U.S. NUCLEAR REGULATORY COMMISSION MANAGEMENT DIRECTIVE (MD)

MD 6.6	REGULATORY GUIDES	DT-22-05
Volume 6:	Internal Management	
Approved by:	Raymond Furstenau, Director Office of Nuclear Regulatory Research	
Date Approved:	July 19, 2022	
Cert. Date:	N/A, for the latest version of any NRC directive or handbook, see the online MD Catalog.	
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EXECUTIVE SUMMARY

Management Directive (MD) 6.6, "Regulatory Guides," is revised to:

- Update the frequency for performing the periodic review of regulatory guides from 5 years to 10 years.
- Reflect the changes in organizational responsibilities (e.g., consolidation of the Office of New Reactors and the Office of Nuclear Reactor Regulation).

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For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index (YA-to-MD index).

I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) that—

- Activities are undertaken in an open and transparent manner.
- Activities are conducted openly; the public is informed of an opportunity to participate in the NRC's regulatory process.
- Staff decisions are sound and consider the need and impact of proposed actions.
- Regulatory guidance is provided to the public to describe one or more methods that the NRC staff considers acceptable for meeting the agency's regulatory requirements.
- Consensus standards, industry guidance documents, and international standards are endorsed in regulatory guides (RGs), as appropriate.

II. OBJECTIVES

- Identify a consistent procedure for developing and processing RGs and ensure that statutory requirements are met.
- Identify consensus standards, industry guidance documents, and international standards, as appropriate, that are endorsed in RGs.
- Ensure the efficient use of staff resources in developing guidance for applicants and licensees.
- Ensure coordination among offices during the development of guidance.
- Ensure that stakeholders (e.g., licensees, applicants, members of the public, Agreement States, Indian Tribes, and non-Agreement States) and appropriate offices within the agency have an opportunity to consider and comment on a new or substantively changed draft regulatory guide (DG) before it is issued as a final (effective) RG.
- Ensure consideration of the Cumulative Effects of Regulation (CER) when creating and revising DGs and RGs, in accordance with Commission direction.
- Ensure that DGs and RGs are reviewed and concurred upon with rulemaking packages, as appropriate.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. General Counsel (GC)

1. Ensures that DGs and RGs are reviewed to be consistent with applicable law and NRC requirements and determines whether legal objections exist.
2. Ensures that RGs are reviewed for compliance with the Congressional Review Act before issuance.
3. Directs the Office of the General Counsel (OGC) Legal Research Center to—
   (a) Provide advice on *Federal Register* notices (FRNs), and
   (b) Coordinate with the Office of the Federal Register to issue FRNs for DGs and RGs.

B. Director, Office of Nuclear Regulatory Research (RES)

1. Has overall responsibility to promulgate DGs and RGs. This includes the delegation to the appropriate division director the authority to concur on the DGs and RGs.
2. Ensures coordination with other NRC offices to facilitate DG and RG development and identify lead office and technical lead (TL).
3. Ensures development tools, such as templates, for consistency, are maintained.
4. Ensures the DG and RG concurrence process is managed in accordance with the procedures of Directive Handbook 6.6.
5. Ensures DGs and RGs are developed, when appropriate, based on technical expertise.
6. Ensures a project manager (PM) is assigned to each RG under development or revision.
7. Reviews DGs and RGs developed by all NRC offices to ensure appropriate consideration of regulatory and policy issues, technical issues, and administrative quality, particularly consistency, in format and in style. Provides comments to the TL.
8. Delegates to the appropriate branch chief the authority to prepare FRNs and coordinate with the OGC Legal Research Center to issue the DG for public comment and issue the final RG.
9. Delegates to the program manager the responsibility for coordination with the TL and others to facilitate the contract management process when developing DGs and RGs needing contractor support.

10. Ensures that the final DGs, FRNs, and RGs are prepared after receiving concurrences from the appropriate program offices and arranges for DGs and RGs to be made publicly available.

11. Ensures the TL branch is alerted when periodic review is due.

C. Directors, Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), Office of Nuclear Security and Incident Response (NSIR)

1. Ensure the development of DGs and RGs, in accordance with the policy and process listed in this MD. This includes the delegation to the appropriate division director the authority to concur on the DGs and RGs.

2. Ensure that a TL is assigned to develop regulatory guidance and the associated regulatory analysis and coordinate with appropriate NRC offices within the agency.

3. Ensure that an RG complies with—

   (a) Applicable backfitting provisions in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76;

   (b) Issue finality provisions in 10 CFR 52.39, 10 CFR 52.63, 10 CFR 52.83, 10 CFR 52.98, 10 CFR 52.145, and 10 CFR 52.171;

   (c) Commission policies on backfitting, issue finality, and forward fitting outlined in MD 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.”

4. Cooperate and coordinate with other NRC offices, as appropriate, in developing regulatory guidance and the associated regulatory analysis.

5. When requested, review DGs and RGs developed by other NRC offices for technical correctness and provide comments to the RES PM and the TL.

6. Perform periodic and on-demand reviews of RGs to ensure that the guidance is current and relevant. On-demand reviews of RGs are equivalent to a periodic review that is performed because of the need to capture information or evaluate whether a revision is needed. These reviews are performed because of a noted problem or issue, needs identified from inspection activities, public comments, an endorsed guidance revision, or other internal or external stimulus.

