May 30, 2000

MEMORANDUM TO: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: William D. Travers ***/RA by Carl J. Paperiello Acting For/***
Executive Director for Operations

SUBJECT: RESPONSE TO STAFF REQUIREMENTS MEMORANDUM – SECY-99-178, TREATMENT OF VOLUNTARY INITIATIVES IN REGULATORY ANALYSES, WITS NO. 9700353

On August 26, 1999, in the subject SRM, the Commission approved the staff's plans to implement the revised policy for the treatment of voluntary initiatives in regulatory analyses and to revise NUREG/BR-0058 (Rev. 2), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (Guidelines), accordingly.

Attachment 1 is the staff's proposed substantive revision to the Guidelines which would appear as a new stand-alone subsection 4.3.1. This material would replace the current discussion on voluntary initiatives which appears in the second and third paragraphs on page 19 of the Guidelines (Attachment 2). In addition, to accommodate the new subsection 4.3.1, minor conforming changes to the Guidelines will also have to be made.

In summary, the new subsection is consistent with earlier policy in that, to the extent practicable, two sets of value impact results will continue to be derived: one based on "no credit" and the other based on "full credit" for industry initiatives. However, if as a result of this variation, the overall value impact conclusion shifts or the final recommendation changes, the analyst would develop best estimate value impact results in which measured credit would be assigned to the industry initiatives in question.

The staff will proceed to publish Rev. 3 to the Guidelines consistent with the changes noted here.

Attachments: As stated

cc w/att.:
OGC
CIO
CFO
OPA
OCA
SECY

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PROPOSED SECTION 4.3.1

4.3.1 Treatment of Industry Initiatives in Estimation of Values and Impacts

Industry initiatives are typically actions performed by licensees that form the bases for either continued compliance with the regulations or obviate the need for new regulations. It must be clear to the public that substituting industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, will in no way compromise plant safety, and does not represent a reduction in NRC's commitment to safety and sound regulation. The NRC and the industry are jointly responsible for the long term success of using industry initiatives as substitutes for NRC regulatory action. Licensees must effectively manage and implement their commitments associated with these industry initiatives and the NRC must provide a credible and predictable regulatory response if licensees fail to satisfy these commitments.

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

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

For the purpose of the regulatory analysis value-impact results are to be calculated based, to the extent practicable, on varied assumptions concerning the future role of industry initiatives. Initially, two sets of value-impact estimates are to be derived: one based on "no credit" and the other based on "full credit" for industry initiatives. These results will have equal weight and will be presented for sensitivity analysis purposes. If the overall value-impact result does not tilt from an overall net cost to an overall net benefit (or vice versa), there is no need to proceed further and the final results would be reported as a range of values that reflect the sensitivity of these results to this assumption. However, if the results are highly sensitive to that level of variation, such that the overall value-impact conclusion shifts or the final recommendation changes, the analyst would proceed to develop a "best estimate" base case.

Under this best estimate base case, the staff will evaluate the specific industry initiatives in question to determine how much credit to give to the industry initiatives. The NRC is currently developing guidelines designed to increase NRC's assurance that industry initiatives will be effective long-term alternatives to regulatory actions. Clearly, the more an industry initiative satisfies these guidelines, the more credit one should give to the industry initiatives. Before these guidelines are formally approved, the staff should rely on relevant features and characteristics of the industry initiatives to assess the weight or amount of credit to attach to any given industry initiative. Relevant characteristics would include:

- costs associated with the industry initiative (if the dominant costs are fixed costs that have already been expended or the future recurring costs to maintain the industry initiative are minimal it is more likely the industry initiative will continue in the future);

- the extent to which written commitments exist (if written commitments exist it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative);

- the degree to which the industry initiative is non-controversial and standard industry practice, the more likely it will continue without the rule change. This may be a function of consistency with provisions of industry codes and standards, the participation rate among relevant licensees, how long the program has been operating, and its effectiveness; and

- the scope and schedule for industry initiatives that are still pending (for industry initiatives that are still work-in-progress, the more well defined the scope and the sooner the initiative is expected to be in place, the more likely it will be available in the future)

Based on such an assessment, the regulatory analysis would contain, to the extent practicable, a best estimate of the values and impacts of the regulation under consideration. These results would serve as the basis for the staff's recommendations to the Commission.
Careful attention is needed when PRA techniques are used to give partial or no credit to industry initiatives. This is because risk estimates from PRAs are based on existing conditions which typically include credit for any industry initiatives that may be in place. When the PRA is modified to eliminate or reduce credit for industry initiatives, the reviewer needs to assure that these changes are properly reflected in the details of the PRA model.

4.3 Estimation and Evaluation of Values and Impacts

The alternatives that survive the screening process of Section 4.2 should be analyzed in the section of the regulatory analysis document covering the estimation and evaluation of values and impacts. The level of detail need not be equivalent for all alternatives. For example, less detail is needed when one alternative can be shown to be clearly superior to the others. Nevertheless, this section will often be the longest and most complex portion of the document.

For the purpose of these Guidelines, the definitions of values and impacts shown below are adopted. These definitions are largely derived from Section 6(a)(3)(C) of EO 12866.

