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DRAFT REGULATORY GUIDE

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PREPARATION OF PETITIONS FOR RULEMAKING UNDER 10 CFR 2.802 AND PREPARATION AND SUBMISSION OF PROPOSALS FOR REGULATORY GUIDANCE DOCUMENTS

A. INTRODUCTION

Any interested person may petition the Nuclear Regulatory Commission to issue, amend, or rescind any regulation. The basic procedure and requirements for submitting a petition for rulemaking (PRM) are set forth in Section 2.802, "Petition for Rulemaking," of Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," in Title 10 of the Code of Federal Regulations (10 CFR 2.802).

The minimum requirements and other information for submittal of a PRM by interested parties are provided in 10 CFR 2.802(c). An individual may consult with the NRC staff before filing a PRM. However, the assistance that may be provided by the NRC staff is limited by 10 CFR 2.802(b) to describing the process, explaining the existing regulations and their basis, and assisting the prospective petitioner to clarify a petition. The NRC staff may not draft or develop text or alternative approaches for petitioners.

This regulatory guide is being developed to provide guidance to persons who submit PRMs to the NRC concerning the type and quantity of information that would allow the NRC to process the PRM in an expeditious manner. This regulatory guide delineates factors the NRC uses in setting priorities for processing PRMs and will make the rulemaking process more open to licensees and the public.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules Review and Directives Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by September 12, 1996.

Requests for single copies of active or draft regulatory guides (which may be reproduced) should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section, or by fax to (301)415-2260. Requests for placement on an automatic distribution list for single copies of future guides in specific divisions should be made to the same address.

This regulatory guide also provides the procedures for the submission of proposals to change existing regulatory guidance documents.

Regulatory guides are issued to describe and make available to the public information such as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the NRC staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received a complete review and do not represent official NRC staff positions.

The information collections contained in this draft regulatory guide are covered by requirements that were approved by the Office of Management and Budget, approval number 3150-0136.

The public reporting burden for persons submitting PRMs to the NRC containing information that would allow the NRC to process the PRM in a more expeditious manner is estimated to average 500 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments on any aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F 33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0136), Office of Management and Budget, Washington, DC 20503.

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The collections associated with this regulatory guide are voluntary.

B. DISCUSSION

Petitions for Rulemaking

The NRC is developing this guidance to expedite the processing of PRMs by the NRC by encouraging the submittal of PRMs accompanied by strong technical support. The NRC believes that technical supporting information in the depth

discussed in this guide would effectively expedite the processing of PRMs. If a petitioner follows this guide, the NRC should be able to review and process the PRM more expeditiously.

In proposing improvements to NRC regulations to reduce the regulatory burden, to enhance safety, or for other objectives, petitioners are encouraged to provide supporting information demonstrating that the proposed changes will result in the desired outcome. Petitioners are also encouraged to use publicly available safety information to support the cost effectiveness of the safety enhancements for which they are petitioning.

PRMs are evaluated and scheduled for the NRC's review and disposition by considering the merits of each PRM. A PRM is judged first by its safety significance and then by the degree of complexity or difficulty of the analysis that the NRC staff must perform to determine the disposition of the petition, that is, whether the petition will be accepted through a rulemaking action or denied. The degree to which a supporting analysis is complete, accurate, and thorough will affect how rapidly the NRC staff is able to make such a determination.

Consideration of the safety significance is the first criterion for reviewing and disposing of PRMs. The NRC's primary concern is to ensure that NRC-licensed activities are conducted in a manner that ensures adequate protection of public health and safety, the environment, and the common defense and security. Therefore, PRMs that raise a valid safety concern receive immediate NRC attention. In assessing the safety significance of petitions, the NRC considers the technical information submitted in support of the petition, the information available to the NRC, and whether the proposal will meet the criteria of the backfit rule, 10 CFR 50.109, if applicable. PRMs that are safety neutral (i.e., their implementation will result in an insignificant change to the level of protection of public health and safety or of the common defense and security) and are supported by the type of information described in this guide will be given the next priority.