7. Consult with States and Indian Tribes during the development of an RG as described in MD 5.1, “Consultation and Coordination with Governments and Indian Tribes.”

8. Ensure compliance with the Office of Management and Budget (OMB) Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities” (81 FR 4673;

January 27, 2016), at https://www.govinfo.gov/content/pkg/FR-2016-01-27/pdf/2016-01606.pdf.

D. Chief Information Officer (CIO)

1. Approves or disapproves proposed information collections for submittal to OMB.
2. Ensures the implementation of agency policies and procedures for information collection activities covered under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).
3. Provides advice to NRC staff and oversight of NRC activities to ensure that the NRC complies with best practices and applicable laws and regulations. These laws include, but are not limited to, the Government Paperwork Elimination Act (44 U.S.C. 3504(a)(1)(b)(vi)) and the Paperwork Reduction Act.
4. Manages, maintains, and monitors information collections and provides reference assistance for both internal and external sources of scientific and technical literature, including international materials.
5. Reviews guidance to validate that the correct OMB control numbers are referenced.

E. Advisory Committee on Reactor Safeguards (ACRS), Advisory Committee on the Medical Uses of Isotopes (ACMUI), and Committee to Review Generic Requirements (CRGR)

The Advisory Committee on Reactor Safeguards (ACRS), the Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the Committee to Review Generic Requirements (CRGR) review and provide comments or recommendations on a DG and RG, as appropriate.

IV. APPLICABILITY

The policy and guidance in this MD apply to all NRC employees involved in the process of developing and issuing DGs and RGs.

V. DIRECTIVE HANDBOOK

Directive Handbook 6.6 contains policy and program guidance for the management and processing of RGs. RES maintains RES-OI-TEC-004, “Regulatory Guide Review, Development, Revision, and Withdraw Process” (ML101750587).

VI. REFERENCES

Code of Federal Regulations

10 CFR 50.55a, “Codes and Standards.”

10 CFR 50.109, “Backfitting.”

10 CFR 52.39, “Finality of early site permit determinations.”

10 CFR 52.63, “Finality of standard design certifications.”

10 CFR 52.83, “Finality of referenced NRC approvals; partial initial decision on site suitability.”

10 CFR 52.98, “Finality of combined licenses; information requests.”

10 CFR 52.145, “Finality of standard design approvals; information requests.”

10 CFR 52.171, “Finality of manufacturing licenses; information requests.”

10 CFR 70.76, “Backfitting.”

10 CFR 72.62, “Backfitting.”

10 CFR 76.76, “Backfitting.”

Executive Orders

Executive Order 12889, “Implementation of the North American Free Trade Agreement,” December 27, 1993.

Executive Order 13563, “Improving Regulation and Regulatory Review,” January 18, 2011 (76 FR 3821; January 21, 2011).

Executive Order 13579, “Regulation and Independent Regulatory Agencies,” (76 FR 41587; July 14, 2011).

Executive Order 13610, “Identifying and Reducing Regulatory Burdens,” May 10, 2012.

International Atomic Energy Agency

Final Integrated Regulatory Review Service (IRRS) Mission Report to the United States of America, IAEA-NS-IRRS-2010/02, March 1, 2011 (ML110630400).

“Nuclear Regulatory Commission International Policy Statement,” (79 FR 39415), July 10, 2014, at https://www.govinfo.gov/content/pkg/FR-2014-07-10/pdf/2014-16173.pdf.

Nuclear Regulatory Commission Documents

Commissioners’ Assistants Note, “Improving the Efficiency of the Regulatory Guide Periodic Review Process,” October 7, 2016 (ML16267A185) (non-public document).

Commission Papers (SECY)—

SECY-18-005, “Policy Statement on Enhancing Participation in U.S. Nuclear Regulatory Commission Public Meetings,” January 11, 2021 (ML21050A046).

SECY-20-0008, Draft Final NUREG/BR-0058, Revision 5, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” January 28, 2022 (ML19261A278), Package: (ML19261A277).

SECY-21-0037, NUREG-1409, Revision 1, “Backfitting Guidelines,” Enclosure 1, NUREG-1409, “Backfitting Guidelines, Final Report,” Revision 1, (ML21006A433), Package (ML21006A431).

SECY-R-577, “Regulatory Guides,” November 20, 1972.

“Committee to Review Generic Requirements Charter,” Revision 9, June 2018 (ML17355A532).

Committee to Review Generic Requirements Information, at http://www.nrc.gov/about-nrc/regulatory/crgr.html.

Management Directives—

MD 3.5, “Attendance at NRC Staff-Sponsored Meetings.”

MD 5.1, “Consultation and Coordination with Governments and Indian Tribes.”

MD 6.3, “The Rulemaking Process.”

MD 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.”

MD 12.6, “NRC Controlled Unclassified Information (CUI) Program.”

NMSS Office Policy and Procedures 6-10, Revision 4, “NMSS Procedures for Preparation and Review of Rulemaking Packages,” March 29, 2021 (ML20244A210) (non-public document).

NMSS SharePoint Site for Forms Templates, and Guidance relating to Congressional Review Act, at https://usnrc.sharepoint.com/teams/NMSS-Congressional-Review-Act (non-public document).

NRC Memorandum to Cindy Bladey, Chair, Rulemaking Coordinating Committee, Office of Administration, from James Biggins, Chair, Subcommittee on Concurrent Publication of Rules and Guidance, Office of the General Counsel, "Identifying the Effects of Commission Direction on Preparing Guidance Documents and Recommending Best Practices for Publication of Guidance Documents," August 14, 2012 (ML12227A355) (non-public document).

