



U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research

RES OFFICE INSTRUCTION

Change Notice

Office Instruction No.	TEC-004, Rev. 1	Approved by: Raymond Furstenu October 11, 2023
Office Instruction Title	Regulatory Guide Review, Development, Revision, and Withdraw Process	
Effective Date	October 11, 2023 – October 11, 2028	
Primary Contact	Meraj Rahimi Chief, Regulatory Guide and Programs Management Branch	
Responsible Division	RES/DE	
ADAMS Accession No.	ML21341A555	
Training	None	
SUMMARY OF CHANGES: <ul style="list-style-type: none">• Addressed change in periodic review frequency.• Added schedules for tracking regulatory guide in process.• Removed duplicated sections of MD 6.4, such as definitions.• Provide detailed milestone steps for flow process of regulatory guide.• Added instructions on writing regulatory analysis.		

Name	Action	Signature	Date
Branch Chief	Concurrence	M. Rahimi	6/2/2023
D:DE	Concurrence	J. McKirgan for M. Sampson	6/9/2023
D:DRA	Concurrence	C. Araguas	6/21/23
D:DSA	Concurrence	K. Webber	7/7/23
D:PMDA	Concurrence	M. Brezovec	6/12/2023
OGC	NLO	H. Benowitz	10/10/2023
RES Mailroom	Logging	J. Littlejohn	10/11/2023
D:RES	Approval	J. Tappert for R. Furstenu	10/11/2023
OI Coordinator	Follow-on Actions	J. Littlejohn/Kevin Johnson	10/11/2023

Table of Contents

- 1. PURPOSE 4**
- 2. BACKGROUND 4**
- 3. DEFINITIONS 4**
- 4. RESPONSIBILITIES AND AUTHORITIES 5**
 - 4.1 MD 6.6 defines the delegation of authority and the responsibilities of the parties involved in the RG process.5
 - 4.2 The director of the Division of Engineering (DE) reports to the RES office director and has the following responsibilities:5
 - 4.3 The chief of RGPMB reports to the DE director and has the following responsibilities:5
 - 4.4 The RGPMB PM reports to the branch chief (BC) and has the following duties and responsibilities:.....5
 - 4.5 The RGPMB Regulatory Guide Specialist (RG specialist) reports to the RGPMB BC and has the following duties and responsibilities:6
- 5. INTRODUCTION 7**
- 6. INSTRUCTIONS..... 9**
 - 6.1. General Comments and Discussion.....9
 - 6.2. General Flowpath and Milestones for DGs and RGs9
 - 6.3. Instructions for Writing a Regulatory Analysis for an RG12
 - 6.4. Instructions for Writing a New or Revised RG.....13
 - 6.4.1. Section A, “Introduction”15
 - 6.4.2. Section B, “Discussion”16
 - 6.4.3. Section C, “Staff Regulatory Guidance”18
 - 6.4.4. Section D, “Implementation”19
 - 6.4.5. References (Optional).....19
 - 6.4.6. Glossary (Optional).....19
 - 6.4.7. Acronym List (Optional).....19
 - 6.4.8. Bibliography (Optional)20
 - 6.4.9. Appendices (Optional).....20
 - 6.5. Instructions for Converting a DG to an RG20
 - 6.6. Instructions for Writing a *Federal Register* Notice for a DG/RG20
 - 6.7. Instructions for Performing Periodic Reviews.....21
 - 6.7.1. Periodic Review Process22
 - 6.7.2. Review Decisions22
 - 6.7.3. Periodic Review Submission Process.....22
 - 6.8. Instructions for Making Administrative Changes to RGs.....23
 - 6.9. Instructions for Writing Trial Use RGs (Pilot Use)23
 - 6.10. Instructions for Withdrawing an RG.....23
 - 6.11. Instructions for Writing an RG Associated with Rulemaking Activities.....24
 - 6.12. Special Processes Supporting the Guidance Process24

6.12.1.	Determination of Whether Guidance Constitutes a Major or Non-major Rule under the Congressional Review Act	24
6.12.2.	Review of Guides Incorporating Controlled Unclassified Information, Sensitive Unclassified Nonsafeguards Information, Safeguards or Classified Information.....	25
6.12.3.	Technical Editing.....	25
6.12.4.	Contractor Support in the Development of Guidance	26
6.12.5.	Release of Draft Guidance to Public.....	26
6.12.6.	Public and Internal Comment Resolution Documentation.....	26
6.13.	Committee Reviews and Approvals	27
6.13.1.	Reviews by the Advisory Committee on Reactor Safeguards.....	28
6.13.2.	Committee to Review Generic Requirements—Backfitting, Forward Fitting, and Issue Finality Reviews	28
6.13.3.	Office of the General Counsel	29
6.14.	Schedules for Tracking RGs	29
6.15.	Authorization, Printing, and Distribution	29
7.	PERFORMANCE MEASURES	30
8.	REFERENCES	31

1. PURPOSE

This office instruction (OI) provides guidance for use in reviewing, developing, revising, and withdrawing regulatory guides (RGs). This OI provides instructions for the regulatory guide (RG) process described in Management Directive (MD) 6.6, "Regulatory Guides."