Proposals for Regulatory Guidance Documents

There is also a need to clarify the procedure for submitting proposals from concerned parties to change existing regulatory guidance documents (RGDs). RGDs include documents such as regulatory guides, bulletins, generic letters, and sections of Standard Review Plans (including branch technical positions).

Because these documents do not have the force and effect of regulations, but serve to identify or clarify methods or positions acceptable to the NRC staff for compliance with NRC regulations, petitioning for a change in a RGD is not normally an effective way to raise a safety concern (unless the petitioner is attempting to point out that a current RGD contains defective guidance that does not comply with the regulation and affects safety).

Any party who has a specific concern about the safe operation of a nuclear power plant or a nuclear materials facility should use the process established in 10 CFR 2.206, concerning the modification, suspension, or revocation of a license, to bring these concerns to the attention of the NRC. Likewise, anyone who is concerned that an existing NRC regulation does not provide adequate protection to public health and safety, the environment, or the common defense and security should do the same through the process established in 10 CFR 2.802, "Petition for Rulemaking."

The public and the nuclear industry currently participate in formulating the final RGDs through the public comment process for new or revised RDGs proposed by the NRC. However, other than for regulatory guides, there is no formal administrative framework for any concerned party to submit proposals recommending changes to existing RGDs. This regulatory guide provides a means for concerned parties to submit such proposals.

C. REGULATORY POSITION

1. PETITIONS FOR RULEMAKING

The materials that should be submitted in a PRM to provide sufficient supporting information for the NRC to consider expedited processing are described in this section. Because these materials must accompany any rulemaking, they are usually developed by the NRC staff for each rulemaking. However, the rulemaking process would be expedited to the extent that the NRC staff can adopt supporting material prepared by the petitioner.

1.1 Regulatory Text

The suggested regulatory text necessary to accomplish the petitioner's desired amendment should be presented and worded as directly, clearly, concisely, and unambiguously as possible. Suggested regulatory text must, to

the extent possible, be presented as amendments to the NRC's regulations as codified in 10 CFR Chapter I.

In developing suggested regulatory text, the petitioner should consider the need for the regulation, the intended effect of the regulation, the basic message of the regulation, the different audiences being addressed by the regulation, and the way the primary audience would use the regulation.

1.2 Statement of Considerations for the Regulation

The statement of considerations contains the supplementary information portion of the preamble to the proposed rule and provides the regulatory history of the PRM. The supplementary information section in the PRM should present the background information and enough specific details to inform interested persons of the issues involved. Background information is required for all PRMs to issue, amend, or rescind a regulation. Petitioners are encouraged to provide actual operating experience and data to support risk-informed and performance-oriented regulations and to assess the values (benefits) and impacts (costs) associated with the proposed regulatory change. This information would be essential in considering either enhancements to or relaxation of existing requirements. As appropriate, the supplementary information should include a discussion of the problem being addressed, how the proposed regulation would solve the problem, the alternatives considered in developing the proposed regulation, and the economic and other impacts of the proposed regulation. The information provided in this section may be used in the statement of considerations that is published as part of the proposed rule in the Federal Register. If the issue being addressed in the petition concerns safety or safeguards adequacy, cost is not a consideration. For this type of petition, information that supports a contention concerning safety or safeguards adequacy should be provided.

1.3 Material To Show Conformance with Legal Requirements

The information in this section is intended to assist the petitioner in considering the impacts of each suggested regulatory alternative in the process

of developing a proposed rule. Section 5 of NUREG/BR-0058[1] describes various legal and procedural requirements for rulemaking. The following legal requirements should be considered by the petitioner, as they must be considered by the NRC staff.

1.3.1 Environmental Impact Under NEPA

The intent of the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 et seq.) is to integrate a consideration of the environmental aspects of the proposed actions into the decisionmaking process. Many rulemaking proceedings will require environmental review. However, the NRC has found that certain types of proposed regulations may be eligible for a categorical exclusion from the requirement for environmental review because these categories of actions do not individually or cumulatively have a significant effect on the human environment. These are listed in 10 CFR 51.22(c).