NRC Memorandum to R. W. Borchardt, Executive Director for Operations, from Annette L. Vietti-Cook, Secretary, "Staff Requirements - SECY-11-0032 - Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," October 11, 2011 (ML112840466).

NRC Regulatory Guides website, at https://www.nrc.gov/reading-rm/doc-collections/reg-guides/.

NRC Principles of Good Regulations, at https://www.nrc.gov/about-nrc/values.html#principles.

OGC Legal Research Center website, at https://intranet.nrc.gov/ogc/31597 (not publicly available).

RES Office Instruction (OI), TEC-004, Revision 0, "Regulatory Guide Review, Development, Revision, and Withdraw Process" (ML101750587).

NUREG-1379, Revision 3, "NRC Editorial Style Guide," April 2022 (ML22115A119).

Federal Register Notices

Notice of Development of New Guide Series (37 FR 28544), December 27, 1972.

Notice of Early Comment Period for Regulatory Guides (39 FR 20628), June 12, 1974.

Notice of Revision of OMB Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (81 FR 4673), January 27, 2016, at https://www.govinfo.gov/content/pkg/FR-2016-01-27/pdf/2016-01606.pdf.

Revision to Policy Statement, "Enhancing Participation in NRC Public Meetings," (86 FR 14964) March 19, 2021, at https://www.govinfo.gov/content/pkg/FR-2021-03-19/pdf/2021-05787.pdf.

Tribal Policy Statement (82 FR 2402), January 9, 2017, at https://www.govinfo.gov/content/pkg/FR-2017-01-09/pdf/2017-00091.pdf.

United States Code

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Congressional Review Act of 1996 (5 U.S.C. 801–808).

Government Paperwork Elimination Act (44 U.S.C. 3504).

National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272).

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

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I. INTRODUCTION

This handbook outlines the types of documents used and the processes followed by the U.S. Nuclear Regulatory Commission (NRC) staff to develop and issue regulatory guides (RGs).

A. Types of Regulatory Guides

1. RGs are categorized in the following 10 broad divisions:

   (a) Power reactors,

   (b) Research and test reactors,[1]

   (c) Fuels and materials facilities,

   (d) Environmental and siting,

   (e) Materials and plant protection,

   (f) Products,

   (g) Transportation,

   (h) Occupational health,

   (i) Antitrust and financial review, and

   (j) General.

[1] This division of regulatory guides for research and test reactors may also have expanded applicability to cover other nonpower production or utilization facilities on a case-by-case basis.

2. There are several types of guides, depending on the usage. The most common are—

   (a) Regulatory Guides - RGs are documents in which the NRC staff describes one or more acceptable methods for meeting the agency's regulatory requirements for its regulated entities. RGs may provide techniques used by the staff for evaluating specific problems or postulated accidents, or data the staff needs for reviewing applications for permits and licenses. The staff uses RGs to endorse consensus standards, industry guidance documents, and international standards, where appropriate.

   (b) Draft Guides - RGs typically are issued first as draft regulatory guides (DGs) for public comment. After the public comments are considered and incorporated as appropriate, the revised guides are issued as final (or effective) RGs. The staff provides the public with notice of both the request for public comment on the DG and the issuance of the RG by publication in the *Federal Register (FR)*.

   (c) Trial Use Regulatory Guides - Staff uses a Trial Use RG (TRG) to allow early use of the guidance on a pilot basis. The staff gathers feedback from the TRG users on their experience with the TRGs before implementing the DG and RG process. TRGs are documents in which the NRC staff proposes methodologies for meeting requirements, but the methodologies are not ready for generic implementation. A TRG methodology is not an approved final NRC methodology for a licensee's compliance with requirements unless the NRC incorporates the specific methodology into a licensee's licensing basis through an NRC-approved licensing action or order. The process for preparing and issuing a TRG is like that for issuing a DG for public comment, except that the Office of the General Counsel (OGC) review to determine applicability of the Congressional Review Act, and coordination with the Office of Congressional Affairs (OCA) if the Congressional Review Act (CRA) is indeed applicable, is required before issuing a TRG. The NRC may issue TRGs for a specified time for a trial period for use by licensees and applicants. The TRG process allows the NRC to capture lessons learned during the trial period and incorporate any improvements into a DG and eventually issue a final RG, thereby enhancing regulatory stability.

   (d) Administratively Changed Guides - These are guides issued as revisions of existing RGs that have no substantive change in the established staff position. They do not go through the draft stage (i.e., no DG is issued). An administratively changed guide (ACG) is intended to be issued with a minimum of administrative burden. An ACG undergoes a minimum review, and the NRC provides the public with notice of an ACG's issuance by publication in the *FR*. ACGs are not considered backfits as described in MD 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests."

