

July 23, 2004

MEMORANDUM TO: All RES Employees

FROM: Carl J. Paperiello, Director */RA/*
Office of Nuclear Regulatory Research

SUBJECT: RES OFFICE LETTER NO. 3D, "MAINTENANCE OF THE
REGULATORY ANALYSIS GUIDELINES"

In January 1983, the U.S. Nuclear Regulatory Commission (NRC) published NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (Guidelines), to clarify and formalize NRC policy concerning the need for and preparation of regulatory analyses. In addition, Section 033 of Management Directive 8.4, "Management of Plant-Specific Backfitting and Information Collection," identifies the Office of Nuclear Regulatory Research (RES) as being responsible for maintaining and revising NUREG/BR-0058. This office letter describes the approved procedures for performing this function.

BACKGROUND

For many regulatory activities, the regulatory analysis (RA) is an integral factor in the NRC's decisionmaking process. The purposes of an RA are to ensure that (1) the agency bases its regulatory decisions on adequate information about the need for and consequences of proposed actions, (2) the agency identifies and analyzes appropriate alternative approaches to achieve its regulatory objectives, (3) none of the alternative approaches is clearly preferable to the proposed action, and (4) the proposed action satisfies the backfit rule requirements.

In effect, NUREG/BR-0058 is the agency's principal policy document for the preparation of NRC regulatory analyses. Since the NRC initially published NUREG/BR-0058 in January 1983, the staff has revised the Guidelines three times, and a fourth revision is in progress. These revisions to the Guidelines have either been directed by the Commission or initiated by the staff for any of the following reasons:

- accumulated experience with implementing the previous Guidelines
- changes in NRC procedures and/or regulations (e.g., the Backfit Rule and the "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants")
- advances and refinements in RA techniques and information
- changes in RA guidance from the U.S. Office of Management and Budget (OMB)
- new standards imposed by OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," dated January 3, 2002
- procedural changes designed to enhance the NRC's regulatory effectiveness

- clarifications and improvements initiated in response to concerns raised by the Commission

Because of its overall importance in supporting NRC's regulatory decisions, the RA Guidelines documented in NUREG/BR-0058 should reflect the current regulatory environment, as well as accumulated experience, improvements in analytical techniques, current Federal standards and guidelines, and other factors.

GENERAL POLICY ON MAINTAINING THE GUIDELINES

The RES Division of Systems Analysis and Regulatory Effectiveness (DSARE) is responsible for determining whether and when NUREG/BR-0058 should be revised to reflect changes to the agency's RA policy. When such revisions are warranted, the DSARE staff will prepare the revised Guidelines, obtain the necessary reviews and approvals, oversee publication, and ensure that all relevant parties are informed of the changes. Throughout this process, DSARE will assign a Project Manager (PM) to implement and coordinate these activities. Under certain circumstances, certain activities leading to publication of the revised Guidelines may be performed elsewhere within the NRC.¹ However, even when another office assumes the lead, it remains important for the DSARE staff to play a supporting role. In so doing, the DSARE staff can ensure that the assessment reflects a historical, agencywide perspective and that the latest revision of NUREG/BR-0058 incorporates all outstanding regulatory analysis issues.

In any case, once the revision is approved, the DSARE staff is responsible for reissuing NUREG/BR-0058. This responsibility entails overseeing the final editing, authorization, printing, and distribution of the revised Guidelines.

The following sections discuss the steps involved in maintaining NUREG/BR-0058.

Identify Need

Except in situations where the Commission or other office identifies a concern regarding the agency's RA policy, the DSARE staff is responsible for identifying any potential need to revise NUREG/BR-0058.

To identify areas that need to be revised, the DSARE PM and other cognizant DSARE staff should discuss RA policy issues with other NRC staff who are responsible for preparing regulatory analyses, as well as members of the Committee To Review Generic Requirements (CRGR) who periodically review many of the agency's regulatory analyses. These discussions should take place on an informal but regular basis (approximately biennially).