If a PRM does not qualify for a categorical exclusion under 10 CFR 51.22(c), at a minimum the petitioner should prepare an environmental report (see 10 CFR 51.68). Information on the contents of an environmental report is found in 10 CFR 51.45. The petitioner should ensure that pertinent information is provided in the environmental report to assist the NRC in its analysis to determine whether an environmental assessment (EA) or an environmental impact statement (EIS) is necessary.

Additionally, if an EA (see 10 CFR 51.21) or an EIS (see 10 CFR 51.20) is required for the PRM, the petitioner may wish to prepare a draft EA or EIS. Information on the preparation and content of an EA can be found in 10 CFR 51.30 and of a draft EIS can be found in 10 CFR 51.70 to 51.73 (see 10 CFR 51.85).

1.3.2 Information Collection Requirements Under the Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) is intended to reduce the time, effort, and financial resources that the private sector expends in providing information to the Federal Government. It is also intended

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[1] NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" Revision 2 (November 1995). Copies of this and other NUREGs may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273, fax (202)634-3343.

to reduce the cost to the Federal Government of collecting, using, and disseminating information and to ensure that the information collected is useful. Each Federal agency must obtain approval from the Office of Management and Budget (OMB) for each information collection activity that affects ten or more persons.

With the PRM, the petitioner should provide an estimate and a justification for the assumptions used for the estimate of the public reporting burden for any collection of information that would be required by the proposed regulation. The public burden estimate should be in terms of average hours needed per response for the collection of information and should include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This information will allow the NRC to prepare the clearance package to be submitted to the OMB and a Paperwork Reduction Act of 1995 statement to be included in the proposed rulemaking.

1.3.3 Economic Impact on Small Entities Under the Regulatory Flexibility Act

The Regulatory Flexibility Act as amended (5 U.S.C. 601 et seq.) requires each Federal agency to fit regulatory and informational requirements to the scale of the entity being regulated. This statute requires each agency to consider the economic effect of its regulations on small entities. For the NRC, this is particularly applicable to byproduct, source, and special nuclear material licensees. If the proposed regulation would have a "significant economic impact on a substantial number of small entities," the NRC must prepare an initial regulatory flexibility analysis.

The size standards adopted by the NRC in 10 CFR 2.810 to determine whether an entity is eligible for consideration as a "small entity" are as follows:

> § 2.810 NRC Size Standards.
> The NRC shall use the size standards contained in this section to determine whether a licensee qualifies as a small entity in its regulatory programs.
>
> (a) A small business is a for-profit concern and is a --
> (1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $5 million or less over its last 3 completed fiscal years; or

(2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

(b) A small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $5 million or less.

(c) 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.

(d) A small educational institution is one that is --
(1) Supported by a qualifying small governmental jurisdiction; or
(2) Not state or publicly supported and has 500 or fewer employees.

(e) For the purposes of this section, the NRC shall use the Small Business Administration definition of receipts (13 CFR 121.402(b)(2)). A licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of this section.

The petitioner should provide an estimate, including the justification or assumptions used, of the annual economic impact on small entities that would be caused by the proposed regulation by changes such as hardware modifications, procedural changes for testing or maintenance, or hiring of additional personnel. The material should contain a description of and an estimate of the number of small entities to which the rule would apply. The material should also describe projected reporting, recordkeeping, or other compliance requirements and the type of professional skills necessary for the preparation of the reports or records. If alternatives are considered, it should be shown that the proposed regulation is the least costly alternative that will provide adequate protection to the public and the licensees. Economic impact should be presented in terms of the total annual cost that would result from the proposed regulation. The estimated percentage of small entities among all licensees affected should be clearly stated. This will allow the NRC to prepare the regulatory flexibility analysis statement in the proposed rulemaking or to support a certification that the proposed action would not have a significant economic impact on a substantial number of small entities.

1.4 Regulatory Analysis

The regulatory analysis is the most significant element developed in support of a proposed rulemaking. This analysis is a structured evaluation of

all factors relevant to making a regulatory decision and is the basis for determining whether to proceed with a proposed rulemaking. For this reason, it is important that the petitioner ensure that all aspects of the regulatory analysis are fully developed and presented in a complete and correct manner.

