



**United States
Nuclear Regulatory Commission**

Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission

Office of the Executive Director for Operations

January 1983

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

December 13, 1982

MEMORANDUM FOR: Office Directors and Regional Administrators

FROM: William J. Dircks
Executive Director for Operations

SUBJECT: ADOPTION OF REGULATORY ANALYSIS GUIDELINES TO REPLACE
VALUE IMPACT GUIDELINES

On December 7, 1981, I appointed an interoffice task group to review the Commission's guidelines for performing value impact analyses and to recommend changes that would improve their use and quality. The revised guidelines, Regulatory Analysis Guidelines, are enclosed. A regulatory analysis, prepared pursuant to these guidelines, must accompany all proposed rules and final rules to which the guidelines apply which are submitted for review by the Committee to Review Generic Requirements and the Deputy Executive Director for Regional Operations and Generic Requirements and for decision by the Executive Director for Operations and the Commissioners.

The guidelines provide for a structured, but general framework for analyzing alternative regulatory actions. They provide instructions for completing tasks necessary for a sound regulatory analysis. They also provide the flexibility to tailor the depth and length of an analysis to the significance of the regulatory action being considered. The procedures also provide for the incorporation of analyses of information collections required by the Paperwork Reduction Act and analyses of impacts on small entities required by the Regulatory Flexibility Act. A checklist approach is recommended for the use by the staff in identifying effects of alternative regulatory actions on other NRC programs, licensee operations, and other activities. A sample checklist is enclosed with the guidelines as well as a list of effects that illustrate consequences that could result in a cost or benefit.

To assure that other rulemaking actions and non-rulemaking generic requirements are also supported by a sufficient analysis, an evaluation of the action being proposed that addresses the topics set forth in Section III.B of the guidelines must be prepared. The evaluation at a minimum must include an assessment of the costs and benefits of the proposed action compared to the existing situation, but need not be as extensive or detailed as required for rules which fall within the coverage of the guidelines. The evaluation

shall accompany all rulemaking actions which do not meet the threshold criteria for performing a regulatory analysis and other generic requirements that are submitted for review to the Committee to Review Generic Requirements or to the Deputy Executive Director for Regional Operations and Generic Requirements, or for decision by the Executive Director for Operations or the Commission.



William J. Dircks
Executive Director for Operations

Enclosures:
As Stated

cc: Chairman Palladino
Commissioner Gilinsky
Commissioner Ahearne
Commissioner Roberts
Commissioner Asselstine
SECY
OGC
OPE
PDR

REGULATORY ANALYSIS GUIDELINES
OF THE
UNITED STATES NUCLEAR REGULATORY COMMISSION

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REGULATORY ANALYSIS GUIDELINES

I

PURPOSE

The principal purpose of these Regulatory Analysis Guidelines is to ensure that the NRC regulatory decisions are based on adequate information concerning the need for and consequences of a proposed regulatory action and to ensure that cost effective regulatory actions, consistent with providing the necessary protection of the public health and safety and common defense and security, are identified. High quality regulatory analyses should serve as the basis for NRC decisions. Therefore, a regulatory analysis must be included in all decision packages on matters covered by these guidelines.

II

COVERAGE

- A. A Regulatory Analysis, which includes a discussion of any reasonable alternatives to the proposed action, shall be prepared for each proposed rule and final rule that, in the determination of the responsible office director or the Executive Director for Operations, will likely result in the following:
- a. An annual effect on the economy of \$100,000,000 or more in direct and indirect costs, or
 - b. A significant impact on health, safety or the environment, or
 - c. A substantial increase in the cost to NRC licensees, permit holders or applicants, to Federal, state or local governments, and geographical regions, or
- *B. A Regulatory Analysis shall also be prepared for other rules and generic requirements not covered above when directed by the Commission or the Executive Director for Operations.

* The EDO has directed that other rulemaking actions not covered by the mandatory review categories above and non-rulemaking generic requirements submitted for review or approval by the Committee to Review Generic Requirements, the Deputy Executive Director for Regional Operations and Generic Requirements, the EDO or the Commission should also be supported by an analysis based on the guidance provided in Part III.B of the Guidelines but much less detail is required.

