APPENDIX E

SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

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E.1 Introduction

The guidance 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, will result in an acceptable document. Although the cost-benefit guidance document, including its appendices, is comprehensive, it should be recognized that not all conceivable possibilities can be anticipated. This appendix is intended to provide general guidance to assist the analyst in working through these circumstances. It should also be recognized that methods used in regulatory analyses, backfit analyses, and environmental analyses continue to evolve and applicable data may change over time. 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.

Also, this appendix discusses the relationship of regulatory analyses to certain statutory procedural requirements applicable to the NRC. The documentation required by the Regulatory Flexibility Act 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, must be developed and approved in tandem with it. The remaining procedural requirements discussed 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 provides a calibration on the significance of the proposed regulatory action. If an initiative 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 staff should forward the issue (and include sufficient supporting information) for office director review.

In comparing the estimated resulting change in CDF for the affected class of plants, contributions from both internal and external events should be considered to the extent that 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, additional insights should be used for issues involving external events.

For the purpose of evaluating regulatory initiatives against safety goals, the magnitude of the change in CDF should be considered in concert with the determination of whether the substantial additional protection criterion of the backfit rule is met. Specifically, a single common criterion is to be used for determining whether a regulatory initiative 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) Section 50.109) and (2) is appropriate, considering the subsidiary safety goal of 10^{-4} in mean CDF per reactor-year. The subsidiary safety goal of 10^{-4} in mean CDF per reactor-year has been determined by the staff to be a useful benchmark, but 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" (Ref. E.4).

If it is not possible to develop adequate quantitative supporting information for the proposed new requirement, then a bounding, quantitative analysis and perspective should be provided to the extent practical. Points and insights should be related to the safety goal screening criteria. For example, how does the proposed initiative affect the CDF and to what extent? How should the risk and the expected improvement be measured or estimated? Additional guidance for performing qualitative analyses is provided in Appendix A of this document.

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 follow-up (e.g., for evaluations regarding potential facility-specific backfits).

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 non-negligible (particularly if the failure occurs 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 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. Sunk costs are not included in cost-benefit analysis, because there is no opportunity cost involved and their inclusion 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 Treatment of Industry Initiatives

Industry initiatives are typically actions performed by licensees that either form the bases for continued compliance with the regulations or obviate the need for new regulations. It should be clear to the public that substituting industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, will in no way compromise plant safety, and does not represent a reduction in the NRC's commitment to safety and sound regulation. The NRC and the

industry are jointly responsible for the long-term success of using industry initiatives as substitutes for NRC regulatory action. Licensees need to effectively manage and implement their commitments associated with these industry initiatives, and the NRC should provide a credible and predictable regulatory response if licensees fail to satisfy these commitments.

Industry initiatives can generally be put into one of the following categories—(1) those put in place in lieu of or to complement a regulatory action to ensure that existing requirements are met, (2) those used in lieu of, or to complement, a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justified by the increased protection, or (3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern. Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives.

The presence of industry initiatives is potentially very important in the estimation of costs and benefits and, as such, its treatment in the regulatory analysis should be explicitly considered. All consequences of a proposed regulatory change are measured relative to the baseline, which is how things would be if the proposed regulation were not imposed. If industry initiatives that complement or substitute for a proposed regulatory action exist, the future role of these industry initiatives needs to be determined. This determination would affect the baseline, which in turn would affect the calculation of incremental costs and benefits. For example, if “full credit” is given to industry initiatives (i.e., it is assumed that complementary industry initiatives will continue in the future), the incremental costs attributable to the proposed regulation are diminished. Alternatively, if “no credit” is given, the incremental costs assigned to the proposed rule are increased.