Information on the form and content of a regulatory analysis is provided in NUREG/BR-0058[1] and NUREG/BR-0184.[2] The guidelines in NUREG/BR-0058 also describe the key objectives that must be met by the regulatory analysis and provide a description of the regulatory analysis process. The guidelines contained in NUREG/BR-0058 also establish a framework for analyzing the need for and consequences of a proposed regulatory action, selecting a preferred alternative, and documenting the analysis in an organized and understandable format. NUREG/BR-0184 is being developed to provide more detailed information on preparing the regulatory analysis. When final, NUREG/BR-0184 will provide the methodology and generic estimates for the quantification of select attributes that are typically included in NRC regulatory analyses.

The regulatory analysis is intended to aid the NRC in determining whether the proposed action is needed and to provide a clear and well-documented explanation regarding the particular action being recommended. It is also intended to ensure that cost-effective regulatory actions, consistent with providing necessary protection for public health and safety and the common defense and security, are identified for each proposed rule. Regulatory analyses must be sufficiently clear and contain sufficient detail to enable NRC staff to easily recognize --

- The problem within the context of the existing regulatory framework;
- The proposed regulatory action;
- The conclusions reached and the bases for these conclusions;
- The specific data and analytical methods used and the logic followed that led to the conclusion that the proposed new requirement was appropriate and justified;
- The sources and magnitude of uncertainties that might affect the conclusions and the proposed new requirement; and
- The sensitivity of the conclusions to changes in underlying assumptions and considerations.

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[2] NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook" (August 1993 Draft). The final report is expected to be issued in the Fall of 1996.

Generally, the appropriate level of detail to be included in a regulatory analysis should be in proportion to the safety significance, complexity, and cost impacts of the proposed rule. Section 2.4 of NUREG/BR-0184 contains information on the scope and level of detail that should be included in the regulatory analysis. The regulatory analyses supporting the relaxation or elimination of regulatory requirements that are marginal to safety can be markedly different from those required to justify the issuance of additional requirements. Section 2.2 of NUREG/BR-0058 describes these differences and the documentation that must be included for those regulatory analyses supporting the relaxation or elimination of marginal safety requirements.

Elements that should be included and addressed in a regulatory analysis, as discussed in NUREG/BR-0058, include:

- A statement of the problem and objectives for the proposed regulatory action;
- Identification and preliminary analysis of alternative approaches to the problem;
- Estimation and evaluation of the values (benefits) and impacts (costs) for selected alternatives, including consideration of the uncertainties affecting the estimates;
- Presentation of results, namely, the conclusions of the evaluation of values and impacts; and
- The decision rationale for selection of the proposed regulatory action.

The elements of a regulatory analysis are presented below. NUREG/BR-0058 and NUREG/BR-0184 should be consulted for additional information on the preparation of a regulatory analysis.

1.4.1 Statement of the Problem and Objective

A concise summary of the problems or concerns that need to be remedied and defined within the context of the existing regulatory framework should be provided in the statement of the problem. The nature and extent of the problem and why it requires action should be presented clearly. In this context, a measure of the action's safety importance needs to be presented on either a qualitative or quantitative basis. This section of the regulatory analysis should demonstrate the need to take action and the consequences of taking no action for this problem.

For some regulatory issues there may be existing NRC or Agreement State regulatory requirements or guidance, industry programs, or voluntary efforts by licensees directed at the same or similar problem. These activities and any variations in industry practice and commitments among licensees should be identified and discussed to the extent applicable. The statement of the problem should identify the specific class or classes of licensees, reactors, or other facilities affected by the problem, as appropriate. A background discussion of the problem should be included. For problems or concerns within the scope of the backfit rule (10 CFR 50.109), the type of backfit needs to be identified.

