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

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MEMORANDUM FOR: All NRR Employees

FROM: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

SUBJECT: NRR OFFICE LETTER NO. 16, REVISION 2 --
REGULATORY ANALYSIS GUIDELINES

This revised office letter supersedes the March 14, 1983, version (Revision 1) of NRR Office Letter No. 16.

The Executive Director for Operations (EDO) has issued NRC-wide regulatory analysis guidelines. These are contained in NUREG/BR-0058, "Regulatory Analysis Guidelines for the U.S. Nuclear Regulatory Commission." (The current version of NUREG/BR-0058 is Revision 1, dated May 1984.) NRR will prepare regulatory analyses in accordance with NUREG/BR-0058 in support of covered submittals for review to the Committee to Review Generic Requirements (CRGR) or to the Deputy Executive Director for Regional Operations and Generic Requirements (DEDROGR) or for decision to the EDO or the Commission. Covered submittals include two categories, as specified in NUREG/BR-0058.

1. Major proposed and final rules, meeting threshold criteria stated in NUREG/BR-0058, Section IIA. There the guidelines apply fully.

2. Other rulemaking actions and non-rulemaking generic requirements or guidance (referenced in Section IIB of NUREG/BR-0058). For these much less detail is required. The extent of detail should be commensurate with the safety importance of the issue, the estimated magnitude of the proposed action's impact, and the complexity and analytical tractability of the issue.

The required content of CRGR review packages and procedures for submitting them are described in NRR Office Letter No. 39. Regulatory analyses constitute a part of such packages (Item 5.1 in Section II of Office Letter 39, Revision 2).

Preparation of the regulatory analyses is the responsibility of the lead Division within NRR for CRGR submittal in accordance with NRR Office Letter No. 39. The Division of Safety Technology (DST) will, as requested by the lead Division, provide assistance in interpreting the guidelines and consultation on regulatory analysis techniques and serve as focal point for NRR requests for assistance of the Cost Analysis Group. The lead Division will coordinate with DST before submitting a regulatory analysis to the Director, NRR, in accordance with Office Letter 39.

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The purpose of this letter is to supplement the NRC-wide regulatory analysis guidelines (NUREG/BR-0058) in some areas with more specific NRR guidance. This supplementary NRR guidance is enclosed.

In accordance with the Commission's Policy and Planning Guidance for 1984 (NUREG-0885, Issue 3), safety goals and associated numerical guidance will not now be used in regulatory analyses; they will be used only as the Commission may direct in the future.

During the two-year safety-goal evaluation period, commencing in March 1983, DST will prepare or will have prepared, after a decision on an issue has been made, a separate evaluation for each NRR-originated major rule (i.e., action meeting the Section IIA criteria of NUREG/BR-0058) and for selected other significant NRR-originated actions. In these evaluations the Commission's proposed safety goals will be used as the basis for the evaluation of the issue. These separate evaluations are intended to contribute to NRC's efforts to evaluate the safety goals. The evaluations will indicate how, if at all, the Commission's proposed safety goals and numerical guidelines might have affected the decisions, and what the effect on the decisions might have been if goals or guidelines other than those issued by the Commission were used. DST has developed, and will update as necessary, guidance for the nature, scope, and format of such evaluations for NRR coordination with the DEDROGR and other NRC offices. These evaluations will be coordinated with the originating Division and prepared for the signature of the Director, NRR, for transmittal to the DEDROGR. Absent special difficulties, each evaluation should be ordinarily completed within two months of the decision involved.

Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Enclosures:
1. Supplementary Guidance for NRR
2. Decision Making Using Value-Impact Analysis
3. Decision Factors Supplementing Value-Impact Ratio
4. Interim Procedures for Requests for Cost Analysis Group Participation in Regulatory Impact Analysis Process

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ENCLOSURE 1

SUPPLEMENTARY GUIDANCE FOR NRR

NOTE: Section numbers refer to correspondingly numbered sections of NUREG/BR-0058, Revision 1, "Regulatory Analysis Guidelines for the U.S. Nuclear Regulatory Commission," May 1984.

III.B.1. Statement of Problem

This section will include a clear definition of the scope and bounds of the issue to which the proposed action is addressed. This is essential in arriving at a sound and applicable analysis since issues are often complex and interrelated with other issues.

