a significant economic impact on a substantial number of small entities, the NRC must prepare an initial regulatory flexibility analysis, consistent with the NRC procedural requirements. After revisions are made to the rule package in response to public comments, the NRC must prepare a final regulatory flexibility analysis to update information and to explain what was done to minimize the adverse economic impact, as appropriate, of the rule on small entities. The agency issues a small-entity compliance guide along with the rule. The regulatory flexibility analysis may be included as an appendix to the regulatory analysis document and as an insert to the proposed rule. The regulatory flexibility analysis need not repeat information discussed in the body of the regulatory analysis; such information may be referenced. If the NRC determines that the rule would not have a significant economic impact on a substantial number of small entities, both the proposed rule and final rule will include a certification to this effect. The regulatory analysis should contain sufficient information concerning the potential impact of the proposed rule on small entities to support this certification.

E.3.4 Small Business Regulatory Enforcement Fairness Act

Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires Federal agencies to publish a small-entity compliance guide for each rulemaking that requires a regulatory flexibility analysis under 5 U.S.C. 605(b). The Fair Minimum Wage Act of 2007 amended the SBREFA and requires agencies to (1) publish, distribute, and post on their public Web sites compliance guides on the same date of publication of the final rule and (2) submit an annual report (signed by the head of the agency) to the appropriate congressional committees, describing the status of the agency's compliance with the Act. The NRC Regulations Handbook

sets out procedural requirements for preparation of regulatory flexibility analyses. The NRC public Web site summarizes these procedures.

E.3.5 National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires Federal agencies to prepare a “detailed statement for major Federal actions significantly affecting the quality of the human environment” (42 U.S.C. 4332). To satisfy this obligation, the NRC prepares environmental impact statements (EIS) according to NRC regulations in 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” Additionally, an environmental assessment (EA) may be prepared to determine whether an EIS is necessary (Spensley, 1997).

Under NEPA, the NRC must assess the environmental impact of each rulemaking action; the NRC includes a statement about the environmental impacts in the supplementary information section of the preamble to each rulemaking. When preparing a regulatory analysis to support a rulemaking, the analysis may include a brief summary of information from the EIS or EA instead of information listed in Sections 2.3.1– through 2.3.3 of this guidance. Where appropriate, the EIS or EA should be referenced at other points in the regulatory analysis to avoid duplication. For example, the alternatives evaluated in the regulatory analysis should be the same as the alternatives evaluated in the EIS or EA.

E.3.6 Information Requests under 10 CFR 50.54(f)

Requirements for NRC information requests directed to production and utilization facility licensees appear in 10 CFR 50.54(f). The regulation requires the NRC to prepare a written statement justifying the reasons for the information request, except when the information is needed to verify licensee compliance with the current licensing basis for the facility. The written statement should establish that the burden imposed on the licensee is justified in view of the potential safety significance of the issue. The cognizant NRC office director or regional administrator should approve the justification statement before issuance of the information request.

Appendix C, item (x), of the CRGR Charter contains additional guidance for information requests affecting multiple nuclear power plants. The CRGR Charter specifies that, when a written justification is required, the written statement is to include the following:

- a problem statement that describes the need for the information in terms of the potential safety benefit
- the licensee actions required and the estimated cost to develop a response to the information request
- an anticipated schedule for NRC use of the information
- a statement affirming that the request does not impose new requirements on the licensee other than submittal of the requested information
- the proposing office director’s determination that the burden to be imposed on the respondents is justified in view of the potential safety significance of the issue

NRC Management Directive 8.4 discusses facility-specific information requests directed at individual nuclear power plants. Written statements prepared according to the preceding requirements to justify information requests are not regulatory analyses within the scope of this document. Nevertheless, the written justification will have many of the elements of a regulatory analysis. The elements of a regulatory analysis discussed in this document can appropriately be included in an information request justification. An information request justification will normally be a more concise document than a regulatory analysis.

E.3.7 Supporting Analysis for Compliance and Adequate Protection

As discussed in the body of this document, a proposed backfitting of one or more facilities regulated under 10 CFR Part 50 does not require a backfit analysis if the proposed action is required for purposes of compliance or adequate protection under 10 CFR 50.109(a)(4). Instead, the NRC must prepare a documented evaluation, including a statement of the objectives of and the reasons for the action, along with the basis for invoking the exception. Requirements for the documented evaluation are stated in 10 CFR 50.109(a)(6). Additional guidance for preparing and processing the documented evaluation appears in Management Directive 8.4. In the case of compliance exceptions under 10 CFR 50.109(a)(4)(i), some consideration of costs is required (NRC, 2016).

E.4 REFERENCES

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NRC, "Summary of COMSECY-16-0020 Recommendation on Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception To Backfit Rule," Memorandum, December 2016. ADAMS Accession No. ML16355A258.

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