III

GUIDELINES FOR PREPARING A REGULATORY ANALYSIS

A. Instructions for Preparing a Regulatory Analysis1. Introduction

The following guidelines are designed to provide a framework for structuring the analysis required to support proposed and final generic regulatory requirements. The analysis is intended to aid the staff and the Commission in determining whether to initiate a regulatory action, in selecting the preferred regulatory alternative, and in providing a coherent, understandable, and well-documented explanation of why a particular action was recommended.

Making the performance of a regulatory analysis an integral part of developing a staff position on a proposed regulatory action, not as an afterthought simply to meet a procedural requirement, a better and more efficiently prepared analysis should result. Also use of the procedures to outline the scope of the analysis could significantly aid in determining the level of effort and associated resources required to perform a regulatory analysis as well as contributing to the early identification of potential alternatives, possible consequences and information that may be needed to perform the analysis.

A regulatory analysis should accompany all proposed rules and final rules which are covered by these guidelines which are forwarded for review by the Committee to Review Generic Requirements or the Deputy Executive Director for Regional Operations and Generic Requirements, or submitted for decision by the Executive Director for Operations or the Commissioners.

2. Scope of the Analysis

The scope of the regulatory analysis should primarily be in proportion to the safety significance of the regulatory action being addressed. However a rule or generic requirement of small safety significance and large potential costs should be rigorously analyzed. The emphasis in implementation of the procedures should be on simplicity, flexibility, and common sense, both in terms of the type of information supplied and in the level of detail provided. Since the principal purpose of the procedures is to assure that the proposed action has been sufficiently analyzed and the rationale for its selection well documented, staff efforts should be primarily dedicated to achieving this purpose rather than spending great effort rigorously analyzing an alternative when it has become apparent that the alternative will not be acceptable. However, the written narrative should indicate the rationale for rejecting any alternative that was seriously considered even though the effort required to reach the decision was limited.

3. Consideration of Alternatives

A Regulatory Analysis prepared for a proposed rule or final rule covered by Section II.A of these guidelines should include a discussion of any reasonable alternatives to the proposed action. Alternatives considered should be confined to major alternative regulatory approaches rather than to relatively minor variations of the proposed action. Among alternatives that could be considered are taking no action at all, making more effective use of existing enforcement mechanisms, establishing performance standards and deregulation when appropriate. The extent to which costs and benefits should be assessed for alternatives is to be determined by the responsible office director.

4. Analyses Required by Statute

Information collection requirements (application, reporting and recordkeeping) affecting ten or more persons or organizations must be approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act. Instructions for addressing factors needed to obtain the OMB's approval are contained in Appendix A. These factors must be addressed in the regulatory analysis when the alternative regulatory actions involve information collections.

Where a rulemaking action is likely to have a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires that the impact be addressed specifically. Appendix B provides guidance on the factors that must be addressed when evaluating economic impacts on small entities.

5. Relationship to the Generic Environmental Impact Statement

In those circumstances where a Generic Environmental Impact Statement (GEIS) has been prepared and forms the basis for the proposed action, a brief summary of the GEIS will be an acceptable substitute for Sections III.B.1,2,3,4 of the regulatory analysis guidelines which address the problem, objectives, alternatives, and consequences, respectively. Staff will have to provide an explanation of the rationale for selecting the proposed action and rejecting other alternatives considered in the GEIS (Section III.B.5), and describe the implementation schedule and relationship of the proposed action to other requirements and programs (Section III.B.6).

B. Contents and Format of the Regulatory Analysis

1. Statement of the Problem

Explain the nature of the problem that will be addressed by the proposed regulatory requirement and why any action is necessary at this time. Identify the class or classes of licensees, reactors or other facilities affected by the problem. Discuss any applicable existing or proposed NRC regulatory actions that currently address the problem, their achievements and costs, and significance of taking no action to address the problem.

2. Objectives

Within the general objectives of protecting the public health and safety and the common defense and security and of identifying cost-effective alternatives, precisely state the specific objectives that the proposed regulatory action is designed to achieve.

3. Alternatives

Identify any reasonable alternatives considered for achieving the specific regulatory objectives.