III.B.4.a. Costs and Benefits of Alternatives

This will always include comparison of the proposed action with the no-action alternative. Other alternatives will be covered only where significant other alternatives exist. The no-action alternative should reflect implementation of all applicable requirements or guidance to date, even if implementation is not completed at the time of analysis.

Where the effect on different classes of plants varies substantially separate estimates will be made and separate conclusions drawn for each class. The analysis should show that the requirement or guidance is directed and focused as narrowly as practical. Where additional information must be obtained from industry to help bound an affected class of plants, obtaining that information should be justified on the basis of its potential safety significance and cost. The regulatory analysis should be reopened for reconsideration should the new information bring into question the soundness of the original conclusion.

The required analysis of costs and benefits constitutes a "value-impact" assessment. NUREG/CR-3568, "A Handbook for Value-Impact Assessment," may be used as a reference on methods for performing such assessments. Professional judgment will be required in choosing among the options presented in the Handbook, in adopting methods to the issue at hand, and in applying methods not specifically covered when special aspects of the subject matter make that appropriate.

A general discussion of decision making using value-impact assessment is enclosed (Enclosure 2 to Office Letter No. 16, Revision 2).

The Costs and Benefits section should ordinarily be organized as outlined below. This outline is done primarily for safety issues, but for issues involving primarily other subjects (environmental protection, licensing and regulatory-process improvement, etc.), following a similar (or analogous) outline is suggested. The outline follows:

(i) Value -- Risk Reduction Estimates

The value is the safety importance of an issue and is usually represented by the change in expected risk that resolution could effect. Risk is ordinarily expressed here in terms of the product of the frequency of an occurrence and the public dose (in man-rem) that would result in the event of the accident. If more than one accident scenario is important within the necessarily rough risk estimates, the risks are summed. Value is attributed to reductions in the average, mean, or expected risk. The dose is calculated for the 50-mile-radius area around the plant.

The public man-rem-based estimate may not be the only appropriate measure of an issue's safety importance in all cases. Alternative measures of safety importance should be used when appropriate. For

example, when a possible core melt or other accident is involved but release outside containment would be minor or highly improbable, or highly uncertain in probability or magnitude, contribution to the core-melt probability should be estimated in addition to (or even in lieu of) the probabilistic public dose effect. There is controversy as to whether such "contained accidents" are a sufficient basis for regulatory action. Since core melts usually have a significant probability of failing containment, this is not an issue for most core melts. However, other accidents can be contained. The information on significant contained accidents should be displayed in the analysis, but the analyst must weigh the significance of this factor in deciding to what extent, if any, it should influence the conclusion. It should be noted that safeguarding against an excessive core-melt frequency may justify imposition of a safety requirement even without demonstration of offsite consequences.

Where significant occupational exposure is incurred in implementing resolution of a safety issue, such exposure is taken into account, but stated separately. Such exposure is viewed as a negative component in the net risk-reduction value.

Where an accident may result in significant occupational exposure due to the accident directly or in post-accident plant cleanup, such exposure is taken into account and stated separately. For plant-wide cleanup after a contained severe core-damage accident causing substantial wide-spread plant contamination, 40,000 man-rem may be used as a rule-of-thumb occupational exposure figure when no better issue-specific figure is available.

Usually public dose is an adequate surrogate for off-site contamination. However, the analyst should be alert to circumstances in which radiological effects not adequately reflected in the public dose as surrogate may be present. Examples include on-site damage, occupational exposure, liquid pathway effects, and supportive medical treatment, among others. Long-term contamination of the environment including water bodies and other agricultural or industrial facilities should be taken into account where that is a principal effect.

(ii) Impacts -- Cost Estimates

In January 1984, the EDO established a charter for the Cost Analysis Group (CAG) formed in the Office of Resource Management. NRR staff is encouraged to seek CAG advice and support, as needed and available, to help develop sound cost analyses for use in regulatory analyses. Requests to CAG should be coordinated through the Division of Safety Technology. The Safety Program Evaluation Branch is the contact point. Procedures are described in the enclosed memorandum, "Interim Procedures for Requests for Cost Analysis Group Participation in Regulatory Impact Analysis Process." (Enclosure 4 to Office Letter No. 16, Revision 2.)

Dependability, in terms of guarding against omission of important or even dominant cost elements, or against inclusion of costs that are not in fact entailed, is more important than high precision of the estimates.