For the purposes of the regulatory analysis, calculation of net benefits should be based, to the extent practical, on varied assumptions concerning the future role of industry initiatives. Initially, two sets of cost-benefit estimates are to be developed: (1) the first is based on no credit, and (2) the second is based on full credit for industry initiatives. These results will have equal weight and will be presented for sensitivity analysis purposes. If the overall cost-benefit result does not tilt from an overall net cost to an overall net benefit (or vice versa), there is no need to proceed further, and the final results would be reported as a range of costs that reflect the sensitivity of these results to the implementation of industry initiatives. However, if the results are highly sensitive to that level of variation, such that the overall net benefit conclusion shifts or the final recommendation changes, the analyst would proceed to develop a “best-estimate” base case.

Under this best-estimate base case, the staff will evaluate the specific industry initiatives in question to determine how much credit to give to the industry initiatives. Clearly, the more an industry initiative satisfies criteria that assure the long-term effectiveness of these voluntary approaches, the more credit the analyst should give to the industry initiative. In performing this evaluation, the analyst should rely on relevant features and characteristics of the industry initiatives to assess the weight or amount of credit to attach to any given industry initiative. Relevant characteristics include the following:

- Costs associated with the industry initiative. (If the dominant costs are fixed costs that have already been expended or the future recurring costs to maintain the industry initiative are minimal, it is more likely the industry initiative will continue in the future.)
- The extent to which written commitments exist. (If written commitments exist, it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative.)

- The degree to which the industry initiative is non-controversial and standard industry practice. (Factors to consider include whether the industry initiative is non-controversial and standard industry practice, consistent with provisions of industry codes and standards, the level of participation among relevant licensees, how long the program has been operating or its effectiveness, and whether the initiative is likely to continue without the rule change.)
- The scope and schedule for industry initiatives that are still pending. (For industry initiatives that are still works in progress, the more well-defined the scope and the sooner the initiative is expected to be in place, the more likely it will be available in the future.)

Based on such an assessment, the regulatory analysis would contain, to the extent practical, a best estimate of the cost and benefits of the regulation under consideration with and without credit for the industry initiative. These results would serve as the basis for the staff's recommendations to the Commission. Careful attention is needed if probabilistic risk assessment (PRA) techniques are used to give partial or no credit to industry initiatives, because risk estimates from PRAs are based on existing conditions that typically include credit for any industry initiative that may be in place. When the cost-benefit analysis and supporting PRA are modified to eliminate or reduce credit for industry initiatives, the analyst needs to ensure that these changes are properly reflected in the details of the PRA model.

E.2.4 Criteria for the Treatment of Individual Requirements

In evaluating a proposed regulatory initiative, 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. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of 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 backfit analysis,[9] the net benefit from one requirement could potentially support another requirement that is not cost justified. This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (though costs may be considered in determining how to achieve a certain level of protection).

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC should determine if 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 the regulatory initiative to resolve the problems and concerns and meet the stated objectives [10] that are the focus of the regulatory initiative. 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.

9 These cost-benefit guidelines were developed so that a regulatory analysis that conforms to this guidance will meet the requirements of the Backfit Rule (e.g., 10 CFR 50.109) and the provision of the CRGR Charter.

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

However, there will also be instances in which the individual requirement is not a necessary component of the regulatory initiative, and thus, the NRC will have some discretion regarding its inclusion. In these circumstances, the NRC should adhere to the following guideline:

> If the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory initiative, it should be included only if its overall effect is to make the bundled regulatory requirement more cost-beneficial. This would involve a quantitative and/or qualitative evaluation of the costs and benefits of the regulatory initiative with and without the individual requirement included, and a direct comparison of those results.

There may be circumstances in which the analyst considers including an individual requirement that is unrelated to the overall regulatory initiative. 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 initiative more cost beneficial. In those instances in which the individual requirement is a backfit, the requirement needs to be addressed and justified as a backfit separately. These backfits are not to be included in the overall regulatory analysis of the remainder of the regulatory initiative.

In general, a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality. 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 non-controversial 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.[11]

In some cases, an individual requirement that is being considered for inclusion in a voluntary alternative to current regulations may be justifiable under the backfit criteria. In these cases, the individual requirement is both cost justified and provides a substantial increase in the overall protection of the public health and safety or the common defense and security. If so, the NRC should consider imposing the individual requirement as a backfit affecting all plants to which it applies, rather than merely including it in a voluntary alternative rule affecting only those plants where the voluntary alternative is adopted.