In addition, the DSARE PM should stay informed about current Government-wide RA-related issues. At a minimum, the PM should review all new OMB publications that bear on regulatory

¹ Others (e.g., the Commission or offices other than RES) may identify a concern regarding the agency's RA policy and may either assume responsibility for revising the Guidelines to resolve the identified concern or assign that responsibility to an office other than RES. However, the Commission or other office may simply ask RES to revise the Guidelines document. In that case, it is appropriate to proceed directly to the activities described herein to "Develop Revision and Obtain Necessary Reviews and Approval." (See below.)

analyses. The most current OMB guidance documents are Circular A-4, "Regulatory Analysis" (September 17, 2003); "Report to Congress on the Costs and Benefits of Federal Regulations" (issued annually); "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (January 3, 2002); and "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements" (March 22, 2000).

Lastly, as part of any periodic review, the DSARE PM needs to assess the continuing appropriateness of the current real discount rate and dollar per person-rem conversion factor, which may significantly affect the value-impact results presented in a given regulatory analysis. NUREG/BR-0058 sets forth the conditions under which the agency must revise the values of these two parameters.²

Develop Revision and Obtain Necessary Reviews and Approval

After identifying the need to revise the RA Guidelines, the DSARE PM and other cognizant DSARE staff should prepare an analysis of the proposed changes, including the rationale for those changes and their implications for NRC's regulatory decisions, and whether immediate or delayed revision is appropriate. With respect to this last point, it is important to recognize that certain desirable changes may not be highly important or time-sensitive. In such instances, it may be more cost-effective and less disruptive to delay the revision of NUREG/BR-0058 until the staff identifies additional changes that, in the aggregate, justify timely resolution.

After completing the analysis of the proposed changes, the staff should forward the package to RES management for approval to proceed. After obtaining RES approval, the PM should follow appropriate procedures for obtaining Commission approval, which generally involve preparing a Commission (SECY) paper when the revision is proposed and another when the revised Guidelines are ready for issuance. The staff's initial analysis of the proposed changes should provide a strong underpinning for both of these Commission papers, and both papers should be reviewed by a technical editor before being submitted for technical reviews by DSARE management, other RES divisions, RES management, and other offices, as appropriate. For all revisions that are initiated by DSARE, the staff should seek concurrence on both Commission papers from the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Material Safety and Safeguards (NMSS), as appropriate. Both Commission papers are also subject to review by the Office of the General Counsel (OGC), to identify any possible legal objections. The staff should also utilize *Federal Register* notices and stakeholder meetings to invite the industry and the public to be meaningfully involved and to submit any relevant comments concerning the proposed revision of the Guidelines. In addition, the staff should communicate the proposed revisions to the CRGR, as well as the Advisory Committee on Reactor Safeguards (ACRS), and possibly the Advisory Committee on Nuclear Waste (ACNW) and the Advisory Committee on the Medical Use of Isotopes (ACMUI).

² See Section 4.3.4 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

Edit, Authorize, Print, and Distribute

After completing all of the above-mentioned reviews and before obtaining Commission approval, the DSARE PM and cognizant DSARE staff must incorporate the proposed changes into NUREG/BR-0058 and revise its foreword to characterize the latest revision. At this point, the revised document should be reviewed by a technical editor for plain language, correct spelling and punctuation, proper grammar and syntax, accuracy, clarity, effective organization, consistency, and format.

After obtaining Commission approval, the DSARE PM should work with the staff of the Publishing and Distribution Services Branch (PDSB) in the Information and Records Services Division (IRSD) of the Office of the Chief Information Officer (OCIO) to obtain a preprint review of the camera-ready manuscript and to finalize the concurrence package through which the staff will request authorization to print and distribute the revised Guidelines. This package should include a *Federal Register* notice announcing publication of the revised Guidelines and should be concurred on by the affected offices and signed by the RES Office Director. The staff will also need to submit the *Federal Register* notice for review and approval by the Rules and Directives Branch (RDB) in the Division of Administrative Services (DAS) in the Office of Administration (ADM).

After finalizing the camera-ready copy of the revised Guidelines and obtaining the necessary authorization, the DSARE PM should send the package to PDSB for printing and distribution, in accordance with the Management Directives 3.7, "NUREG-Series Publications," and 3.13, "Printing." In so doing, the DSARE PM should provide input to PDSB concerning the appropriate distribution codes to be used in disseminating the revised Guidelines. Because of its important role in the NRC's regulatory activities, each revision of NUREG/BR-0058 should receive wide distribution. In general, this distribution should include all NRC managers at the Branch Chief level or above, as well as members of the NRC's advisory committees, licensees, organizations that represent licensees, and NRC contractors that support the RA function. In addition, the DSARE PM should coordinate with OCIO to ensure that the latest version of the Guidelines continues to be accessible on the NRC's external Web site at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/>.