4. Consequences

Provide an analysis of each alternative considered that discusses the following factors:

a. Costs and Benefits of Alternatives

For proposed rules and final rules above the thresholds set forth in Section II the regulatory analysis should describe the benefits and the costs, including any cumulative effects, that may result from the implementation of the proposed requirement or any reasonable alternative that was considered. Examples of the types of effects that could result in a cost or benefit are listed in Appendix D. The analysis should also identify the classes of persons or organizations who will receive the benefits, or incur the costs from the proposed alternatives. These could include licensees, vendors, licensee suppliers or contractors, the NRC staff, Federal, State or local governments or small business establishments and other small entities. Any effects on geographical regions should also be identified.

The sources of cost data and methodologies for deriving costs and benefits should be identified and referenced. Every attempt should be made to quantify the costs and benefits that may result from a particular alternative, even if uncertainties in the data prevent a precisely accurate numerical estimate. Where it is not possible to quantify costs and benefits, the reason should be indicated; and the analyst should describe the nature and extent of the costs or benefits in as precise and succinct a manner as possible. All assumptions and uncertainties underlying the data and methodologies should be stated.

Where possible, costs and benefits should be expressed in safety, occupational exposure or monetary terms. Monetary costs and benefits should be expressed in present value through the use of an annual discount rate of ten percent (10%). However, other discount rates may be used to test the sensitivity of the analysis. All benefits and costs which are expressed in monetary terms should be converted to constant dollars (i.e., dollars should not be adjusted to reflect anticipated inflation).

The cost of complying with the proposed requirement or part of the proposed requirement through the use of a Regulatory Guide or other means deemed acceptable by the NRC should be specifically identified.

b. Impacts on Other Requirements

The effect of an alternative on all other NRC programs and requirements, as well as those of other government entities and licensees, should be considered. Any associated costs or benefits should be indicated. The extent to which these effects are addressed should be in proportion to the significance of their impact on the other programs. Common sense should be used to avoid such considerations becoming a major study effort. To assist the staff in identifying impacts on other requirements or programs, use of a checklist such as the one described in Appendix C is recommended.

c. Constraints

Identify any constraints that affect the implementation of the alternative, including scheduling, enforceability, policy, institutional, or legal considerations.

5. Decision Rationale

Explain why, in light of the analyses performed, the proposed action is recommended and why other alternatives considered were rejected. Identify and reference the data or studies on which the decision is based, including ANSI or ASME standards, staff papers or other documents. Identify any decision criteria used. Also, it should be indicated if the proposed action represents the staff's definitive position on the subject, or if the requirement is the first or part of a series of related requirements to be issued.

6. Implementation

a. Schedule for Implementing the Proposed Requirement

Describe the steps and schedule, or alternative schedules, that will likely be required to implement the proposed requirement. Include in the schedule any staff actions which will be needed. Sufficient information should be provided to demonstrate that the schedule or alternative schedules are realistic. When the proposed action involves short-term and long-term requirements, those requirements should be stated.

Where one or more classes of reactors or other facilities are affected, it should be demonstrated that sufficient time is provided to make required computations, allow the licensee, permit holder or applicant to design any needed new systems or modifications to existing systems, obtain any needed NRC approval of designs or changes in technical specifications, test and evaluate designs, procure equipment and labor, install equipment, develop operating procedures and train operators. Plant conditions which are necessary for installing equipment, conducting preoperational tests

and operable tests should be described. The length of time a plant must be shut down to meet the proposed requirements should be indicated. Also indicate whether any required new equipment is available in sufficient quantity to meet the needs of all affected licensees or whether it must be designed.

b. Relationship to Other Existing or Proposed Requirements

Indicate the relationship of the proposed action to other existing or proposed requirements, its effect on priorities for implementing other requirements for related activities, and if the proposed action means that other actions or systems or prior analyses need to be reassessed.