B. Usage of the Regulatory Guides

1. The use of RGs by licensees and applicants is not mandatory unless a licensee's licensing basis incorporates an RG as a requirement. Applicants or licensees may use alternatives to the guidance in an RG if the applicants or licensees demonstrate that the alternatives satisfy the applicable NRC requirements.
2. The methods, techniques, or data described in an RG are acceptable to the NRC staff for meeting NRC requirements. Using the methods, techniques, or data described in an RG relieves the applicant or licensee of the burden of demonstrating that the methods, techniques, or data satisfy the applicable NRC requirements. Hence, the use of RGs by applicants and licensees can conserve NRC staff resources and simplify licensing actions.
3. When new or different requirements are promulgated in rulemaking, new or revised RGs can be issued in conjunction with the rule to describe methods acceptable to the staff for meeting these new or changed requirements. The new or revised RGs are generally issued at the same time that the final rule is published in the *FR*. The *Federal Register* notice (FRN) for the final rule also notices the issuance of the RG.
4. The NRC staff regularly reviews and, as necessary, revises RGs to incorporate lessons learned and include more up-to-date methods and guidance to make the RGs more useful. Licensees and applicants can continue to use RG versions that were previously approved for use by the NRC. However, these previous versions will not have the benefit of updated methodologies and guidance that are incorporated into the latest revisions of the RGs.
5. The NRC staff may withdraw an RG that the staff determines is no longer appropriate or useful.
6. When the staff withdraws, revises, or issues a new RG, it must consider backfitting and issue finality regulations and the Commission's backfitting, issue finality, and forward fitting policies in MD 8.4 (Section III.F of this handbook has additional information).

II. REGULATORY GUIDE FORMAT

A. Required Sections

Each RG deals with a specific, limited topic. The Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research (RGPMB/DE/RES) maintains and provides templates for DGs and RGs for standardization and consistency. RGs are divided into the four main sections listed below.

1. Section A: Introduction

   Section A describes the purpose of the RG, identifies the entities to which the RG applies, and lists the applicable requirements and related guidance. This section also includes the relevant Office of Management and Budget (OMB) statement on information collections and the appropriate OMB clearance numbers.

2. Section B: Discussion

   Section B outlines the subject addressed by the RG and, if appropriate, briefly states the basis or rationale for each of the staff positions in the Staff Regulatory Guidance section. It also includes the reason for the RG revision and may contain technical methods or analyses used to develop the staff regulatory guidance. Appendices are used to provide detailed information, if needed.

3. Section C: Staff Regulatory Guidance

   (a) Section C contains suggested methods, techniques, or data that are acceptable to the staff for meeting the requirements cited above in Section II.A.1, “Section A: Introduction” of this handbook. The guidance should be clearly identified in consecutively numbered, organized paragraphs and should be clear and concise with little accompanying discussion.

   (b) In their applications, licensees and applicants may propose methods different from an RG’s staff position. As a result, the word “should” is generally appropriate for use in this section when describing how the licensee or applicant would implement the stated staff position. “Shall” or “must” is used only in an attributed quotation of, or direct reference to, a requirement.

4. Section D: Implementation

   (a) Section D states that the NRC staff may use an RG, when applicable, as a reference in its regulatory processes, such as licensing, inspection, or enforcement. The implementation section contains a statement as to whether issuance of the RG constitutes backfitting, as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, “Backfitting,” and as described in MD 8.4; affects the issue finality of an approval issued under 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”; or constitutes forward fitting as that term is defined and described in MD 8.4. In addition, NUREG-1409, “Backfitting Guidelines,” provides guidance to NRC staff on implementation of the Commission’s backfitting, issue finality, and forward fitting policies. In addressing backfitting, forward fitting, and issue finality, staff should ensure that the latest guidance is being used by confirming the guidance with the NRC Backfitting and Forward Fitting Community of Practice.

   (b) Staff positions in RGs do not constitute requirements; rather, they are the NRC’s conclusions that use of the methodology, technique, or data in the RG is acceptable. When an applicant or licensee voluntarily incorporates or asks the

NRC to incorporate an RG into its licensing basis, the NRC staff can use the staff position(s) in the RG to evaluate compliance with the applicable requirements for license applications or license amendment requests. Otherwise, applicants or licensees can propose alternative methods for meeting requirements.

(c) When the NRC staff promulgates a new or revised requirement through rulemaking, it may issue an accompanying RG that provides one acceptable means for implementing the new or revised requirement. The Preamble for the rulemaking describes the RG, the regulatory analysis, and, if applicable, the backfitting assessment for the rulemaking. The costs and benefits of the rulemaking captured in the regulatory analysis would include the development and implementation of the RG. The rulemaking's backfitting assessment would also include the RG.

B. Additional Sections

1. References

References used in the regulatory guides should follow the guidance in NUREG-1379, Revision 3, "NRC Editorial Style Guide." In accordance with this guidance, references to selected NRC regulatory guidance documents (e.g., RGs, standard review plans) are not required to include dates, revision numbers, or ADAMS accession numbers. However, a revision number and date need to be given if the staff intends to use a specific revision of a guidance document. Note that the references in RGs should be available to the public and the source should be clearly identified.

2. Bibliography

If the guide was developed using several documents that are not referenced in the guide, then a bibliography may be included as an aid to the reader.

3. Glossary

(a) Because the agency uses many abbreviations and terms or phrases with specific, and not necessarily common, meanings, a glossary may be added to enable the reader to find frequently used abbreviations, terms, and phrases. This will be especially helpful for large guides. The glossary should follow the format in the DG template.

(b) For efficient communication, an appendix or attachment can provide useful supporting information in an RG. Tabular data are normally provided in an appendix. To facilitate the Staff Regulatory Guidance section's presentation in a clear and concise manner, the section can be augmented by including the text from a regulation, detailed information, or other supporting information as an appendix. The use of an appendix will ensure that the information is close at hand without distracting from the key points made in the Staff Regulatory

Guidance section. In this configuration, the material in the appendix supports explanation but does not normally define the staff position.