While this OI provides the best information currently available, it does not represent the only process that can be used. Exigent or other circumstances may necessitate variation from the process outlined here. Should a variation prove to be potentially beneficial for general use, the staff may incorporate it into this OI as part of a future revision. This document is intended for internal use by NRC staff.

This OI was written to conform with instructions in RES-OI-ADM-001, "Preparing and Maintaining RES Office Instructions," Sections 5 and 7, which state that "[a]n OI is intended to facilitate staff compliance with higher level requirements such as statutes, regulations, federal standards (e.g., Office of Management and Budget (OMB) Circulars), and agency policies such as those contained in management directives."

2. BACKGROUND

MD 6.6 provides the policies and procedures of the U.S. Nuclear Regulatory Commission (NRC) for developing, maintaining, and issuing RGs. MD 6.6 also assigns lead responsibility for RGs to the Office of Nuclear Regulatory Research (RES). Within RES, the Regulatory Guide and Programs Management Branch (RGPMB) administers the agency program for RGs.

The NRC issues RGs to describe one or more methods that the NRC staff considers acceptable for meeting the agency's regulatory requirements, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. RGs do not impose requirements, and compliance with RGs is not required. Methods and solutions that differ from those set forth in RGs can be acceptable for the issuance or continuance of a permit or license if supported by a basis found acceptable by the NRC to satisfy underlying regulations. It is the staff's intent that the use of RGs by applicants and licensees will conserve staff resources and simplify licensing because RGs describe methods that the staff has already determined to be acceptable approaches to meeting the regulations. RGs are not substitutes for regulations, and compliance with them is not required.

Applicants and licensees may submit alternative methods or approaches for meeting requirements, which the staff will review on a case-by-case basis.

3. DEFINITIONS

MD 6.6 provides a glossary of terms related to the RG program.

4. RESPONSIBILITIES AND AUTHORITIES

- 4.1 MD 6.6 defines the delegation of authority and the responsibilities of the parties involved in the RG process.
- 4.2 The director of the Division of Engineering (DE) reports to the RES office director and has the following responsibilities:
- a. Delegated by RES management, the DE director approves issuance of draft regulatory guides (DGs), RGs, and related Federal Register notices (FRNs).
 - b. The DE director approves requests for funds to support contracts.
- 4.3 The chief of RGPMB reports to the DE director and has the following responsibilities:
- a. Manages the process of developing, revising, and issuing RGs.
 - b. Oversees policy issues pertaining to RGs.
 - c. Delegated by RES management, issues FRNs.
 - d. Assigns project managers (RG PMs) in RGPMB as leads for DG/RGs.
 - e. Submits budget allocations to ensure that the branch has adequate resources.
 - f. Manages contracts for the development of RGs and requests for assistance used in the RG process.
- 4.4 The RGPMB PM reports to the branch chief (BC) and has the following duties and responsibilities:
- a. Coordinates the development and review of assigned DGs/RGs with appropriate technical leads (TLs) within the program offices.
 - b. Prepares a schedule of significant milestones in the RG process and shares this information with internal stakeholders.
 - c. Updates and maintains the status of assigned DGs/RGs in the SharePoint website (not publicly available):
<https://usnrc.sharepoint.com/teams/RES-RGPMB/Lists/RGGIB%20Staff%20Work%20Assignments/AllItems.aspx>.
 - d. Reviews DGs/RGs for format and regulatory correctness. Verifies that reference documents are publicly available, as appropriate.
 - e. Collects public and stakeholder comments. Works with the TL to assemble comments into a public comment resolution document, and coordinates staff responses.
 - f. Works with the TL to revise the guidance in response to internal and external comments.

- g. Develops draft language for the concurrence memoranda, FRN, public comment resolution document, and Executive Director for Operations (EDO) note.
- h. Prepares a review package for each DG/RG. Coordinates reviews and concurrences of the DG/RG from the appropriate program offices.
- i. Obtains no legal objection (NLO) determination from the Office of the General Counsel (OGC) before DGs/RGs are issued.
- j. Coordinates reviews of DGs/RGs by appropriate committees (e.g., 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)).
- k. Coordinates the periodic review (PR) of RGs with the lead technical office (LTO).