APPENDIX A

Analysis Required to Support the Imposition of Information Collection Requirements

The Paperwork Reduction Act (P.L. 96-511) requires agencies to obtain a clearance from the Office of Management and Budget (OMB) for all information collection requirements (applications, reporting, recordkeeping) that affect 10 or more persons. The analysis required for OMB clearance must consider the necessity for the proposed information collection, its practical utility, the economic and time burden placed on the person subject to the requirement, and its cost to the federal government. All regulatory actions proposed by the staff that involve information collections, whether mandatory or voluntary, must be accompanied by an OMB Supporting Statement that justifies and describes the requirement. The regulatory analysis may constitute the supporting statement. The following factors must be addressed in any regulatory analysis involving an action which imposes an information collection requirement.

1. Justification

a. Need for The Information Collection

Explain why the information collection is needed (i.e., describe any problems that justify the need for the requirement and explain how it is the best means of achieving the regulatory objective).

b. Practical Utility of the Information Collection

Explain to whom the information is to be reported and for what purpose it will be used. Describe the NRC's capability to use the reported information in a timely and useful fashion. Explain the purpose for requiring respondents to maintain information not required to be submitted to NRC.

c. Duplication With Other Collections of Information

If the requirement duplicates or overlaps other information collections made by the NRC or other government agencies, identify those information collections and explain why that information cannot meet the need being addressed.

d. Consultations Outside the NRC

Describe any consultations with other Federal, state or local government agencies or with other organizations or individuals regarding the information collection.

e. Other Supporting Information

Discuss any other information which may help in understanding and evaluating the need for and use of the information collection requirement.

2. Description of the Information Collection

a. Number and Type of Respondents

Identify the number and type of respondents to which the information collection requirement applies annually.

b. Reasonableness of the Schedule for Collecting Information

Describe the schedule for imposing the information collection requirement and explain why it is reasonable within the context of the need for the information.

c. Method of Collecting the Information

Discuss alternative methods, if any, for collecting the information. If alternatives are available, explain why the information collection requirement selected is the least burdensome method for achieving the regulatory objective, and is consistent with sound management practices. Examples of less burdensome methods include verification and review of a record at the licensee site rather than submission of a report, submission of reports or retention of records in microform rather than in paper copy, transmission of reports through use of automated word processing or computer means rather than by paper or microform, reduction in the number of copies distributed, simplification of format, accepting a similar report containing the same information, consolidation of two or more reports into a single report, or conducting interviews or telephone surveys of a sample segment of the licensees affected.

d. Record Retention Period

Identify the record retention period and explain why it is necessary. Provide justification where records are required to be retained for more than four years.

e. Reporting Period

Identify the frequency with which the report must be submitted to the NRC or other organizations. If the report is required to be submitted more often than quarterly, the need for this more frequent reporting should be specifically described.

f. Copies Required to be Submitted

Identify the number of copies to be submitted, their distribution and usage. Provide justification where more than three (3) copies are required to be submitted.

3. Estimate of Burden

a. Estimated Hours Required to Respond to the Collection

Indicate how much time (staff hours) the respondent will spend annually if it is a recurring or multi-year requirement to comply with the information collection requirement.

b. Estimated Cost Required to Respond to the Collection

Indicate how much it will cost (dollars) the respondent annually to comply with the information collection requirement.

c. Source of Burden Data and Method for Estimating Burden

Indicate the sources from which burden estimates were obtained and the method used to estimate the burden.

d. Reasonableness of Burden Estimates

Explain why the burden estimates are reasonable.

4. Estimate of the Cost to the Federal Government

Describe the annual cost of the information collection to the NRC in terms of staff time and administrative expense. Costs include time and resources required to obtain, process and store the information, such as "the cost of information collection design development, tests, printing forms, mailing list compilation and maintenance, editing, coding, tabulation analyses and publication. If contractors are involved in the information collection, then their cost should be included."

Commission procedures for implementation of the Paperwork Reduction Act require each office, through its Information Management Coordinator, to submit the Supporting Statement to the Office of Administration for review before it is submitted to OMB for approval. Further information on procedures related to the Act will be published in NRC Manual Chapter 0230 "Federal Reports Management."