Values The beneficial aspects anticipated from a proposed regulatory action such as, but not limited to, the (1) enhancement of health and safety, (2) protection of the natural environment, (3) promotion of the efficient functioning of the economy and private markets, and (4) elimination or reduction of discrimination or bias.

Impacts The costs anticipated from a proposed regulatory action such as, but not limited to, the (1) direct costs to NRC and Agreement States in administering the proposed action and to licensees and others in complying with the proposed action; (2) adverse effects on health, safety, and the natural environment; and (3) adverse effects on the efficient functioning of the economy or private markets.

The staff should consult the Handbook and any relevant NRC reports or documents issued subsequently to these Guidelines and the Handbook for additional guidance on estimating and evaluating values and impacts. General principles to be followed are discussed in this section.

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 and/or Agreement States, employees of licensees, contractors and vendors, the NRC, and other Federal agencies. Within each affected group, further differentiation, for example, licensee suppliers or contractors, may be necessary if the proposed action affects segments of the group differently. Under these circumstances, separate estimates and evaluations of values and impacts should be made for each distinct category. Such estimates and evaluations should include transfer payments (see Section 4.3.2). The categorization of licensees may be appropriate for a variety of reasons. For example, the effects of a new requirement can be markedly different between newer facilities that have had safety features installed during construction and older facilities.

For each affected group, the attributes that characterize the consequences of the proposed action should be identified. The Guidelines (especially Sections 4.3.1 and 4.3.2) and the Handbook should be reviewed before selecting appropriate attributes.

Value and impact estimates are to be incremental best estimates relative to the baseline case, which is normally the no-action alternative.[17] When possible, best estimates should be made in terms of the "mean" or "expected value." However, depending upon the level of detail available from the data sources employed in the regulatory analysis, acceptable estimates could include other point estimates such as the median. However, the rationale for use of estimates other than mean values should be provided. The definition of the baseline case requires specific attention to ensure against double counting of either the values or impacts in the regulatory analysis. For example, in evaluating a new requirement for existing plants, the staff should assume that all existing NRC and Agreement State requirements have been implemented. Consequently the values and impacts associated with these requirements are not part of the incremental values or impacts associated with the regulatory action under consideration. Similarly, insofar as new regulatory requirements may affect future plants, the reference point for these plants should also be the existing regulatory requirements. To ensure against double counting of either the values or impacts in the regulatory analysis, the staff should be aware of values and impacts associated with other formally proposed regulatory actions related to the subject action that are likely to be implemented.

The NRC encourages voluntary actions that enhance safety. When voluntary actions are being implemented on an industry-wide basis with no evident safety problem, great weight and due consideration should be given to these initiatives before imposing requirements to codify them in the regulations. However, when voluntary initiatives are in place over only a portion of the industry, or when they achieve only part of the safety objectives associated with a regulatory change under consideration, codifying the practice may be necessary. In these instances, voluntary actions, by demonstrating their practicality and effectiveness, will be important inputs in the staff's development of rules, particularly performance-based rules, and thus benefit those who have taken such action. For purposes of the regulatory

[17] Procedures for making best estimates are discussed in the Handbook.

analysis however, no credit should be given for the voluntary actions taken by licensees. This means that when calculating the values and impacts of a proposed regulatory requirement and its alternatives, the costs and benefits should not be reduced by the extent to which they may already be lessened by voluntary activities. Since the base case regulatory analysis takes no credit for voluntary actions, a sensitivity analysis should be performed and the regulatory analysis results displayed reflecting due consideration of voluntary actions.

Most voluntary actions are discretionary, and their impacts are primarily ongoing and future oriented. Voluntary programs might be characterized as adopting vague requirements, lacking in NRC enforceability, and resulting in nonuniform programs across all licensees. The NRC intends to be able to impose regulatory requirements in lieu of voluntary programs that, for any number of reasons, are not providing the level of safety assurance the NRC deems necessary. This would be the case, for example, when voluntary programs are nonuniform across all licensees. As a result, some licensees may not have a program, or established programs could easily dissipate by licensee action alone, perhaps without NRC's knowledge. Furthermore, if credit is provided for voluntary initiatives and values and impacts associated with the proposed regulatory action are reduced, meaningful health and safety improvements could not be assumed in the future because they would remain uncodified and voluntary in nature, not subject to enforcement on the part of the NRC.

Uncertainties are important to consider 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. Hypothetical best- and worst-case values and impacts can be estimated for sensitivity analyses. Sensitivity analysis can be used in addition to or in lieu of formal uncertainty analysis; the former option should be exercised when uncertainty analysis is impractical or exceedingly complicated and costly. Additional information on incorporating uncertainties and sensitivities in a regulatory analysis is in the Handbook. The Handbook also discusses the distinction between them.

Values and impacts should be estimated 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.

Estimated values and impacts should be expressed in monetary terms whenever possible and expressed 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. In this regard, many regulatory actions, such as those affecting non-power reactor and materials licensees, may not be supported by available PRA analysis, and probabilistic analysis techniques may not be practical for some actions. However, the staff 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 staff 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.