4.5 The RGPMB Regulatory Guide Specialist (RG specialist) reports to the RGPMB BC and has the following duties and responsibilities:

- a. In support of branch activities, provides programmatic support to maintain and update the DG and RG records in the Agencywide Documents Access and Management System (ADAMS).
- b. Coordinates technical editing of DGs/RGs.
- c. Assists the RGPMB PM in preparing memoranda and notices, including FRNs, Congressional Review Act (CRA) forms, and related documents announcing the opportunity for stakeholders to submit comments on a DG, the availability of an RG, or the withdrawal of an RG.
- d. Coordinates with TLs in the transmittal and distribution of sensitive documents (i.e., official-use-only security-related information (OUO-SRI) and safeguards information) to cleared stakeholders for comment. (Classified documents are excluded and remain the responsibility of the TL.)
- e. Coordinates with the Office of Administration (ADM) and the Office of Information Services as needed to arrange for DGs/RGs to be distributed and displayed on the appropriate NRC web pages.
- f. Distributes any internal and external comments and information on specific DGs/RGs to the appropriate RG PM.
- g. Provides programmatic support and assistance with the updating of the internal SharePoint website (<https://usnrc.sharepoint.com/teams/RES-RGPMB/SitePages/Regulatory-Guides.aspx>) in support of branch activities.

5. INTRODUCTION

MD 6.6 establishes that RGs be periodically reviewed every 10 years or when special circumstances warrant an earlier review—for example, in response to licensee or applicant requests, or when the staff determines that the current guidance no longer provides the best available method or technique for demonstrating compliance with the underlying regulations. Reviews performed before the scheduled review date are called “on-demand” or “triggered” reviews. PRs of an RG are performed by the LTO assigned to the RG. Based on the review results, the NRC technical branch recommends the appropriate action to be taken. PRs fulfill the underlying purpose of both Executive Order 13563, “Improving Regulation and Regulatory Review” ([76 FR 3821](#); January 21, 2011), and Executive Order 13579, “Regulation and Independent Regulatory Agencies” ([76 FR 41587](#); July 14, 2011), with respect to retrospective review of regulations.

The staff may use RGs to endorse third-party documents (e.g., consensus codes or standards) consistent with the provisions of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (5 U.S.C. 801–808), and OMB Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.” MD 6.5, “NRC Participation in the Development and Use of Consensus Standards,” provides agency guidance for implementing these requirements.

In addition, the NRC has established a goal of harmonizing RGs with international safety standards (see response to suggestion no. 2 made in the 2010 Integrated Regulatory Review Service (IRRS) Followup Report (Agencywide Documents Access and Management System (ADAMS) under Accession No. [ML14265A068](#))). These include safety standards developed by the International Atomic Energy Agency (IAEA) and by other organizations, such as the International Organization for Standardization and the International Electrotechnical Commission (IEC). When issuing regulations and guides, the NRC considers all relevant international standards. The NRC reviews each proposed IAEA safety standard and benchmarks it against current NRC regulations and guides. MD 6.6 details implementing guidance for a 10-year PR of RGs, taking into account operating experience feedback and the development of international safety standards, and especially mentioning the IAEA safety standards. When updating existing regulatory guidance, the staff should review and consider IAEA guidance.

Before issuing a new RG or a final revision to an existing RG, the staff typically issues a DG to provide an opportunity for public comment, thereby involving the public in the development of the agency’s regulatory positions. DGs are issued as pre-decisional regulatory guidance for the purpose of developing the final guidance and do not represent official NRC staff positions. When finalizing an RG, the staff considers all comments received during the public comment period and revises the RG as appropriate. An RG is not normally released to the public until approvals described in MD 6.6 are completed. Public comments and staff responses are collated and made publicly available when the RG is finalized, as appropriate.

The NRC’s RGs are organized into the following 10 topical divisions:

- (1) Power Reactors
- (2) Research and Test Reactors
- (3) Fuels and Materials Facilities
- (4) Environmental and Siting
- (5) Materials and Plant Protection

- (6) Products
- (7) Transportation
- (8) Occupational Health
- (9) Antitrust and Financial Review
- (10) General

The reasons to develop new or revised guidance can come from a variety of sources. Typical sources of new or revised information include the following:

- Commission direction—For example, a new or revised regulation may precipitate the need for new or revised guidance.
 - The Commission directed several process enhancements to address the cumulative effects of regulation (CER) in SRM-SECY-11-0032, “Staff Requirements—SECY-11-0032—Consideration of the Cumulative Effects of Regulation in the Rulemaking Process,” dated October 11, 2011 (ADAMS Accession No. [ML112840466](#)). Among these enhancements was the direction to publish draft guidance concurrently with proposed rules and to publish final guidance concurrently with final rules.
 - RGs developed to support new or revised regulations are part of the rulemaking package; see “Identifying the Effects of Commission Direction on Preparing Guidance Documents and Recommending Best Practices for Publication of Guidance Documents,” dated August 14, 2012 ([ML12227A355](#)).
- Licensing activities—For example, RGs may need to incorporate precedents set in licensing activities; lessons learned from operating experience, responses to generic communications, or relief requests; or temporary guidance, such as branch technical positions and interim staff guidance.
- Inspection activities—For example, RGs may need to incorporate lessons learned from operating experience, inspector feedback, or external stakeholder input from frequently asked questions.
- Emerging staff positions—For example, RGs may need to incorporate information from generic communications, interim staff guidance, or licensing and inspection activities.
- Industry drivers and inputs—For example, RGs may be updated to incorporate information from:
 - white papers,
 - documents from the Nuclear Energy Institute (NEI), or the Electric Power Research Institute (EPRI),
 - industry or stakeholder requests or comments,
 - topical reports,
 - changes to the Standard Technical Specifications, or
 - input from standards development organizations (SDOs).

Once the need for new or revised guidance has been articulated, an LTO is identified, and that office identifies a TL for the guide. Upon receiving a request from the LTO, the RGPMB BC assigns responsibility for the guide to the RGPMB office point of contact (POC) or PM.

6. INSTRUCTIONS

6.1. General Comments and Discussion

For classified, safeguards, and sensitive material, the staff will use the Secure Local Area Network Electronic System (SLES). MD 12.6, “NRC Controlled Unclassified Information (CUI) Program,” and MD 12.7, “NRC Safeguards Information Security Program,” contain additional information.

Standardization is implemented through the use of templates for DGs, regulatory analyses (RAs), FRNs, and RGs. Templates serve as guidelines; deviations from the templates may be appropriate in some situations and should be discussed between the TL and the RG PM. Templates can be obtained by contacting the RG PM, RG Specialist, or point of contact, or through the “Draft Regulatory Guides Template Package,” (Package No. [ML14303A137](#)). Available templates include, but are not limited to, RA, DG, RG, FRN, and public comment resolution documents.

6.2. General Flowpath and Milestones for DGs and RGs

The development and issuance of new or revised RGs follow a standard review and concurrence process so that all interested NRC offices and committees, licensees, applicants, and the public can review and comment on the DG. This OI details the process step by step. Attachment 2 provides a pictorial flowpath for the typical process.

The following are milestones in the DG/RG process:

- **Program Office—Technical Branch**
 - (1) The TL prepares an RA providing justification for the new or revised RG.
 - (2) The TL prepares a DG for the proposed new or revised RG.
 - (3) The TL has a Quality Technical Editing (QTE) review performed.
 - (4) The TL BC sends the DG to the RG BC.
 - (5) The RG BC assigns a PM.
 - (6) The RG PM reviews the RA and DG and sends any comments to the TL.
 - (7) The TL resolves comments and returns the RA and DG to RG PM.
 - (8) The RG PM prepares a project sheet with a schedule.
- **RES—RGPMB**
 - (9) The RG PM prepares a concurrence package that includes the DG together with a concurrence memorandum, FRN, RA, and EDO note.
 - (10) The RG PM sends the DG to QTE if a QTE review has not already been performed, then reviews and incorporates comments as applicable.
 - (11) The RG PM transmits the documents to the RG specialist for review.
 - (12) The RG specialist reviews the documents and prepares an e-concurrence package.
 - (13) The RG specialist transmits the e-concurrence package to the following individuals for review and concurrence:
 - the RG BC
 - the TL and the TL BC
 - (14) The RG BC, TL, and TL BC review and concur on the package.