APPENDIX B

Analyses Required When a Substantial Number of Small Entities Will Be Impacted

The Regulatory Flexibility Act (P.L. 96-534) requires an analysis of any proposed rule, or final rule that is preceded by a proposed rule, which is likely to have a significant economic impact on a substantial number of "small entities" (small business establishments, non-profit organizations, and small government jurisdictions). The analysis must indicate the criteria used to identify the small entities (annual receipts for sales or service, number of employees, etc.) and explain how the regulatory action will affect the small entity. The analyst must determine whether a significant number of the small entities affected are likely to experience substantial economic consequences including additional burdens associated with information collection requirements as a result of the proposed rulemaking action. It must also include consideration of alternatives which could accomplish the objective of the proposed regulation while minimizing the economic impact on small entities.

In cases where a proposed rule will not have a significant economic impact on a substantial number of small entities, a "regulatory flexibility certification" to this effect must be included in the Federal Register Notice. It should be noted that the Regulatory Flexibility Act applies only to rulemaking actions.

All the information required for purposes of the Regulatory Flexibility Act should be contained in the analysis prepared pursuant to the Regulatory Analysis Procedures and a separate analysis need not be prepared. For more information on the Act and its requirements, see "Guidance for Implementing the Regulatory Flexibility Act and the Preparation of Regulatory Flexibility Analyses," dated April 1, 1981 (Division of Rules and Records, Office of Administration).

APPENDIX C

Checklist for Identifying Potential Impacts on NRC Programs, Licensee Operations and Other Activities

Alternative: _____

Analyst: _____

Date: _____

Instructions:

This sample checklist is designed to aid the analyst in identifying the impacts of each alternative regulatory action on other NRC programs, licensee operations and other activities. It is not intended to be all inclusive. Rather, it is intended to serve as a guide for the analyst who may develop a more comprehensive checklist that would apply to the particular program area. The analyst should indicate whether each alternative being considered will affect (1) NRC programs and requirements, (2) licensee programs and operations, (3) interagency or intergovernmental agreements between NRC and other agencies, (4) U.S. international agreements and commitments, and/or (5) other analyses required by law. The staff responsible for a specific activity should be consulted if the analyst cannot independently determine if an impact on the activity would result. Each area or program identified as being affected should be evaluated and addressed in the regulatory analysis.

Checklist

A. NRC Programs and Requirements and Licensee Operations

1. Indicate the areas or programs which may be affected by each alternative regulatory action being considered for each of the categories listed below:

	NRC programs and requirements			licensee implementation*		
	NRC regulations**	Licensing actions under review	Inspection/enforcement program	Operating facilities	Facilities in early construction stage	Facilities in late construction stage
<u>(a) Reactors</u>						
i. Reactor construction, for example:						
a. Seismology	_____	_____	_____	_____	_____	_____
b. Welding	_____	_____	_____	_____	_____	_____
c. Concrete	_____	_____	_____	_____	_____	_____
d. Fire protection	_____	_____	_____	_____	_____	_____
e. Other (specify)	_____	_____	_____	_____	_____	_____
ii. Reactor operations, for example:						
a. Control room	_____	_____	_____	_____	_____	_____
b. Safety checks/tests	_____	_____	_____	_____	_____	_____

* Licensee programs and operation.

** Proposed or existing regulations or any implementing guidance such as Regulatory Guides, or NUREGs.

	NRC programs and requirements			Licensee implementation		
	NRC regulations	Licensing actions under review	Inspection/enforcement program	Operating facilities	Facilities in early construction stage	Facilities in late construction stage
ii. Site operations etc.						
a. Public health	_____	_____	_____	_____	_____	_____
b. Environmental considerations	_____	_____	_____	_____	_____	_____
iii. Closure, decommissioning and long-term care, etc.	_____	_____	_____	_____	_____	_____
iv. Transportation	_____	_____	_____	_____	_____	_____

2. Indicate whether or not the NRC staff will have difficulty in inspecting or enforcing the alternative regulatory action being considered. _____
3. Indicate whether the alternative regulatory action being considered will have an impact on the operational status of the facility _____
4. Indicate if the alternative regulatory action being considered will have an impact on the NRC:
 - i. Export/Import Responsibilities _____
 - ii. Rules of Practice (e.g., 10 CFR Part 2) _____
 - iii. Other (specify) _____