1.4.2 Identification and Preliminary Analysis of Alternative Approaches

After the need for action has been established, the regulatory analysis should next focus on identifying reasonable alternatives that have a high likelihood of resolving the problems or concerns. An initial list of alternatives should be identified and analyzed as early in the regulatory analysis process as possible. This list should be reasonably comprehensive to ensure that the range of all potentially reasonable and practical approaches to the problem are considered. In identifying alternatives, the following issues should be considered: (1) What action should be taken? (2) Whose responsibility should it be to take action? (3) How should it be done? (4) When should it become effective?

Following the identification of the initial list of alternatives, a preliminary analysis of the feasibility, values, and impacts of each alternative usually eliminates some of the alternatives. The elimination of alternatives from further analysis can be based on factors such as clearly exorbitant impacts in relation to values, technological impracticality, or severe implementation difficulties. The initial set of alternatives should be refined because information is generated as part of the preliminary analysis of the alternatives. For each alternative that survives the preliminary screening, a general description of the activities required of licensees and the NRC to implement the alternative should be provided.

The section on alternatives in the regulatory analysis should list all significant alternatives considered. A brief explanation of the reason for elimination should be included for alternatives not selected for further study.

1.4.3 Estimation and Evaluation of Values and Impacts

An estimation and evaluation of values and impacts on the alternatives that survive the screening process should be provided in this section of the regulatory analysis. The level of detail need not be the same for all alternatives. This section generally is the longest and most complex of all the sections in a regulatory analysis.

In the context of the regulatory analysis, "values" are defined as the beneficial aspects anticipated from a proposed regulatory action such as, but not limited to, the enhancement of health and safety, protection of the environment, promotion of the efficient functioning of the economy and private markets, and elimination or reduction of discrimination or bias. "Impacts" are defined as the costs anticipated from a proposed regulatory action such as, but not limited to, the direct costs to NRC and Agreement States in administering the proposed action and to licensees and others in complying with the proposed action; adverse effects on health, safety, and the natural environment; and adverse effects on the efficient functioning of the economy or private markets.

Categories of groups affected by the proposed regulatory action should be identified. Groups may include, but are not limited to, the general public, units of State and local Government, Indian tribes, licensees of the NRC or Agreement States, employees of licensees, contractors and vendors, the NRC, and other Federal agencies. For each affected group, the attributes that characterize the consequences of the proposed action should be identified.

Estimates of value and impact are to be incremental best estimates relative to the baseline case, which is normally the no-action alternative. Best estimates, when possible, should be made in terms of the mean (expected value). However, depending on the level of detail available from the data sources employed in the regulatory analysis, acceptable estimates could include other point estimates. In this case, the rationale for the use of estimates other than mean values should be provided.

It is important to consider uncertainties in developing a regulatory analysis. The sources and magnitudes of uncertainties in value and impact estimates and the methods used to quantify uncertainty estimates should be discussed in all regulatory analyses. A sensitivity analysis can be used in addition to or in lieu of a formal uncertainty analysis. Hypothetical best- and worst-case values and impacts can be estimated for sensitivity analyses.

Estimates of value and impact should be made by year for the entire period that groups will be affected by the proposed regulatory action. For licensed

facilities, estimates should be made for the remainder of the operating license or projected useful life of the facility (i.e., extended into the license renewal period). For nuclear power reactors, separate estimates for a license renewal term should be made if the analyst judges that the results of the regulatory analysis could be significantly affected by the inclusion of such a renewal term. If not, the basis for the judgment or conclusion that there would not be a significant effect should be stated for future reference.

Whenever possible, value and impact estimates should be expressed in monetary terms and in constant dollars from the most recent year for which price adjustment data are available. Consequences that cannot be expressed in monetary terms should be described and quantified in appropriate units to the extent possible. Many regulatory actions, such as those affecting non-power reactor and materials licensees, may not be supported by an available probabilistic risk assessment (PRA) analysis. Also, probabilistic analysis techniques may not be practical for some actions. The analyst needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective and useful trends concerning the value of the proposed action. Even inexact quantification with large uncertainties is preferable to no quantification, provided the uncertainties are appropriately considered. The analyst should use care to verify that neither values nor impacts are double counted. Values and impacts that are determined to be unquantifiable should be identified and discussed qualitatively. An attribute should not be omitted from a regulatory analysis document simply because it is determined to be unquantifiable.