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 codes. Guidance for addressing consensus standards is provided in Appendix D to this document.

E.2.5 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, OMB continues to see value in applying discount rates of 3 and 7 percent. However, ethical and technical arguments can also support the use of lower discount rates. Thus, if a rule will have

11 See NUREG/BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook," for discussion of how to treat comments.

important intergenerational consequences, the analyst should consider supplementing the analysis with an explicit discussion of the intergenerational concerns such as how future generations will be affected by the regulatory decision. 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, no calculation of the resulting net cost should be made. 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 Executive Director for Operations (EDO) approval or disapproval of requirements or NRC staff positions to be imposed on one or more classes of power reactors and, in some cases, on nuclear material licensees. The review applies to requirements or positions that reduce existing requirements or positions and proposals that increase or change requirements. The CRGR's purpose, membership, scope, operating procedures, and reporting requirements are set out in the CRGR Charter. The most recent version of the charter is Revision 8, issued in 2011.

Appendix C of the charter lists the information that is required to be submitted to the CRGR for review of proposed actions within its scope. One item (identified in Appendix C, item (v) of the charter) is a regulatory analysis conforming to the direction in this guidance.[12] There are other requirements as included in the CRGR Charter, Appendix C, as shown in Table E-1. Table E-1 includes the citation to the portion of the CRGR Charter where the requirement is found and also indicates where in the regulatory analysis the discussion of each item should normally appear. The analyst should generally ensure that each item in Table E-1 is included in a regulatory analysis prepared for CRGR review. The items included in Table E-1 are identified and discussed at appropriate parts of this guidance.

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

Table E-1 Checklist for Specific CRGR Regulatory Analysis Requirements

CRGR Charter Citation	Information Item To Be Included in a Regulatory Analysis Prepared for CRGR Review	Section of the Regulatory Analysis Where Item Should Normally Be Discussed
Appendix C, item (i)	The new or revised generic requirement or staff position as it is proposed to be sent out to licensees or to be issued for public comments.	Implementation Identification of Alternatives
Appendix C, item (iii) and Section III	The sponsoring office's position on each proposed requirement or staff position as to whether the proposal would modify requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions. Moreover, the staff shall indicate if the proposed relaxations are voluntary or mandatory.	Presentation of Results
Appendix C, item (iv)	The proposed method of implementation and resource implications along with the concurrence (and any comments) from the Office of General Counsel on the method proposed and the concurrence of all affected offices including regions or an explanation of any non-concurrences.[a]	Implementation
Appendix C, item (vi)	Identification of the category of power reactors, new reactors, or nuclear materials facilities or activities to which the proposed generic requirement or staff position is applicable (i.e., whether it is only applicable to future plants, operating plants, all pressurized-water reactors, all boiling-water reactors, specific nuclear steam supply system vendor types, specific vintage types plants, gaseous diffusion plants).	Problem Statement Identification of Alternatives
Appendix C, item (vii) And Appendix C, item (viii)	For proposed backfits other than either the compliance or the adequate protection backfits, a backfit analysis as defined in the Backfit Rule (10 CFR 50.109 for power reactors and 10 CFR 76.76 for the gaseous diffusion plants) should be performed.[b,c,d] The backfit analysis shall include, for each category of nuclear power reactor, new reactor, or nuclear materials facility or activity, an evaluation that demonstrates how the proposed action should be prioritized and scheduled in light of other ongoing regulatory activities. The backfit analysis shall document for consideration of pertinent information available concerning any of the following factors, as appropriate, and any other information that is relevant and material to the proposed action. (These items are included in Appendix C of the CRGR Charter).[e]	See main document, Table 1-1