- (15) The e-concurrence package proceeds to the RES division director for review and concurrence.
 - (16) The RES division director reviews and signs out a memorandum requesting program office concurrence.
 - (17) The e-concurrence package proceeds to applicable program office division directors for review, comments, and concurrences.
- **Program Office**
 - (18) The program office division directors review, comment as appropriate, and concur on package.
- **RES—RGPMB**
 - (19) The RG PM works with the TL to incorporate any comments on documents.
- **Review Committees and OGC—ACRS, ACMUI, CRGR, OGC**
 - (20) The RG PM coordinates with the ACRS, ACMUI, and CRGR for appropriate reviews.
 - (21) The RG PM receives any comments from the committees and works with the TL to incorporate the comments as necessary into the documents.
 - (22) OGC performs legal review and provides comments; the RG PM and TL resolve comments with OGC.
 - (23) OGC provides an NLO determination.
- **RES—RGPMB**
 - (24) The RG PM prepares an EDO note and transmits it to management.
 - (25) The RG PM works with the RG specialist to prepare the package for issuance for public comment.
 - (26) The e-concurrence package is prepared and to the TL, TL's BC, RG PM, RG BC, the Office of the Chief Information Officer (OCIO), and technical (program) offices for signature.
 - (27) The RG PM resolves any comments and works with the TL to incorporate the comments as necessary into the documents.
 - (28) The RG specialist sends work request worksheet to OGC for an NLO and CRA review.
 - (29) OGC performs legal review and provides comments; the RG PM and TL resolve comments with OGC.
 - (30) OGC provides an NLO.
 - (31) The RG specialist makes the RA and DG publicly available.
 - (32) The RG PM prepares an EDO note and sends it to the DE technical assistant.
 - (33) The RG PM sends an email to the RG specialist for final processing.
 - (34) The RG specialist sends a draft of the FRN to the Legal Resource Center (LRC). The LRC directs the publishing of the notice in the *Federal Register*.
 - (35) The LRC sends the final FRN to the RG BC for a digital signature.
 - (36) The RG BC signs the FRN; sends the digitally signed FRN to the LRC for publication in the *Federal Register*, with carbon copies to the RG specialist and the RG PM; and saves the signed FRN in the Notices folder (G:/DE/RGPMB/FRN).
 - (37) The RG specialist arranges for the DG to be distributed and displayed on appropriate NRC websites and the RGPMB internal SharePoint website.
 - (38) The LRC directs the noticing in the *Federal Register*.

- **Public**
 - (39) The public provides input during the public comment period.
- **Program Office—Technical Branch**
 - (40) The RG PM collects any public comments and sends them to the TL.
 - (41) The TL reviews public comments and makes any necessary revisions to the DG.
 - (42) The TL prepares a document of NRC responses to public comments.
 - (43) The TL transmits the public comment resolution document and revised DG to the RG PM.
- **RES—RGPMB**
 - (44) The RG PM converts the DG into the RG format and prepares a new FRN, EDO note, and concurrence memorandum.
 - (45) The RG PM transmits the documents to the RG specialist.
 - (46) The RG specialist reviews the documents and prepares ADAMS and e-concurrence packages.
 - (47) The RG specialist transmits the e-concurrence package to the following individuals for review and concurrence:
 - RG BC
 - TL BC
 - (48) The RG BC and TL BC review and concur on the package.
 - (49) The e-concurrence package proceeds to the DE director for review and concurrence.
 - (50) The DE director reviews and signs out a memorandum requesting program office concurrence.
 - (51) The e-concurrence package is transmitted to applicable program office division directors and to the OCIO Agency Clearance Officer for review, comments, and concurrences.
- **Program Offices**
 - (52) Program offices review and concur on the package.
- **RES—RGPMB**
 - (53) The RG PM works with the TL to incorporate any comments on the documents.
- **Review Committees and OGC—ACRS, ACMUI, CRGR, OGC**
 - (54) The RG PM coordinates with the ACRS, ACMUI, and CRGR for appropriate reviews.
 - (55) The RG PM receives any comments from the committees and works with the TL to incorporate the comments as necessary into the documents.
 - (56) The RG PM coordinates meetings with any review committees (e.g., ACRS, ACMUI, CRGR) and resolves any concerns.
 - (57) The RG specialist transmits the package to OGC for an NLO and CRA review.
 - (58) OGC performs legal review, provides comments, and confirms CRA applicability.
 - (59) Once OGC provides comments, the RG PM and TL resolve comments with OGC, incorporate any changes to the documents, and return the package to OGC for an NLO determination.
 - (60) OGC provides an NLO determination.
If the RG meets the CRA threshold as a major rule, then the RG PM will work with the Office of Nuclear Material Safety and Safeguards (NMSS) on appropriate actions.

- **RES—RGPMB**
 - (61) The RG PM prepares an EDO note and sends it to the DE technical assistant.
 - (62) The RG PM sends an email to the RG specialist for final processing.
 - (63) The RG specialist makes the RG and comment resolution document publicly available.
 - (64) The RG specialist sends CRA forms and a copy of the final RG to the Office of Congressional Affairs.
 - (65) The RG specialist sends a draft of the FRN to the LRC. The LRC directs the publishing of the notice in the *Federal Register*.
 - (66) The LRC sends the final FRN to the RG BC for a digital signature.
 - (67) The RG BC signs the FRN; sends it to the LRC for publication in the *Federal Register*, with carbon copies to the RG specialist and the PM; and saves the signed FRN in the Notices folder (G:/DE/RGPMB/FRN).
 - (68) The RG specialist processes the remaining documents in ADAMS to make an official record.
 - (69) The RG PM updates the SharePoint page, marks that line item as “completed,” and initiates a new line item pending a 10-year review.