III. PROCESS FOR DEVELOPING REGULATORY GUIDES

The following sections describe key points in the development and revision process for an RG. For NRC staff, refer to Office of Nuclear Regulatory Research (RES) Office Instruction (OI) TEC-004, "Regulatory Guide Review, Development, Revision, and Withdrawal Process," (RES-OI-TEC-004) for additional detailed instructions for processing an RG (non-public, ML20352A168).

A. Need for Guidance Identified

1. User Need Requests

   The need for a new or revised RG, or withdrawal of an existing RG, is usually identified by one of the technical offices or is necessary as part of a periodic update process. RGs may be needed to—

   (a) Support a new regulation or rulemaking,

   (b) Incorporate advances in technology or operating experience,

   (c) Incorporate staff positions from generic communications or licensing reviews, or

   (d) Endorse new, revised, or reaffirmed domestic and international standards.

2. Regulatory Analysis

   (a) The staff must provide a regulatory analysis to explain the basis for the agency's decisions and show that a systematic decisionmaking process is being followed. By issuing the regulatory analysis with a DG and requesting comments on it, the staff demonstrates the NRC's Principles of Good Regulation, particularly openness and clarity (https://www.nrc.gov/about-nrc/values.html#principle). The staff may use an existing analysis that was prepared for a previous version of the RG or was prepared for a related rule that is still valid and includes consideration of any additional direction in the most recently approved version of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." NUREG/BR-0058 provides the staff with specific guidance for preparing a regulatory analysis.

   (b) The staff should reference the ADAMS accession number of the regulatory analysis in the footer on the first page of the DG and the RG.

3. Trial Use Regulatory Guides (Pilot Use)

   (a) The main steps for processing, preparing, and issuing a TRG are the same as those for a DG.

   (b) The staff develops an RG for trial use based on the determination that there are remaining technical issues that are best resolved by testing the methodology against different uses by licensees in actual trial applications (pilot applications).

   (c) The staff will issue the TRG for post-promulgation comments. The main public comments from the post-promulgation public comment period will be included in the FRN that will announce the RG ready for the trial use period. The staff's position(s) described in the TRG could change as the staff proceeds in the development of a DG and then a final RG based on the post-promulgation comments, the feedback from the trial use period, and additional NRC staff comments, and industry responses. The DG and the final RG will follow the established RG process.

   (d) The TRG needs to include a statement that the TRG does not establish approved staff positions or an approved final NRC methodology for compliance with regulations. Therefore, the TRG does not raise backfitting, issue finality, or forward fitting concerns. However, the NRC can incorporate the methodology into a licensee's licensing basis through a licensing action or order, in which the staff would consider backfitting, issue finality, and forward fitting implications as described in MD 8.4.

4. Consideration of International Standards

   International standards provide approaches to safety issues worldwide. Often, existing regulatory guidance has been based on endorsement of domestic standards. When existing regulatory guidance is being updated, international standards such as those promulgated by the International Organization for Standardization or the International Electrotechnical Commission should be considered for endorsement or reference, if appropriate and if aligned with current NRC regulations and the policies of the Commission. Similarly, safety standards such as those promulgated by the International Atomic Energy Agency should be considered for use in RGs. When sufficiently detailed, and if otherwise appropriate, the international standards could be considered for endorsement as a staff position reflecting an acceptable method for meeting the Commission's regulations. When broadly written, the international standard could be discussed in the introduction or discussion sections of an RG where the staff could explain how the RG meets the intent of the international standard. Some of the recommendations issued by these international organizations do not correspond to the requirements specified in the NRC's regulations. In such cases, the NRC's requirements take precedence.

B. Processing a Periodic Review of a Regulatory Guide

1. The RGPMB/DE/RES will work with program offices periodically (within a maximum of 10 years) to evaluate whether to revise or withdraw an RG or do neither. The RG PM alerts the lead technical branch when a periodic review of an RG is due. The lead technical branch will then review the RG and provide the results of the periodic review to the RG PM.
2. The review should support considerations required by Executive Order 13563, "Improving Regulation and Regulatory Review," dated January 18, 2011. RGs will typically be evaluated every 10 years in accordance with Commissioners' Assistants Note, "Improving the Efficiency of the Regulatory Guide Periodic Process," dated October 7, 2016 (ML16267A185). Refer to RES-OI-TEC-004 for additional information on the contents of a periodic review.
3. The staff may perform periodic reviews sooner than 10 years based on a rule change, changed staff positions, new technology, or new or reaffirmed domestic and international standard.

C. Processing a Draft Regulatory Guide

1. Before the NRC issues an RG, it should first issue a DG and make it available to the public for comment. However, a DG is not required for the following types of actions on RGs:
   (a) ACG: Revising an existing RG when there are no substantive changes, including no changes to the Staff Regulatory Guidance section, does not require a DG to be issued. In this case, the staff can process a revision as an ACG according to Section III.E of this handbook.
   (b) Withdrawal: Withdrawing an existing RG does not require that a DG be issued. However, if withdrawing an existing RG potentially involves backfitting or forward fitting, or affects issue finality, then this action must be completed in accordance with MD 8.4. In this case, the RG can be withdrawn according to Section III.F of this handbook.
2. If the NRC determines that a revision to the RG is appropriate or if a new RG is needed, then the lead technical branch prepares a DG.
3. The technical lead (TL) is responsible for the following:
   (a) Developing the DG and the RG, writing or identifying the associated regulatory analysis, and obtaining the appropriate level of agreement from the staff and management needed to support issuance of the RG,
   (b) Determining if any domestic or international standards exist that can be used in support of the RG and ensuring that the staff's position on any standard is fully understood and reflected in the staff's regulatory guidance,

(c) Addressing and resolving any public comments and advisory committee review comments before issuance of the final RG.