CRGR Charter Citation	Information Item To Be Included in a Regulatory Analysis Prepared for CRGR Review	Section of the Regulatory Analysis Where Item Should Normally Be Discussed
Appendix C, item (ix)	For adequate protection or compliance backfits affecting power reactors, new reactors, or materials evaluated pursuant to the applicable backfit provisions as appropriate, 1) A documented evaluation consisting of: a) The objectives of the modification. b) The reasons for the modification. c) If the compliance exception is invoked, i) The requirements or written licensee commitments for which compliance is sought. ii) An assessment of risk/safety implications of not requiring licensees to immediately restore compliance, and the basis for determination that a reasonable concession could be allowed to defer restoration of compliance at a later time. iii) Demonstrated consideration of other possible alternatives and rationale for rejecting them in favor of compliance backfitting. iv) Evaluation from cost-benefit considerations (not a full regulatory analysis) and a rationale for compliance exception. d) If the adequate protection exception is invoked, the basis for concluding that the matter to be addressed involves adequate protection and why current requirements or written licensee commitments do not provide adequate protection. In addition, for actions that were immediately effective (e.g., issued without prior CRGR review), the evaluation shall document the safety significance and appropriateness of the action taken and (if applicable) consideration of how costs contributed to selecting the solution among various acceptable alternatives.	Decision Rationale

CRGR Charter Citation	Information Item To Be Included in a Regulatory Analysis Prepared for CRGR Review	Section of the Regulatory Analysis Where Item Should Normally Be Discussed
Appendix C, item (xi)	For each proposed power reactor backfit analyzed pursuant to 10 CFR 50.109 (a)(2) (i.e., backfits other than either adequate protection or compliance backfits), an assessment is provided that describes how the proposed action relates to the Commission's Safety Goal Policy Statement.[f] (Ref. 9)	Estimation and Evaluation of Costs and Benefits

CRGR, Revision 8, 2011 (Ref. E.5)

[a] These concurrences and related information can be included in the transmittal memorandum to the CRGR and need not be included in the CRGR regulatory analysis.

[b] As a legal matter, the Backfit Rule does not strictly apply unless a backfit is required by, for example, a rule or an order. However, the NRC backfit process, including the CRGR Charter, is defined on the principle that new positions as well as new requirements are to be reviewed for backfitting considerations and, if appropriate, meet the standards of the backfit rule before they are issued to the licensee(s). New generic positions in documents, such as generic letters, bulletins, and regulatory guides, whether affecting power reactors or nuclear materials facilities/activities, are to be considered and backfitting considerations addressed before they are issued.

[c] Types of actions to which the standards of the backfit rule do not apply include (1) voluntary actions and voluntary relaxations (as described in footnote 5 to the CRGR Charter), (2) actions mandated by statute, and (3) requests for information. (See Section 3.2 of the main document for further discussion.)

[d] Reporting requirements such as those contained in 10 CFR 50.72 and 10 CFR 50.73 (for power reactors) or those contained in 10 CFR 70.50 and 10 CFR 70.52 (for nuclear materials activities) are more akin to the information requests covered under 10 CFR 50.54(f) than they are to modifications covered under the backfit rule (10 CFR 50.109). They should be justified by an evaluation against criteria similar to the analogous provision in 10 CFR 50.54(f) (i.e., by demonstrating that the burden of reporting is justified in view of the potential safety benefits to be obtained from the information reported).

[e] Appendix C, item (viii) of the CRGR Charter also requires a determination by the proposing office director that there is 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. A statement of this determination may be included in the transmittal memorandum to the CRGR rather than in the CRGR regulatory analysis. Guidance on application of the "substantial increase" standard is in Appendix D to the CRGR Charter.

[f] Guidance for addressing the Commission's safety goals is contained in Chapter 2 of the main document.

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

The backfit rule applies to proposed backfitting of production or utilization facilities (see NUREG/BR-0058, Revision 5). The term "backfitting" is defined at 10 CFR 50.109(a)(1). The terms "production facility" and "utilization facility" are defined at 10 CFR 50.2. Backfitting can apply to one facility ("facility-specific backfitting") or to multiple facilities ("generic backfitting"). This guidance is intended for both generic and facility-specific backfits. This directive contains facility-specific regulatory analysis requirements, and thus, when preparing a facility-specific analysis, this directive should be consulted.