6.3. Instructions for Writing a Regulatory Analysis for an RG

The TL is responsible for writing the RA or identifying the RA associated with rulemaking. In addition, the TL is responsible for obtaining the appropriate level of approval from their management to support development and issuance of the RG.

An RA is an analytical tool provided to decisionmakers that does the following:

- recommends a preferred alternative out of the potential courses of action studied,
- contains estimates of benefits and costs, and concludes whether the proposed regulatory action is cost beneficial,
- documents the analysis in an organized and understandable format, and
- documents the regulatory basis to justify that the RG is tied to existing requirements and regulations.

The RA should be performed on a new or revised RG. The RA provides the justification for the work to be performed. If there is no strong regulatory basis for the revision or for the development of a new RG, then the work may be cancelled later in the process.

The NRC's current RA guidance is NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission” ([ML19261A278](#)).

As mentioned in NUREG/BR-0058, NRC policy is that an RA should be performed when a proposed action does any of the following:

- establishes or communicates requirements, guidance, requests, or staff positions that would result in a change in licensee resources,
- involves backfitting licensed facilities,
- imposes generic requirements on one or more classes of the agency's reactor and materials licensees.

On May 5, 2023, the RES director issued guidance ([ML23033A392](#)) to the staff waiving development of quantitative regulatory analyses for non-rulemaking RGs, stating that the staff should perform qualitative RAs when revising existing RGs or issuing new RGs outside of rulemaking activities. The guidance directed further that, in the event that an RG can be interpreted as imposing a requirement or impact the costs included in the RA that supported the promulgation of the regulation, the staff should perform a quantitative analysis. For RGs associated with rulemakings, the RAs continue to evaluate both the rule and the associated RGs and include quantification of costs and benefits.

The qualitative RA should do the following:

- identify issues that warrant either new guidance or revision of existing guidance,
- justify that the guidance is tied to existing requirements and regulations,
- state the impact of the issues identified or the resources required to provide guidance,
- describe why the RG is being changed (or created) and identify what is being changed in a revised guide,
- evaluate the need for and consequences of the proposed revision to the guidance,
- include a qualitative summary of costs and benefits to the NRC, the industry, and the public, as appropriate.

Qualitative summary of costs and benefits may include the following:

- reductions in public and occupational radiation exposure,
- enhancements to health, safety, or the natural environment,
- averted onsite impacts,
- averted offsite property damage,
- savings to licensees,
- savings to the NRC,
- savings to State, local, or Tribal governments,
- improved plant availability,
- promotion of the efficient functioning of the economy,
- reductions in safeguards risks,
- effects on regulatory efficiency or scientific knowledge needed for regulatory purposes.

The RA is a separate document that travels as part of the RG review and concurrence package. It can be referenced in the DG and RG. A final RG usually references the final RA used for the development of the DG because both guides are a product of this single initiative.

For revised guidance, the RA can be limited to summarizing changes and explaining how the changes will affect the nature of the guidance.

RGPMB maintains an example of an RA in ADAMS with other example documents used in the RG process.

6.4. Instructions for Writing a New or Revised RG

RGPMB highly encourages the use of templates in order to maintain consistency in the format of documents. Templates are guidelines used for formulating DGs, RAs, FRNs, and RGs. Deviations from the templates may be appropriate in some situations, but the TL should discuss any deviations with the RG PM. Templates can be obtained by contacting the RG PM, or

available in ADAMS. In ADAMS the templates are located in a folder in the directory under RES/DE/Regulatory Guides/Templates. Inside folder, "New Templates (2014 -)," there are templates that support the following:

- Administrative Change RG,
- DGs,
- RGs,
- FRN,
- Public comment resolution document,
- EDO notes.

For RGs containing security-related or safeguards information, there is a cover sheet located in the "Regulatory Guides" folder called "Security Access Form and Notices."

The TL is responsible for performing the necessary research to develop the guidance, writing the DG and the RG, and obtaining management agreement needed to support issuance of the RG.

The TL may solicit technical input from other program offices by circulating the proposed guidance before finalizing the DG.

All transmittal emails from the TL should reflect supervisory awareness that a request to process guidance has been made to the RGPMB staff. This is typically accomplished by having the TL's supervisor, management, or both copied on the email. This ensures that management supports the work activities and has designated a responsible individual.

DGs and RGs generally have the following sections:

- Section A, "Introduction"
- Section B, "Discussion"
- Section C, "Staff Regulatory Guidance"
- Section D, "Implementation."