4. DGs in support of rulemakings should follow the same schedule as the rulemaking. Revision of existing RGs outside of the rulemaking process is normally scheduled to be completed within 1 year from when the RG PM receives the initial first version of the DG from the TL.

5. The RG normally will be issued first as a DG to allow for public comment. For DGs, the NRC staff will publish an FRN soliciting public comments on the DG by a specific date. The comment period is typically 30, 45, or 60 days, as directed by the TL.

6. In rulemakings, the staff often holds public meetings to improve stakeholder understanding of the proposed rule provisions and draft guidance and enhance feedback on the proposed rulemaking and guidance.

7. The RG PM does not need to obtain OGC review for applicability of the CRA before issuing a DG for public comment. However, the RG PM must obtain an OGC review for applicability of the CRA prior to issuance of the final RG. In addition, the RG PM must obtain an OGC no legal objection (NLO) review before issuing either a DG or RG.

D. Processing a Final Regulatory Guide after the DG Process Is Complete

1. When RGs are required to support rulemaking, the RGs are processed similarly to the non-rulemaking process. However, additional steps are involved because of the required additional reviews and approvals of rulemaking documents. Similar documents are prepared (e.g., regulatory analysis, FRN, Concurrence Memorandum) and issued along with the proposed and final rulemaking documents and are included in the same published FRN.

2. After the public comment period noted in the FRN ends, the RG PM and TL will compile summaries of the public comments received. The TL will review the public comments, make any required changes to the RG, and provide a response to each public comment summary, including whether the NRC took any action based on each comment received and the changes made, if any.

3. Once all the required documents are complete (e.g., RG, Responses to Public Comments, and FRN), if significant changes have been made to the RG, then the RG PM will circulate the documents for concurrence to the RG Program management and the applicable program offices, for OGC NLO, and, if requested, for a final review by applicable review committees (e.g., Advisory Committee on Reactor Safeguards (ACRS), Committee to Review Generic Requirements (CRGR), or Advisory Committee on the Medical Uses of Isotopes (ACMUI)).

4. Once the required reviews and approvals are completed, the RG PM will email the proposed FRN to "Notice_Publish Resource."

5. An RG is considered final when the NRC declares the document as an "Official Agency Record" (OAR).
6. If the RG is associated with a rulemaking, then the RG should not be available for use until the final rule goes into effect. If the RG is not part of a rulemaking, then the staff should include in the FRN the date when the RG is available for use.
7. Once declared as an OAR, then the RG PM informs OCA if the new or revised RG qualifies as a "rule" and if so, whether the RG is a "major rule," under the CRA. OCA is responsible for informing the U.S. House of Representatives, Senate, and Government Accountability Office.

E. Processing an Administrative Change of a Regulatory Guide

1. When an RG is updated for the purpose of correcting typographical errors or changing the format and has no substantive change to an established staff position, the RG may be processed as an ACG.
2. The ACG is intended to ease the administrative burden of staff review of non-substantive matters. The PM or the TL prepares the ACG and proposed FRN, which is reviewed to ensure that no substantive change has been made to the staff regulatory guidance directly or indirectly because of the administrative changes. The FRN should include a summary of the rationale behind the decision to issue the RG without a DG.
3. Following editing, OGC reviews the ACG and proposed FRN to determine that there is no legal objection to the RG.
4. When the OGC review is complete, the RG PM will email the proposed FRN to "Notice_Publish Resource."
5. The RG PM will update the status on the NRC Regulatory Guide website to reflect the revision of the RG. The staff may prepare a regulatory analysis, if needed. However, for a purely administrative change, the NRC staff does not need to perform a regulatory analysis. (The NRC Regulatory Guides website is available at https://www.nrc.gov/reading-rm/doc-collections/reg-guides/.)

F. Processing a Withdrawal of a Regulatory Guide

1. When an RG is no longer an acceptable means of complying with requirements or no longer used to comply with requirements, or the associated guidance has been relocated, it may be withdrawn. There are specific circumstances for withdrawal of an RG.

   (a) The NRC determines that the guidance document should be withdrawn because it contains methods that are no longer an acceptable means of complying with the applicable requirements.

Caution: If the NRC determines that the RG contains methods that are no longer an acceptable means of complying with the applicable requirements, then withdrawing that guidance document may constitute a backfit or a change affecting issue finality for those licensees using the guidance document. In such circumstances, the staff should perform a backfit assessment before withdrawing the RG. If the NRC staff determines that withdrawing the RG would constitute backfitting but cannot justify the backfitting, then the NRC staff cannot withdraw the RG.

(b) The NRC has relocated the guidance in other documents.

Caution: If the NRC relocates guidance that is being used by an entity, then to preclude potential backfitting implications, the staff should include a statement in either Section B, "Background," of the RG if relocated into an RG, or the document where the information is relocated:

(i) Describing the material that was relocated,

(ii) Including a reference to the original source (i.e., the withdrawn RG),

(iii) Explaining that relocated guidance is still acceptable and that licensees who use the withdrawn RG are under no obligation to revise their licensing bases to reflect the new location.