Backfitting can arise through a variety of mechanisms, including rulemakings, bulletins, generic letters, and regulatory guides.

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

that a modification is necessary to bring a facility into compliance with a license, a Commission requirement, or a written commitment by the licensee

that a regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security

that the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security is regarded as necessary for adequate protection

If a backfit meets these exception criteria, costs are not to be considered in justifying the proposed action. However, a documented evaluation is to be prepared that includes the objectives of and reasons for the backfit as well as the reasons for invoking the particular exception (Ref. 8). Procedural requirements for preparing and processing the documented evaluation are in the NRC Management Directive (MD) 8.4 for facility-specific backfits and in Appendix C, item (ix) of the CRGR Charter for generic backfits.

A regulatory analysis incorporating the documented evaluation may also be prepared in these instances 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 (44 U.S.C. 3501 et seq.) 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, and State and local governments. The NRC's internal procedures for complying with the Paperwork Reduction Act and preparing justifications for OMB approval of information collections are in the NRC Regulations Handbook and in Office of the Chief Information Officer (OCIO) guidance (Ref. E.9).

Whenever a proposed regulatory action will probably involve information collections subject to OMB approval, an OMB clearance package must be prepared 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 clearance package must be approved by the OCIO for its submittal to OMB before the rule can be submitted to the Office of the Federal Register for publication.

Agencies are required to obtain OMB approval for collections of information under any of the following conditions—(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 1320.5, "General Requirements").

OMB's criteria for approval of 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)).

In the event that 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).

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 size standards used by the NRC to qualify a licensee as a small entity, codified at 10 CFR 2.810, are as follows:

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.

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 preparation of regulatory flexibility analyses. The NRC public Web site provides a summary of these procedures (Ref. E.13). If a proposed rule would likely have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis must be prepared consistent with the NRC procedural requirements. After revisions are made to the rule package in response to public comments, a final regulatory flexibility analysis must be prepared to update information contained herein and to explain what was done to minimize the adverse economic impact of the rule on small entities. In addition, a small entity compliance guide is issued 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, a certification to this effect must be included in the proposed rule and repeated in the final rule. The regulatory analysis must 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 SBREFA was amended by the Fair Minimum Wage Act of 2007, which requires agencies to 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 provides a summary of these procedures (Ref. E.13).

E.3.5 National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires Federal agencies to prepare an environmental impact statement (EIS) for major Federal actions significantly affecting the quality of the human environment (42 U.S.C. 4332(2)(C)). The NRC procedures for implementing NEPA are in 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” The NRC Regulations Handbook contains additional information. When a generic or programmatic EIS has been prepared that forms the basis for a proposed regulatory action, a brief summary of the EIS will be an acceptable substitute for the information and analysis requirements as discussed elsewhere in this document. The EIS may be referenced at other appropriate points in the regulatory analysis to avoid duplicating existing written material.

When a regulatory analysis and an EIS or environmental assessment (EA) are being prepared for a proposed regulatory action, preparation of the two documents should be coordinated as much as possible. For example, the alternatives examined in the regulatory analysis should correspond as much as possible to the alternatives examined in the EIS or EA.

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

Procedures for NRC information requests directed to production and utilization facility licensees appear in10 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 is to establish that the burden imposed on the licensee is justified in view of the potential safety significance of the issue. All justification statements must be approved by the cognizant NRC office director or regional administrator 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

The NRC MD 8.4, "Management of Facility-Specific Backfitting and Information Collection" 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 backfit to one or more facilities regulated under 10 CFR Part 50 does not require a regulatory analysis if the resulting safety benefit is required for purposes of compliance or adequate protection under 10 CFR 50.109(a)(4). In these cases a documented evaluation must be prepared, including a statement of the objectives of and the reasons for the action, along with the basis for invoking the exception. These requirements are stated at 10 CFR 50.109(a)(6). Additional guidance is in the supplementary information portions of the *Federal Register* notices for the final backfit rule (Refs. 116 and E.17). As discussed in the backfit portions of the main document, the concept of what constitutes adequate protection is determined on a case-by-case basis. Such determinations may change over time to reflect new information pertinent to whether improvements are needed to ensure adequate protection.