At the discretion of the technical staff preparing an RG, other sections may be included, such as the following:

- table of contents,
- list of references,
- bibliography,
- acronym list,
- glossary,
- appendices or attachments.

RGPMB maintains the Regulatory Guidance System database on its SharePoint site. The database was created to assist the development and update of RGs. The database provides a cross-reference search capability for NRC documents. The PM and TL should use the database during the development and revision of RGs. The database can be found on the SharePoint site at <https://usnrc.SharePoint.com/teams/RES-RGS>.

6.4.1. Section A, “Introduction”

Section A, “Introduction,” states the reason the staff is issuing the guide. It should contain the following subsections:

- Purpose,
- Applicability,
- Applicable Orders and Regulations,
- Related Guidance,
- Purpose of Regulatory Guides,
- Paperwork Reduction Act,
- Public Protection Notification.

The first page (footer) of the DG or RG should identify the ADAMS accession numbers for supporting documents (e.g., the DG, RG, RA, and staff responses to public comments).

The “Purpose” section should contain a short paragraph describing the reason for issuing the new or revised RG.

The “Applicability” section should describe the applicants and licensees to which the RG is applicable; it should usually state the specific parts of 10 CFR under which the intended users are licensed.

The “Applicable Orders and Regulations” section should contain a bulleted list of the NRC orders, NRC bulletins, and regulations that apply to the RG.

The “Related Guidance” section should contain a bulleted list of significant guidance (e.g., other RGs, standard review plans, NUREGs) that applicants and licensees should consider when using the RG. The list should not include guidance that is being endorsed in section C, “Staff Regulatory Guidance.”

The “Purpose of Regulatory Guides” section does not change for the majority of RGs. Usually, the words for this section should be taken directly from the template and should be similar to the following:

The NRC issues RGs to describe methods that are acceptable to the staff for implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

The “Paperwork Reduction Act” section should follow the example provided in the template and include applicable regulations and appropriate control numbers. It should be similar to the following:

This RG provides voluntary guidance for implementing the mandatory requirements in 10 CFR Parts 20,40, 50, 52, 70, 72, and 73, that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. Seq.). These

information collections were approved by the Office of Management and Budget (OMB), under control numbers 3150-0014, 3150-0020, 3150-0011, 3150-0151, 3150-0009, 3150 0132, and 3150 0002, respectively.

Send comments regarding this information collection to the FOIA, Library and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0014, 3150-0020, 3150-0011, 3150-0151, 3150-0009, 3150 0132, and 3150-0002), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC20503; e-mail: oir_submission@omb.eop.gov.

The “Paperwork Reduction Act” and “Public Protection Notification” sections support the implementation of agency policies and procedures for information collection activities covered under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), including, but not limited to, the Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504(a)(1)(b)(vi)) and the Paperwork Reduction Act.

The RG PM should consult with the NRC Clearance Officer on the Information Collections Team (OCIO/GEMSD/FLICB/ICT) to verify that proper control numbers were approved by the OMB. The NRC’s current clearance inventory can be found by going to <https://www.reginfo.gov/public/do/PRAMain> and entering “Nuclear Regulatory Commission” in the Current Inventory menu.

The “Public Protection Notification” section does not change for the majority of RGs. Usually, the words for this section should be taken directly from the template and should be similar to the following:

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

6.4.2. Section B, “Discussion”

It is important that section B should not provide any regulatory positions and should not refer to a staff position that is not specified in section C, “Staff Regulatory Guidance.”

Section B should contain the following subsections:

- Reason for Revision or Reason for Issuance,
- Background,
- Consideration of International Standards,
- Documents Discussed in Staff Regulatory Guidance (if endorsing a standard).

The “Reason for Revision” or “Reason for Issuance” section should briefly describe why the guide is being revised or issued. For revisions to existing RGs, section B typically begins by summarizing the significant changes in the revised RG. For new RGs, section B should have an introductory paragraph discussing why the RG is being issued.

The “Background” section should contain supporting information and the technical basis for the regulatory positions in section C. It should identify source documents referenced for the technical basis. The first paragraphs should explain the history of the development of the guide and the associated technical issues, if known; they may include the “Reason for Revision” paragraphs from previous versions of the guide. The subsequent paragraphs should describe the development of the current revision of the guide, in a way that helps explain the regulatory positions in section C. Section B should describe the relationship of the RG to other topics or guidance, outline the subjects addressed by the RG, and provide explanatory or supporting information for the regulatory positions in section C, if needed or desired.