(c) The NRC determines that the guidance concerns an aspect of a facility's design or operation that is no longer used to meet the governing requirements.

2. The TL prepares a justification for withdrawing the RG. The RG PM incorporates the justification into a FRN announcing the withdrawal.

3. The FRN containing the withdrawal bases is reviewed and concurred upon by the applicable program offices, like the process used for revising an RG (refer to RES-OI-TEC-004 for additional guidance on processing a withdrawal). If the NRC staff withdraws an RG, then the staff will issue a final revision of the RG marked as "withdrawn from further use" (refer to RES-OI-TEC-004 for additional, specific instructions). The RG is considered withdrawn either on the date of publication of the FRN or an alternate date if provided within the FRN. The RG PM will update the status of the RG on the NRC Regulatory Guide website to reflect the withdrawal.

G. Release of Pre-decisional Regulatory Guide Language

1. DGs are issued as pre-decisional regulatory guidance for the purpose of developing the final guidance.

2. An RG is not normally released to the public until the required approvals are completed as described in this MD.

3. To facilitate the ACRS hosting a public forum to review a proposed new RG or revision to an existing RG, the RG PM makes publicly available a copy of the RG with the watermark “Pre-Decisional” across each page.

H. Reviews and Approvals

1. The TL develops a DG of a proposed new or revised RG and obtains approval of the DG from the TL’s branch chief and the appropriate program office division director if the RG would create or change staff positions.
2. After obtaining approvals, the TL transmits the DG to the RG PM for processing.
3. The TL and RG PM will ensure that a CUI review is completed and documented before transmitting the DG or RG to RES.
4. The RGPMB is responsible for reviewing the proposed new or revised RG for policy considerations, content, and conformity to the template.
5. The TL is responsible for submitting the draft for technical editing.
6. The RG PM is responsible for circulating the DG or RG for concurrence. The RG PM should use the NRC “e-Concurrence” or other NRC system to electronically track the progress of concurrence on the DG and RG.
7. OGC performs an NLO review of the DG and the RG following the program offices’ concurrence.
8. The Office of the Chief Information Officer (OCIO) reviews an RG for proposed information collection activities and validates that the OMB control numbers (for purposes of the Paperwork Reduction Act) are correct before submittal of the RG to OMB.
9. OGC reviews the RG for applicability of the CRA. If OGC determines that the RG is a rule under the CRA, then the RG PM is responsible for coordinating with NMSS to determine whether the RG is a major rule.

I. Advisory Committee on Reactor Safeguards (ACRS), Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the Committee to Review Generic Requirements (CRGR)

1. The TL and RG PM coordinate the submission of a DG or RG for advisory committee review (e.g., presentation, one-pager, draft of documents to be reviewed).
2. The RG PM obtains documentation of the ACRS, ACMUI, or CRGR review either by email or memorandum. The documentation should be kept in the same file as the concurrence package (either electronic or hard copy).

3. CRGR

   (a) Upon request, the RG PM should provide a draft of the proposed new or revised DG or RG to the CRGR to enable a review by the committee to ensure that the MD 8.4 backfitting, issue finality, and forward fitting policies are properly followed.

   (b) The NRC staff is expected to be diligent in recognizing that backfitting, issue finality, or forward fitting concerns may be raised during internal staff review, advisory committee review, or stakeholder review.

   (c) If a review raises any valid backfitting, issue finality, or forward fitting concern at any point, the CRGR will be engaged for further evaluation. Depending on the complexity of the issues raised, the NRC staff may also consult with the Backfitting and Forward Fitting Community of Practice to support resolution.

   (d) The CRGR Charter specifically states the following:

> [T]he CRGR will review specific draft regulatory guides at the request of the proposing staff. However, the staff is required to engage the CRGR if a valid documented backfitting claim has been made during the public comment phase. Both interactions may result in a potential CRGR review.

   (e) The CRGR Charter identifies backfitting and issue finality provisions of applicable NRC regulations (i.e., 10 CFR 50.109, 10 CFR 52.39, 10 CFR 52.63, 10 CFR 52.83, 10 CFR 52.98, 10 CFR 52.145, 10 CFR 52.171, 10 CFR 70.76, 10 CFR 72.62, or 10 CFR 76.76).

4. ACRS

   (a) The RG PM should contact the ACRS during the development of a new or revised RG. The PM should offer the ACRS an opportunity to review both DGs and RGs before their publication in the *FR*.

   (b) The ACRS has communicated to the RGPMB that it prefers to review a revision to an RG after public comments are incorporated into the document; for a new RG, the ACRS may opt to review the DG during the DG stage.

   (c) The TL and RG PM consider ACRS comments and incorporate any changes resulting from the comments into the DG or RG.

5. ACMUI

   (a) The RG PM should contact ACMUI during the development of a new or revised RG. The PM should offer the ACMUI an opportunity to review both DGs and RGs before their publication in the *FR*.

   (b) The TL and RG PM consider ACMUI comments and incorporate any changes resulting from the comments into the DG or RG.