1.4.4 Presentation of Results

A net value calculation, i.e., the summation of positive and negative attributes, should be computed and displayed in the regulatory analysis for each alternative considered. This calculation requires, to the extent possible, that all values and impacts be quantified in present-worth monetary terms and added together (with the appropriate algebraic signs) to obtain the net value in dollars. The analyst may elect to display the results based on the ratio of values to impacts. However, this method of display is supplemental and not a replacement for the net value method. In the ratio method, the numerator represents the sum of all quantifiable present-worth estimates for values, while the denominator does likewise for impacts. The net value method is generally

the preferred method of the two because it provides an absolute measure of the aggregate net effect of the proposed action.

1.4.5 Decision Rationale for Selecting the Proposed Action

The reason the proposed action is recommended over the other alternatives considered should be explained in this section of the regulatory analysis. The decision criteria used for selecting the proposed action should be identified. The criteria should include, but are not limited to:

- The net value and value-impact computations,
- The relative importance of attributes that are quantified in terms other than monetary,
- The relative importance of unquantifiable attributes,
- The relationship and consistency of the proposed alternatives with the NRC's legislative mandates, safety goals, and policy and planning guidance that are in effect at the time the proposed alternative is recommended, and
- The impact of the proposed action on existing or planned NRC programs and requirements.

In addition, this section should also include a statement of the proposed generic requirement, a statement as to whether the proposed action would increase or relax (or reduce) existing requirements, and a statement on whether the proposed action is interim or final, and if interim, the justification for imposing the proposed requirement on an interim basis.

1.5 Response to the Backfit Rule

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

A backfit may be imposed on a nuclear power facility that already provides adequate protection of public health and safety and common defense and security only if the backfit analysis as required by 10 CFR 50.109 indicates that (1)

there would be a substantial increase in the overall protection of public health and safety or the common defense and security derived from the backfit and (2) the direct and indirect costs that would result from the implementation of the backfit are justified. A backfit analysis is not required when (1) a modification is necessary to bring a facility into compliance with a license or the rules or orders of the NRC, or into conformance with written commitments by the licensee, (2) the 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, or (3) the regulatory action involves defining or redefining the level of protection to public health and safety or common defense and security that should be regarded as adequate.

Details of the backfitting process and the preparation of a backfit analysis are provided in NUREG-1409, "Backfitting Guidelines."[3] Relaxations of requirements affecting nuclear power plants that result in significantly reduced regulatory burden with minimal impact to overall safety (safety neutral) are not backfits and thus do not fall within the scope of the backfit rule. However, a relaxation of requirements is subject to a regulatory analysis as described in section 2.4, "Regulatory Analysis."

Section 2.3 of NUREG/BR-0058 provides information on preparing the backfit analysis. Section 2.0 of NUREG/BR-0184[2] describes how the information required for the backfit analysis should be included in the regulatory analysis.

1.6 Guidance Document, When Applicable

A regulatory guide is frequently developed to provide guidance on methods for meeting a performance-based regulation. Performance-oriented rather than programmatic, prescriptive, and compliance-based regulations could be developed using risk insights (such as those obtained from probabilistic risk assessment) and safety goal[4] considerations to establish regulatory objectives. This approach should result in improved safety by allowing more available resources

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[3] D.P. Allison, J.H. Conran, C.A. Trottier, "Backfitting Guidelines," NUREG-1409, USNRC, July 1990. Copies may be purchased from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

[4] See "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement," August 4, 1986; 51 FR 28044, as corrected and republished August 21, 1986, 51 FR 30028.

to be used for the more important safety issues. However, the use of performance-oriented regulations will entail developing performance criteria and methods of measuring performance. In addition, changing to performance-oriented regulations means that details, if needed to show an acceptable way of complying with the regulations, would be published in a guidance document. The effect of the method adopted in the guidance document should be considered in the values and impacts assessment of the regulatory analysis. The format and content of any typical NRC regulatory guide could be used for the preparation of a guidance document.