It is particularly important to determine correctly whether plant downtime (or prolongation of downtime incurred for unrelated reasons, such as refueling) will be involved, and if so, to

estimate well the duration of the outage. Downtime costs, when involved, are often larger than all other costs. When no more specific basis exists for estimating daily cost of plant outage for the issue at hand, a figure of $500,000 per day may be used.

It should be borne in mind that procedural changes and professional work are not cost-free, and may have costs that are substantial.

Both industry and NRC costs (as well as costs to others when involved) should be estimated. Transfer costs (e.g., insurance) need not be calculated in NRC regulatory analyses since our perspective is a net national impact.

In some cases plant-damage costs averted by the proposed action can substantially affect the cost-benefit evaluation. Estimates for such averted costs are developed and used in separately stated calculations, so that the results both with and without adjustment for averted plant-damage costs are readily apparent. The averted costs may include those of averted equipment failures, limited-time plant outage, or limited plant-contamination cleanup. In the extreme, they can also include averted permanent loss of use of the plant, and plant-wide cleanup, multiplied in each case by the reduction in frequency of such events that would be brought about by resolution of the generic safety issue. In the absence of better issue-specific estimates, the estimated cost of plant-wide cleanup, before discounting to present worth, may be taken as $1.2 billion (1984 dollars; based on TMI estimates). While again a controversial issue, plant damage is to be considered an impact and not a value in NRR analyses. Should a favorable conclusion about a proposed generic requirement be contingent on taking plant damage into account, the analyst should state that conclusion together with a statement of the sensitivity of the conclusion to this factor.

When the discount rate is an important factor in the evaluation of the worthwhileness of a proposed action, the sensitivity of the results to the discount rate should be tested, as suggested in NUREG/BR-0058 (at III.B.4.a). Alternative real discount rates should include a 5 percent rate, in addition to the 10 percent rate specified in NUREG/BR-0058. High discount rates reduce the impact (present worth) of future accidents but also reduce the impact of the continuing costs associated with implementing new requirements or guidance.

(iii) Value/Impact Ratio

The total net safety value of the proposed action, typically in man-rem of public dose avoided, is related to total net costs (NRC, industry, plus any other) in terms of a ratio, typically dollars/man-rem. This ratio, along with safety importance, can be used as a supplementary basis for comparing alternatives, including evaluation against the no-action alternative, and ranking for implementation priority in relation to other issues.

(iv) Uncertainty Bounds

Major sources of uncertainty in the benefits and costs should be identified and judgments as to their quantitative significance indicated as information warrants. However, particular attention should be paid to those factors that have associated uncertainties of a substantially different nature or magnitude than those encountered in typical risk or cost analyses.

(v) Special Considerations

The value-impact analyses should be as quantitative as the situation reasonably permits. Items i to iv, above, emphasize the quantitative aspects. However, while the calculated risks and value-impact ratios are often valuable aids to judgment, other considerations not adequately reflected, or not reflected at all, in the basic numerical formula employed are often helped in corroborating or adjusting the results. Decision making is helped by explicit identification of such other considerations and explanation of how they bear on the conclusions. A partial list and discussion of decision factors which might supplement the calculated risk and value-impact ratio is enclosed (Enclosure 3 to Office Letter No. 16, Revision 2).

III.B.5. Decision Rationale

This section should include a recapitulation of the main points of the rationale underlying the value-impact conclusion concerning the proposed action, including critical information on importance to the safety (or other) values expected to be obtained, costs, value-impact relation, uncertainties, and any special considerations.

Rules and other existing requirements are not, in themselves, justification for a decision; they can be changed (by the Commission or authorized staff) on just the sort of regulatory analysis basis as is involved here. For requirements established by law, the regulatory analysis should, when appropriate, weigh alternative means of implementing the law.

ENCLOSURE 2

DECISION-MAKING USING VALUE-IMPACT ASSESSMENT

1. General Principles of Cost-to-Benefit Comparisons

The decision process and decision considerations are similar when cost-benefit comparisons are close and when they are not. The value-impact approach, as a disciplined process, employed in conjunction with good engineering analysis, helps guard against errors regardless of the relative magnitudes of costs and benefit.