RELATED CONSIDERATIONS

Since the mid-1980s, RES has overseen the development of software and a variety of studies in support of the RA function. These resources include the following examples:

- (1) NUREG/CR-4012, Vol. 4, "Replacement Energy Costs for Nuclear Electricity-Generating Units in the United States: 1997-2000," September 1997.
- (2) NUREG/CR-5595, "FORECAST: Regulatory Effects Cost Analysis Software Manual, Version 4.1," July 1996.
- (3) NUREG-1530, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy," December 1995.
- (4) NUREG/CR-6349, "Cost-Benefit Considerations in Regulatory Analysis," October 1995.

- (5) NUREG/CR-5344, "Replacement Energy Cost Analysis Package (RECAP): User's Guide," July 1994.
- (6) NUREG/CR-6212, "Value of Public Health and Safety Actions and Radiation Dose Avoided," May 1994.
- (7) NUREG/CR-6080, "Replacement Energy, Capacity, and Reliability Costs for Permanent Reactor Shutdowns," October 1993.
- (8) NUREG/CR-4627, "Generic Cost Estimates," Rev. 2, February 1992.
- (9) NUREG/CR-5236, "Radiation-Related Impacts for Nuclear Plant Modifications," October 1989.
- (10) NUREG/CR-4555, Rev. 1, "Generic Cost Estimates for the Disposal of Radioactive Wastes," September 1988.
- (11) NUREG/CR-5160, "Guidelines for the Use of the EEDB at the Subcomponent and Subsystem Level," May 1988.
- (12) NUREG/CR-5138, "Validation of Generic Cost Estimates for Construction-Related Activities at Nuclear Power Plants," May 1988.
- (13) NUREG/CR-5035, "Database of System-Average Dose Rates at Nuclear Power Plants," October 1987.
- (14) NUREG/CR-4921, "Engineering and Quality Assurance Cost Factors Associated with Plant Modification," April 1987.
- (15) NUREG/CR-4764, "Energy Economic Data Base (EEDB) Program," December 1986.
- (16) Science & Engineering Associates, "The Identification and Estimation of the Cost of Required Procedural Changes at Nuclear Power Plants," December 1986.
- (17) Science & Engineering Associates, "Generic Methodology for Estimating the Labor Cost Associated with the Removal of Hardware, Materials, and Structures from Nuclear Power Plants," June 1986.
- (18) NUREG/CR-4546, "Labor Productivity Adjustment Factors," March 1986.
- (19) NUREG/CR-3971, "A Handbook for Cost Estimating," October 1984.
- (20) Idaho National Engineering Laboratory, "Generic Cost Analysis for Steam Generator Repairs and Replacements," August 1984.
- (21) Science & Engineering Associates, "Generic Cost Estimates for Reactor Shutdown and Startup," June 1984.

In general, these resources provide more detailed guidance, data, and methods for quantifying cost-benefit attributes in regulatory analyses. The most important of these resources is NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook" (Handbook), dated January 1997. This Handbook, which is viewed as the NRC's principal RA guidance document, expands on the policy concepts presented in NUREG/BR-0058 and provides more detailed guidance and implementing methods for preparing regulatory analyses. As a result, the staff considers it essential for the Handbook to consistently provide the latest and best information available. Consistent with this objective, the DSARE PM should consider revising the Handbook whenever improved guidance, data, and/or methods become available and whenever the agency adopts changes in its RA policy. In addition, to facilitate timely revisions and replacement of affected pages (including the cover and title pages showing the revision number and date), the staff publishes the Handbook in loose-leaf format.

Similarly, the DSARE PM should review the other RES-sponsored software and studies that support the RA function to determine whether they should be revised to reflect the agency's latest RA policy and/or to resolve any related concerns that may be raised either within or outside the agency. However, since these materials typically have a more narrow focus than either the Guidelines or the Handbook, and since the NRC's regulatory interests are continually evolving, any such review must first consider whether there is a sufficient continued need for the particular software or study in the current regulatory environment. If not, the DSARE PM may conclude that it is unnecessary to revise the particular software or study.

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