

NUCLEAR REGULATORY COMMISSION

[NRC-2017-0091]

Regulatory Analysis Guidelines

AGENCY: Nuclear Regulatory Commission.

ACTION: NUREG; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. NRC." This revision to NUREG/BR-0058 updates and restructures the NRC's cost-benefit guidance documents by incorporating information contained in NUREG/BR-0184, "Regulatory Analysis Technical Handbook," into NUREG/BR-0058 and provides cost-benefit guidance for NRC's regulatory, backfit, forward fit, issue finality, and National Environmental Policy Act (NEPA) environmental review analyses across NRC program offices. Additionally, the update incorporates improvements in methods for assessing factors that are difficult to quantify, incorporates relevant cost estimating best practices, and includes improvements in uncertainty analyses for use in cost-benefit analyses.

ADDRESSES: Please refer to Docket ID NRC-2017-0091 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0091. Address questions about NRC dockets to Carol Gallagher;

telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual(s) listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" section of this document.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Pamela Noto, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-6795, e-mail: Pamela.Noto@nrc.gov, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

Revision 5 to NUREG/BR-0058 is the first of two phases of updates to the NRC's cost-benefit guidance documents, NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. NRC," and NUREG/BR-0184, "Regulatory Analysis Technical Handbook." This update consolidates these two guidance documents and identifies changes to current methods and tools related to performing cost-benefit analyses in support of regulatory, backfit, forward fit, issue finality, and environmental review analyses.

The 2011 accident at the Fukushima Dai-ichi nuclear power plant in Japan initiated discussion regarding how the NRC's regulatory framework would consider offsite property damage and the associated economic consequences caused by a significant radiological release from an NRC-licensed facility. In response to this discussion, the NRC staff recommended enhancing the consistency of the agency's existing regulatory analysis guidance and bringing it up-to-date through revisions to cost-benefit analysis guidance documents, including aligning cost-benefit guidance across the agency in both reactor and materials program areas.¹ In the staff requirements memorandum (SRM) to SECY-12-0110, dated March 20, 2013, the Commission approved this recommendation and directed the NRC staff to identify potential changes to current methodologies and tools to perform cost-benefit analyses in support of regulatory, backfit, and environmental analyses. Further, the Commission directed the NRC staff to provide a regulatory gap analysis prior to developing new cost-benefit guidance.

¹ SECY-12-0110, "Consideration of Economic Consequences in the NRC's Regulatory Framework," dated August 14, 2012.

In response to Commission direction, the NRC staff prepared SECY-14-0002, “Plan for Updating NRC’s Cost-Benefit Guidance;” dated January 2, 2014; SECY-14-0087, “Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses;” dated August 14, 2014; and SECY-14-0143, “Regulatory Gap Analysis of the NRC’s Cost-Benefit Guidance and Practices,” dated December 16, 2014.

The NRC staff issued SECY-14-0002, which identified potential changes to current methodologies and tools related to performing cost-benefit analyses in support of regulatory, backfit, and environmental analyses. In this document, the NRC staff recommended a two-phased approach to revise the content and structure of the cost-benefit guidance documents. Phase 1 is a restructuring of the three main NRC cost-benefit guidance documents, where NUREG/BR-0184 and NUREG-1409, “Backfitting Guidelines,” would be incorporated into NUREG/BR-0058. However, in response to Commission and other senior management direction,² the NRC staff determined that NUREG-1409 should be kept as a standalone document and the revision to NUREG-1409 is being addressed through a separate effort. Additionally, Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” has been updated to provide additional guidance to the staff.

In Phase 1, the staff begins to align regulatory guidance across the agency in both reactor and materials program areas by restructuring cost-benefit guidance documents and pursuing policy revisions. Specifically, NUREG/BR-0058, Revision 4, and NUREG/BR-0184 were revised and consolidated into a single guidance document that includes updated data, methods, and references, as well as best practices from GAO audit findings and case-study

² See NRC “Staff Requirements - COMSECY-16-0020 - Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule,” SRM-COMSECY-16-0020, November 29, 2016. *See also* NRC “Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission’s Implementation of Backfitting and Issue Finality Requirements,” July 19, 2017. ADAMS Accession No. ML17198C141.

recommendations. Subsequently, Phase 2 will identify and discuss policy issues for Commission consideration that could affect the NRC's cost-benefit guidance.

In response to Commission direction, the NRC staff proposed updating the cost-benefit guidance to include a set of methods that could be used for qualitative consideration of factors within a cost-benefit analysis for regulatory and backfit analyses.³ The Commission approved the staff's plans for updating guidance regarding qualitative factors, including the treatment of uncertainties, and directed the update to focus on capturing best practices for the consideration of qualitative factors. The Commission also directed the NRC staff to develop a toolkit for analysts to assist them in clearly articulating how they considered qualitative factors. Appendix A, "Qualitative Factors Assessment Tools," of the revision to NUREG/BR-0058 provides this toolkit.

In 2014, the U.S. Government Accountability Office (GAO) conducted a performance audit to review the NRC's cost-estimating procedures. The resulting report, GAO-15-98, "NRC Needs to Improve Its Cost Estimates by Incorporating More Best Practices," recommended that the NRC align its cost estimating procedures with relevant cost estimating best practices identified in the "GAO Cost Estimating and Assessment Guide" (GAO-09-3SP). The NRC staff has addressed the GAO recommendations in Appendix B, "Cost Estimating and Best Practices," of the revision to NUREG/BR-0058.