The calculated cost-benefit -- or value-impact -- ratio, whether nearly balanced or unbalanced, is a factor in the decision, but should not be regarded as the lone or even the generally determinative factor. Other factors such as special risks or costs, subjective perceptions, time-related factors, regulatory stability or implementation feasibility can be important. These factors, when present to some particular extent, are more likely to be controlling when the value-impact comparison is close than when values and impacts are unbalanced.

All decisions based on risk or cost analyses must recognize that the uncertainty of the estimates of the factors can be -- and in most cases is -- large. Uncertainty includes not only the variability of data, but also incompleteness whether from ignorance or error. When there is a large imbalance between safety values and impacts, uncertainty is less important. For close balances, uncertainty is likely to be an important consideration.

The values considered should be strictly limited to those results affecting the protection of public health, safety and property which the NRC is authorized to regulate. All other consequences of a proposed action should be included only as impacts. Even if the net impact is favorable, this, by itself, is not a justification for imposing an action. The absolute safety

value needs to be taken into account. Issues of small or no safety value usually are not worthwhile considering, since there is an irreducible minimum cost associated with any issue and trivial safety values are therefore not cost effective. In addition, while issues of small value may have small overall costs (and therefore appear to be justified) these costs are not uniformly distributed. For example, in most cases of small issues, these costs fall primarily on the licensing staff of the utility and the NRC. These staffs are limited and the proliferation of issues with small safety values would divert them from significant issues which may have much greater overall costs, but not much greater use of a limiting resource such as licensing staffs. Such reasons as these for dismissing issues of small value should be explicitly stated in the analysis.

2. No Set Formula

The significance of various potential decision factors and their interplay vary according to the issue. All relevant and significant factors should be recognized and taken into account according to the facts and the issue. Some general guidance can be developed, but a prescribed and ostensibly exhaustive checklist or weighting formula is likely to constrain decision making in counterproductive ways. The analyses involved, especially when the decisions are close, are often complex and difficult. They require exercise of judgment, for which there is no effective simpler substitute. But value-impact analyses, or at least one case for all analyses, should usually be done with a standard method and set of assumptions to allow meaningful comparisons between issues; work is needed to develop appropriate assumption sets. Other cases with assumptions or method most appropriate to the issue under study can then be done.

3. Development and Display of Facts

No decision involving value-impact considerations can be dependable unless it rests on a sufficiently comprehensive factual analysis of values and impacts. This is, of course, especially true for close decisions.

"Sufficiently comprehensive" cannot be defined beforehand but must be judged for each issue. Methods and procedures for verifying the accuracy and completeness of the factual analysis must be used. These include internal and public review and comment. This assurance of accuracy and completeness is most important when the decision is close. However, a lack of data or uncertainty of the data used to determine values and impacts cannot be used as a basis to defer a decision since both action and inaction are decisions. One course or another must be taken on the basis of the information currently available no matter how good or poor it may be. If the information base is weak, the likelihood that inaction (as well as action) may be wrong needs to be carefully considered.

The analysis should include:

(a) Identification of value and impact elements that may be significant for the issue.

(b) Realistic quantitative estimates, wherever estimates are reasonably possible.

(c) Estimates of uncertainties, where practical, and comments on any unusual aspects in the nature and structure of uncertainties.

(d) Qualitative description of unquantified value and impact elements.

The bases and assumptions for all calculations and qualitative statements should be made clear since decision outcomes may be sensitive to them. Where important alternative bases and assumptions exist, sensitivity to them should be explored.

4. Conclusions

The basis for the decision should be stated. Trade-off factors, what factors and analytical results were considered, and how the various considerations entering a decision were weighed should be stated explicitly.

Decisions to take no action are usually more difficult. One, or a few identified possible sequences that contribute to a significant risk, may be sufficient to justify a decision to require action. A no-action decision requires as much care as an action decision, in order to ensure that no significant factors have been omitted. This is particularly true of close no-action decisions.

5. Reverse Decision Analysis

Reverse analysis may be used to determine whether a value-impact imbalance could be upset by countervailing considerations. (A "reverse calculation" concerns the question, "What facts would justify the action?", rather than "What action do the facts justify?") The advantage of such an approach is that it diminishes pressures for quantifying factors that are problematical to quantify. One need not determine what quantitative value to assign to an unquantified factor: it suffices to determine whether the quantitative value should be above or below the value that would establish value-impact equipoise.