NUREG/BR-0058[1] (the NRC Regulatory Analysis Guidelines) states that safety goal evaluation is applicable only to power reactor regulatory initiatives considered to be generic safety enhancement backfits defined by the backfit rule (10 CFR 50.109). Relaxations of requirements affecting nuclear power plants are not subject to the safety goal evaluation requirements.

2. PROPOSALS FOR REGULATORY GUIDANCE DOCUMENTS

Regulatory guidance documents (RGDs) are NRC documents such as regulatory guides, bulletins, generic letters, and sections of Standard Review Plans (including branch technical positions). These documents do not have the force and effect of regulations, but they frequently provide guidance on methods or positions acceptable to the NRC staff for compliance with NRC regulations. Most of these RGDs are issued for public comment so that licensees and the public can participate in formulating the final staff positions.

Any submittal recommending changes to an existing RGD must meet the following criteria before it can be considered by the NRC office responsible for that particular document.

1. The proposed change to an RGD is applicable to a number of licensees rather than to a particular licensee.
2. The submittal contains a detailed analysis to ensure that the proposed alternatives will comply with NRC regulations and the requirements that public health and safety, the environment, and the common defense and security are adequately protected.
3. The submittal contains an estimate of impacts on costs for the proposed alternatives compared withe costs for the methods or positions in the existing RGD.

4. The text of the proposed changes to the RGD is included in the submittal, and the format of the text follows that of the existing RGD as much as possible.

Submittals recommending changes to an existing RGD will be considered by the NRC office responsible for that document, and the NRC office must first determine whether the submittal meets the criteria above. Proposals regarding RGDs should be addressed to the Director of the NRC office responsible for the issuance of these RGDs. The RGDs and the responsible offices are as follows.

- Regulatory Guides - Office of Nuclear Regulatory Research

- Bulletins, Generic Letters - Office of Nuclear Reactor Regulation for all proposals related to construction, operation, and decommissioning of nuclear reactor facilities. Office of Nuclear Material Safety and Safeguards for proposals related to activities involving safety, quality, approval, and inspection of the use and handling of licensed nuclear and other radioactive materials; nuclear fuel fabrication and fuel development; medical, industrial, academic, and commercial uses of radioactive isotopes; material control, accounting, and physical protection of special nuclear material; safeguards design basis threat; transportation of nuclear materials; spent fuel storage at a location away from a reactor; safe management and disposal of low-level and high-level radioactive waste; international safeguards and nonproliferation; and management of related decommissioning.

- Standard Review Plans - Issuing office

Within a reasonable time after a proposal to change an existing RGD has been received, the Director of the NRC office responsible for the issuance of the RGD should advise the party who made the proposal in writing whether the modification of the RGD will proceed or will not proceed in whole or in part, with respect to the proposal, and the reason for the decision.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees, applicants, and the public regarding the NRC staff's plans for using this regulatory guide.

This draft guide has been released to encourage public participation in its development. Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods to be described in the active guide reflecting public comments will be used in the evaluation of petitions for rulemaking submitted under 10 CFR 2.802 and of changes to regulatory guidance documents.

REGULATORY ANALYSIS

The Administrative Procedure Act requires each Federal agency to give interested persons the right to petition for the issuance, amendment, or repeal of a rule. This regulatory guide will facilitate more expeditious disposition of petitions by the NRC, and it does not affect any existing rights. The cost involved in its promulgation and implementation is necessary and appropriate.

The NRC originally considered a rulemaking on the type and level of information needed for expedited processing of PRMs. The NRC decided against this course of action after evaluating public comments received on the proposed rulemaking. The majority of the public comments stated that it is unnecessary to codify this guidance because it is general guidance and does not impose any mandatory requirements. Although an alternative would be to not provide any guidance, this alternative clearly would not accomplish the original objective. Because the majority of the material in this regulatory guide has already been developed during the proposed rulemaking activity, the resources for preparing this guide are insignificant and outweighed by the benefits.

Federal Recycling Program

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