This revision to NUREG/BR-0058 makes three main changes. First, it consolidates cost-benefit guidance that is used across the agency. The document provides additional discussion of cost-benefit guidance for NRC's regulatory, backfit, forward fit, issue finality, and NEPA environmental review analyses.⁴

³ NRC "Staff Requirements - SECY-14-0087 – Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," SRM-SECY-14-0087, March 4, 2015.

⁴ NRC "Staff Requirements Memorandum – SECY-18-0042 – Draft Final NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'" SRM-SECY-18-0042, July 26, 2019.

Second, this revision provides methods for assessing factors that are difficult to quantify, incorporates cost-estimating best practices, and expands on methods to quantify uncertainties. This includes guidance intended to enhance the clarity, transparency, and consistency of analyses for the decisionmaker.

Finally, the appendices provide detailed technical material that is subject to future changes. These appendices will be issued and controlled separately to keep this information current and relevant. The following Appendices were developed during Phase 1: Appendix A, "Qualitative Factors Assessment Tools;" Appendix B, "Cost Estimating and Best Practices;" Appendix C, "The Treatment of Uncertainty;" Appendix D, "Guidance on Regulatory Analysis Related to American Society of Mechanical Engineers (ASME) Code Rules;" and Appendix E, "Special Circumstances and Relationship to Other Procedural Requirements."

The NRC staff held a Category 3 public meeting on July 16, 2015, to discuss the proposed structure and changes to the cost-benefit guidance in Phase 1. The staff's presentation can be found in ADAMS under Accession No. ML15189A463, and the meeting summary can be found under Accession No. ML15217A415. The NRC staff held a second Category 3 public workshop on March 3, 2016, to discuss activities to improve the agency's cost-benefit guidance including the newly developed qualitative factors assessment tools, cost estimating and best practices, and the treatment of uncertainty. The NRC presentation can be found in ADAMS under Accession No. ML16061A139, and the meeting summary can be found under Accession No. ML16084A167. The NRC staff published the draft revision, in the *Federal Register* (82 FR 18163, April 17, 2017) for a 60-day public comment period. To encourage public comment, the NRC held a Category 3 public meeting on May 22, 2017, during the public comment period, to present the proposed changes to the cost-benefit guidance. The NRC staff's presentation can be found in ADAMS under Accession No. ML17135A037, and the meeting summary can be found under Accession No. ML17156A014. The NRC staff received three comment submissions with a total of 58 individual comments. Two submissions were

from the Nuclear Energy Institute, and one submission was from a private citizen. The public comment response document can be found in ADAMS under Accession No. ML17221A011. The NRC staff briefed the Committee to Review Generic Requirements (CRGR) on January 10, 2017. Additionally, the NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS) Regulatory Policies and Practices Subcommittee on February 7, 2017, and with the ACRS Full Committee on March 9, 2017. During this meeting, the staff stated that seven of the twelve appendices remained under development. The ACRS determined that, “[b]ecause...conforming changes are expected to be required as the appendices are completed...[t]he Committee should have another opportunity to review Revision 5 to NUREG/BR-0058 after all appendices are completed and prior to its issuance.” The ACRS plans to review the NUREG in its entirety during Phase 2 of the update.

II. **Procedural Requirements**

This NUREG is a rule as defined in the Congressional Review Act ([5 U.S.C. 801-808](#)). However, the U.S. Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

III. Availability of Documents

The documents identified in the following table are publicly available.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / FEDERAL REGISTER CITATION
NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. NRC"	ML17221A000 (Package)
NRC Response to Public Comments on Draft NUREG/BR-0058, Revision 5	ML17221A011
NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. NRC"	ML042820192
NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook"	ML050190193
SECY-14-0002, "Plan for Updating NRC's Cost-Benefit Guidance," January 2, 2014	ML13274A519
SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," September 11, 2014	ML14127A458 (Package)
SECY-14-0143, "Regulatory Gap Analysis of the NRC's Cost-Benefit Guidance and Practices," December 16, 2014	ML14280A426 (Package)
SECY-12-0110, "Consideration of Economic Consequences within the U.S. NRC's Regulatory Framework," August 14, 2012	ML12173A478 (Package)
SRM-SECY-12-0110, "Consideration of Economic Consequences within the U.S. NRC's Regulatory Framework," March 20, 2013	ML13079A055
SRM-SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," March 4, 2015	ML15063A568
SRM-SECY-18-0042, "Draft Final NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'" July 26, 2019	ML19207A042
NUREG-1409, "Backfitting Guidelines"	https://www.nrc.gov/reading-rm/doc-collections/nureqs/staff/sr1409/
MD 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests"	ML18093B087

"Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission's Implementation of Backfitting and Issue Finality Requirements," July 19, 2017	ML17198C141
SRM-COMSECY-16-0020, "Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," November 29, 2016	ML17198C141
GAO-15-98, "NRC Needs to Improve its Cost Estimates by Incorporating More Best Practices"	http://www.gao.gov/assets/670/667501.pdf
GAO-09-3SP, "GAO Cost Estimating and Assessment Guide"	http://www.gao.gov/new.items/d093sp.pdf
ACRS Regulatory Policies and Practices Subcommittee Transcripts, February 7, 2017	ML17058A357
ACRS Meeting Transcripts, March 9, 2017	ML17086A361

Dated at Rockville, Maryland, this [redacted]th day of [redacted] 2019.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

SUBJECT: DRAFT FINAL NUREG/BR-0058, REVISION 5, "REGULATORY ANALYSIS GUIDELINES OF THE U.S. NUCLEAR REGULATORY COMMISSION" **DATED:**

ADAMS Accession Number: ML19261A289

*via e-mail

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