ENCLOSURE 3

DECISION FACTORS SUPPLEMENTING CALCULATED VALUE-IMPACT RATIO

A calculated value-impact comparison generally reflects a necessarily simplified evaluation, focusing on public dose and direct cost impact. The possible importance of other factors and the limitations of an often incomplete and imprecise data base point to a need to corroborate or adjust the formula results by other considerations. Some such effects -- occupational exposure, averted plant-damage costs, uncertainty bounds -- require careful consideration for all issues. Others thought to be significant should be identified and considered--quantitatively when practical, but at least qualitatively. Some special considerations may be quite specific to an issue. This list is not complete and the analyst should assure that all significant and relevant factors are considered.

1. Special Risk and Cost Aspects

Special risk and cost aspects potentially affecting net value or net impact but not routinely included in numerical formula:

Special Risks and Value Aspects

(a) A significant net change in occupational doses. [See discussion of occupational exposure in a preceding enclosure (Enclosure 1 to Office Letter No. 16, Revision 2)].

(b) Loss or severe degradation of a layer in the defense-in-depth concept (e.g., all but one mode of core cooling, or all modes of containment cooling).

(c) Circumstances imparting unusual significance to radiological or other accident consequences (such as ingestion-pathway effects or great psychological stress) or mitigating measures (such as evacuation, sheltering, or supportive medical attention) that are not directly included in the public dose calculations.

(d) Enhancement or impairment of the value of the proposed action by environmental or safeguards benefits or impairments in addition to its safety value.

(e) Potential for substantial unusual off-site damage aspects not adequately reflected in the public radiation dose as surrogate.

Special Costs and Other Impacts

(a) Any significant non-radiation related occupational risk.

(b) Averted cost of plant damage and outage not only from the postulated accident but also its precursors.

(c) Potential for substantial secondary cost impacts not reflected in the cost estimates.

(d) Significant impact on small entities (protected by the Regulatory Flexibility Act).

2. Uncertainties

Factors related to uncertainties stemming from an incomplete or imprecise data base for the value-impact formula:

(a) Uncertainty bounds, imbalance in uncertainty factors, certainty of cost to fix versus uncertainty that safety is really improved and the true extent of such improvement.

(b) Situations where uncertainty is extraordinarily large (in accident probability or consequences or in cost, or any or all of these), for example, where unusually great plant-specific variability of risks and costs defeats dependability of generic estimates, or where data about a risk are lacking.

(c) The potential for a proposed change to affect more than one accident or transient sequence, thus affecting risk to a greater or lesser degree than assessed in the current description of the issue; notably, the potential for a new safety decrement, or increase in risk, due to suspected unidentified effects of a proposed change, or added complexity, or for other reasons.

(d) The value inherent in reduction of uncertainty.

(e) The potential for human intervention, using available equipment.

3. Subjective Perceptions

Perceptions and judgments that cannot (or cannot readily) be quantified:

(a) Public concern about a particular issue, or special Commission or Congressional concern. The effect that a proposed regulatory action (or inaction) may have on such subjective perceptions can be quirksome: additional safety measures may be perceived as confirmatory of a concern and heighten it rather than quell it. Usually, NRR decisions should be based on objective factors, but a discussion of such subjective factors can be provided as supplemental information.

(b) Acute knowledgeable professional controversy concerning the importance of an issue or modes of dealing with it, or about the implementation costs of the proposed action.

4. Time-Related Factors

(a) How rapidly the action can be implemented.

(b) The potential for a better resolution becoming available later, or for an issue disappearing in light of future improved knowledge (balanced against (c), below, when applicable).

(c) Potential substantial deterioration of the value/impact ratio while awaiting a better regulatory resolution (e.g., a potential design fix that is inexpensive to apply before construction, much more expensive after the plant is largely built, and extremely expensive and problematical to apply to an operating plant).

5. Regulatory Stability

(a) Consistency with the principle of keeping the number of alterations to existing requirements to a reasonable minimum.

(b) The extent to which the proposed action affords better prospects for subsequent regulatory stability and predictability.

(c) The extent to which licensee latitude is restricted without good reason.

6. Implementation Feasibility

(a) The ease of implementation from technical, human-factors, and regulatory standpoints.

(b) How readily compliance is verifiable.

(c) Vulnerability of the proposed change to lapses in implementation.