If immediately effective regulatory action is needed, the required documented evaluation for either compliance or adequate protection may follow the issuance of the regulatory action.

E.4 References

E.1 5 U.S.C. 601 et seq. Regulatory Flexibility Act of 1980, as amended. Accessed at http://www.nmfs.noaa.gov/sfa/laws_policies/economic_social/rfa_revised_through_2010_jobs_act.pdf.

E.2 44 U.S.C. § 3501 et seq. Paperwork Reduction Act of 1995, as amended. Accessed at http://www.reginfo.gov/public/reginfo/pra.pdf.

E.3 10 CFR Part 50. *Code of Federal Regulations,* Title 10*, Energy*, Part 50, "Domestic Licensing of Production and Utilization Facilities." Washington, D.C. Accessed at http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/.

E.4 U.S. Nuclear Regulatory Commission (NRC). 2013. "Glossary of Risk-Related Terms in Support of Risk-Informed Decisionmaking. NUREG-2122." Washington, D.C. Accessed at http://www.nrc.gov/docs/ML1331/ML13311A353.pdf.

E.5 U.S. Nuclear Regulatory Commission (NRC). 2011. "Charter: Committee To Review Generic Requirements," Revision 8, ADAMS Accession No. ML110620618.

E.6 U.S. Nuclear Regulatory Commission (NRC). 2005. "United States Nuclear Regulatory Commission Regulations Handbook," NUREG/BR-0053, Revision 6, ADAMS Accession No. ML052720461.

E.7 U.S. Nuclear Regulatory Commission (NRC). 1986. 51 FR 30028 (August 21, 1986). "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement; Republication." *Federal Register*, U.S. Nuclear Regulatory Commission, Washington, D.C. Accessed at http://www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf.

E.8 U.S. Nuclear Regulatory Commission (NRC). 1988. "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," Management Directive 8.4, NRC Manual Chapter 0514, ADAMS Accession No. ML003705015.

E.9 U.S. Nuclear Regulatory Commission (NRC). 2014. "Guidance for Preparing a Supporting Statement," ADAMS Accession No. ML14310A737.

E.10 5 CFR Part 1320. *Code of Federal Regulations*, Title 5, *Administration*, Part 1320, "Controlling Paperwork Burdens on the Public." Washington, D.C

E.11 5 U.S.C. 603, Initial regulatory flexibility analysis.

E.12 10 CFR Part 2. *Code of Federal Regulations*, Title 10*, Energy*, Part 2, "Agency Rules of Practice and Procedure." Washington, D.C. Accessed at http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/part002-0810.html.

E.13 U.S. Nuclear Regulatory Commission (NRC). 2016. "Regulatory Flexibility Act Compliance." Accessed at http://www.nrc.gov/about-nrc/regulatory/rulemaking/flexibility-act.html.

E.14 42 U.S.C. 4321 et seq. National Environmental Policy Act of 1969, as amended. Accessed at https://www.gpo.gov/fdsys/pkg/USCODE-2014-title42/pdf/USCODE-2014-title42-chap55-sec4321.pdf.

E.15 10 CFR Part 51. *Code of Federal Regulations*, Title 10, *Energy*, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Washington, D.C.

E.16 50 FR 38097, 38102, September 20, 1985. "Revision of Backfitting Process for Power Reactors." *Federal Register*, Office of the President, Washington, D.C.

E.17 U.S. Nuclear Regulatory Commission (NRC). 1988. 53 FR 20603 (June 6, 1988) "Revision of Backfitting Process for Power Reactors – Final Rule." *Federal Register*, U.S. Nuclear Regulatory Commission, Washington, D.C