B. Licensee Capabilities

1. Indicate whether or not the alternative regulatory action being considered will have an impact on:

- i. The size or quality of the licensee's staff _____
- ii. The licensee's ability to:
 - a. Develop new equipment or designs _____
 - b. Acquire contract services _____
- iii. The licensee's program for complying with the requirements of the license?
(e.g., QA tests, training, reporting) _____

C. Interagency or Intergovernmental Agreements

- 1. Indicate whether or not the alternative regulatory action being considered will have an impact on:
 - i. The NRC State Agreements Program _____
 - a. Licensing of byproduct, source and small quantities of SNM (specifically address changes that may be required of individual states' licensing programs) _____
 - ii. Any agreements (MOUs) between NRC and other U.S. Agencies (e.g., DOE, FEMA, EPA, DOT, DOL, DOJ) _____
 - iii. Other regulatory programs of Federal and State Agencies _____

D. U.S. International Agreements

- 1. Indicate whether or not the alternative regulatory action being considered will have an impact on:
 - i. Bilateral or multilateral agreements between U.S. and other nations relative to nuclear trade, imports or exports: _____
 - ii. U.S. agreements with international agencies (e.g., U.S. - United Nations IAEA Safeguards agreement) _____

E. Applicability of Other Analyses Required by Law

- 1. Indicate whether or not the alternative being considered will impose an information collection (application, reporting, or recordkeeping) requirement? If applicable, refer to Appendix A. _____

2. Indicate whether or not the alternative being considered is likely to have a significant impact on a substantial number of small entities including those which may be licensees, vendors, or suppliers? If applicable, refer to Appendix B.

F. Indicate Impacts Not Referenced in Sections A through E

1. Specify _____

APPENDIX D

Examples of Effects that could Result in a Cost or Benefit

1. RADIOLOGICAL SAFETY CONSEQUENCES

- (a) Change in accident probabilities; specify the accidents (old, new probabilities)
- (b) Change in failure probabilities; describe the equipment directly and indirectly affected by the proposed action (old, new probabilities)
- (c) Change in population at risk (percent and absolute)
- (d) Change in occupational exposure; during installation, operation or maintenance (rem)
- (e) Change in unplanned radioactive releases offsite (curies)
- (f) Change in routine radioactive effluent releases (curies)
- (g) Change in operator response times (seconds/minutes)
- (h) Change in maintenance capability (yes/no) (explain)
- (i) Change in NRC's inspection and enforcement capabilities (yes/no)

2. SAFEGUARDS IMPACTS

- (a) Change in facility security (yes/no) (explain)
- (b) Change in materials control and accountability (yes/no) (explain)
- (c) Change in transportation security (yes/no) (explain)

3. OPERATIONAL IMPACTS

- (a) Change in reactor availability (hours/days)
- (b) Change in facility downtime beyond that normally scheduled (hours/days)
- (c) Change in allowable reactor rating (percent and absolute)

4. ECONOMIC IMPACTS

- (a) Construction cost change (dollars)
- (b) Operating cost changes (dollars)
- (c) Retrofit costs (dollars)
- (d) Recordkeeping and reporting cost changes (staff-hour; dollars)
- (e) Change in onsite personnel requirements (staff-hours)
- (f) NRC costs change; include contractor technical assistance costs (staff-hours or dollars)
- (g) Other increases in applicant expenditures for compliance with regulatory requirements (staff-hours or dollars)
- (h) Change in expected direct cost of an accident (dollars)

5. ENVIRONMENTAL IMPACTS

- (a) Change in water quality
- (b) Change in air quality

6. INFORMATION COLLECTION IMPACTS (Resulting from application, reporting or recordkeeping requirements)

- (a) Annual licensee/applicant staff hours (hours)
- (b) Annual licensee/applicant cost (dollars)
- (c) Annual cost to the NRC (hours/dollars)

7. OTHER IMPACTS (for example)

- (a) Consequences for small business (dollars/hours)
- (b) Significant impacts on vendors, and equipment suppliers (yes/no)
- (c) Anti-competitive consequences (impact on viability of existing firms to complete or provide equipment)

- (d) Availability of skilled labor/professional assistance (regional employment figures by a relevant category)
- (e) Number of licensees affected