J. Security Review of Regulatory Guides for CUI (includes within its scope Safeguards Information) or Classified Information

1. The TL and the RG PM should always maintain awareness of all sensitive and classified information associated with the DG, stakeholder's comments, and RG and take the appropriate precautions when dealing with security related material.
2. All program offices are responsible for the control of CUI and classified information consistent with the scope of work performed on RGs.
3. A small number of RGs are not publicly available because of the inclusion of CUI or classified information. These RGs are processed with controlled distribution to cleared stakeholders for DGs and cleared recipients for the users of the RGs. The need for and dissemination of guidance that includes safeguards or classified information should be coordinated with the Office of Nuclear Security and Incident Response (NSIR) following the guidance in the NRC Security Program. Safeguard's information guides will be retained on the NSIR computer system (Safeguards Local Area Network and Electronic Safe (SLES)). NSIR will arrange for interaction and discussion with selected cleared stakeholder representatives. When possible, redacted versions of DGs and RGs should be made available for the public.
4. In general, the RG PM is responsible for maintaining accessibility of RGs on the NRC public website. However, security-related RGs are not made publicly available on the NRC public website. For these RGs, the NRC public website provides only a list of the RG number, title, and instructions on how to obtain a copy of the RG.

K. Editing

The TL should submit both the DGs and RGs for technical editing before transmittal to RES for processing. The technical editor reviews the DG or RG and ensures that it is in the correct format, is grammatically correct, is written in plain language, and conforms to guidance in NUREG-1379, “NRC Editorial Style Guide.” The RG PM and RG specialist check all citations and references for accuracy and for public availability. In addition, the RG PM and RG specialist issue DG and RG numbers.

L. Authorization, Printing, and Distribution

1. The RG PM assigned to a DG or RG is responsible for processing the regulatory guide. Refer to RES-OI-TEC-004 for additional instructions.
2. The RG specialist is a RES staff member assigned to assist in processing and publishing RGs.
3. The RG specialist prepares the documents associated with the issuance and availability of the DG or RG. Refer to RES-OI-TEC-004 for additional instructions.
4. The RG specialist coordinates the release and issuance of the DG, RG, and FRN.
5. The RG specialist maintains a link to the DGs and RGs on the NRC public website.

IV. GLOSSARY

Advisory Committees

Includes the Advisory Committee on Reactor Safeguards (ACRS), the Committee to Review Generic Requirements (CRGR), and the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

Concurrence Package

Contains, as appropriate, the RG, DG, FRN, RA, and public comment response document, and any other necessary supporting documents. The associated memorandum asks for concurrences from each applicable program office; documentation of the Office of the General Counsel's statement of "no legal objection"; documentation of each appropriate advisory committee regarding its review; and a statement on the security review of the regulatory guide.

Endorsement

In an RG, the staff has evaluated the material to be endorsed and has found that it is acceptable for use, either in whole or in part, by applicants or licensees as discussed within the RG. The endorsement must be discussed sufficiently to identify any limitations. To constitute endorsement, the subject document must be described in the Section C, "Staff Regulatory Guidance." Listing a document in the reference or bibliography sections or discussing it outside of the Staff Regulatory Guidance section, does not constitute an endorsement.

Lead Office

The technical office responsible for preparing the RG and obtaining the appropriate input and agreement in preparation of a DG and RG. The lead office assigns a technical lead to be the point-of-contact and primary contributor for the development of the RG.

Major Rule

As defined in 5 U.S.C. (US Code) 804(2), a "major rule" is a final action under the Congressional Review Act that will result in, or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets. The "Congressional Review Act SharePoint Site" and Management Directive 6.3, "The Rulemaking Process," contain more information on major rules.

No Legal Objection

A finding by the Office of the General Counsel that the document it reviewed is not contrary to the law (e.g., statute or regulation), would not lead to some action contrary to the law, and is otherwise legally sufficient.

Office Concurrence

Means that the concurring office:

1. Agrees with the overall approach, objective, technical content, and resource impacts of the RG.
2. Agrees that the guidance as proposed will not adversely affect or conflict with other NRC programs and policies.
3. Agrees that the material for which the office has a programmatic basis for judgment is factual and accurate.

Office Liaison

The person in the lead office acting as the point-of-contact who coordinates all actions submitted by the Office of Nuclear Regulatory Research related to the review, development, revision, and withdrawal of RGs.

Regulatory Guide and Programs Management Branch (RGPMB)

The branch in the Division of Engineering in the Office of Nuclear Regulatory Research that is responsible for processing RGs.

Regulatory Guide (RG) Project Manager (PM)

The RG PM has overall responsibility for coordination of activities involving the review and issuance of a new or revised RG. The RG PM facilitates interoffice reviews of an DG or RG and maintains timeliness in processing the DG or RG. The RG PM secures concurrences and approvals needed to publish a DG or RG.

Regulatory Guide Specialist (RGS)

The RES staff member assigned to assist in processing and publishing RGs. The RG Specialist provides expertise in preparing the RGs for issuance in the *Federal Register*.

Staff Position

Within the context of this management directive, an explicit NRC staff interpretation of actions that, if implemented, will satisfy the more generally stated, legally binding body of NRC regulations found in Title 10, Chapter I, of the *Code of Federal Regulations* and other applicable requirements. In RGs, the staff positions are contained in the Staff

Regulatory Guidance section and the applicable requirements are discussed in Section II.A.1, “Section A: Introduction” of this handbook.

Technical Lead (TL)

The technical staff member in the Lead Office responsible for developing the new or revised RG and its technical basis. The TL ensures that technical issues are coordinated with the appropriate program offices and addresses public comments on the DG.