The “Consideration of International Standards” section should list relevant IAEA guides or documents and should describe their relationship to the RG. Usually, the words for this section should be taken directly from the template, but modified to express the degree of correlation between the RG and the documents listed; they should be similar to the following:

The International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA develops Safety Requirements and Safety Guides for protecting people and the environment from the harmful effects of ionizing radiation. This system of safety fundamentals, safety requirements, safety guides, and other relevant reports reflects an international perspective on what constitutes a high level of safety. To inform its development of this RG, the NRC considered IAEA Safety Requirements and Safety Guides pursuant to the Commission’s International Policy Statement and Management Directive and Handbook 6.6, “Regulatory Guides.”

The following IAEA Safety Requirements and Guides were considered in the development/update of the Regulatory Guide: [followed by a list of IAEA documents considered]

If no international standards were considered, the section should end as follows:

The NRC staff did not identify any IAEA Safety Requirements or Safety Guides containing information related to the topic of this RG.

For security-related guides, the wording should be similar to the following:

The International Atomic Energy Agency (IAEA) works with member states and other partners to promote the safe, secure, and peaceful use of nuclear technologies. The IAEA has established a series of security guides to address nuclear security issues relating to the prevention and detection of, and response to, theft, sabotage, unauthorized access, and illegal transfer or other malicious acts involving nuclear material and other radioactive substances and the associated facilities. IAEA security guides present international good practices and increasingly reflect best practices for achieving high levels of security. To inform its development of this RG, the NRC considered IAEA requirements and guides pursuant to the Commission’s International Policy Statement and Management Directive and Handbook 6.6, “Regulatory Guides.”

The following IAEA requirements and guides were considered in the development/update of this RG: [followed by a list of IAEA documents considered]

The “Documents Discussed in Staff Regulatory Guidance” section articulates the regulatory status of “secondary references,” that is, references in any of the codes or standards that the staff endorses in section C. In simple terms, this paragraph states that these secondary references are not enforceable, unless endorsed elsewhere by the NRC. If there are no codes or standards endorsed in section C, the RG should not include this section. Usually, the words for this section should be taken directly from the template and should be similar to the following:

This RG endorses [, in part,] the use of one or more codes or standards developed by external organizations, and other third-party guidance documents. These codes, standards, and third-party guidance documents may contain references to other codes, standards, or third-party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in an RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in an RG, then the secondary reference is neither a legally binding requirement nor a “generic” NRC-approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

If the body of the RG references a source document that is not from a U.S. Government agency, then the RG should state whether that document is endorsed by the NRC and, if so, should identify the NRC document that endorses it. If the document is currently not NRC endorsed, but it contains information that may be useful to the licensee or applicant using the RG, then the RG should add a disclaimer when referring to the source, stating that the RG is not endorsing that particular document. The following text contains an example of such a disclaimer:

IEEE Std. 946-2020, “IEEE Recommended Practice for the Design of DC Power Systems for Stationary Applications,” provides guidance on lead-acid and nickel-cadmium storage batteries, static battery chargers, and distribution equipment. The NRC staff has reviewed IEEE Std. 946-2020 and found that it contains additional technical information on emergency power furnished by batteries that licensees and applicants may find useful. However, the NRC staff does not endorse IEEE Std. 946-2020 in this revision of RG 5.44.

6.4.3. Section C, “Staff Regulatory Guidance”

It should be emphasized that any text that is not a position should be in section B, not in section C.

Section C describes in detail the methods, approaches, or data that the staff considers acceptable for meeting the requirements of the regulations cited in the introduction. This section should be clear and concise and should not include discussion. Above all, it should be absolutely clear that the methods, approaches, or data described in the staff positions are not requirements; the text should use “should” instead of “shall,” “will,” or “must,” unless directly citing the related regulatory requirements.

6.4.4. Section D, “Implementation”

Section D provides information to applicants and licensees regarding the NRC staff’s plan for using the RG and discusses the staff’s compliance with the applicable backfitting, forward fitting, and issue finality requirements and policies. Section D typically supports the staff’s determination that the staff’s implementation of the RG will not constitute backfitting or forward fitting or affect the issue finality of an approval issued under 10 CFR Part 52. The basis for this determination generally is that the NRC does not intend to impose the staff’s regulatory positions in the RG upon the applicable regulated entities.

The “Implementation” section should follow the examples provided in the templates (Package No. [ML20293A415](#)) depending on the subject matter of the RG.

6.4.5. References (Optional)

If references are used, they should follow the format shown in NUREG-1379, “NRC Editorial Style Guide.”

In accordance with the style guide, references to certain NRC regulatory guidance documents (e.g., RGs, standard review plans, ASME and IEEE codes incorporated into 10 CFR 50.55a) are not required to include dates, revision numbers, or ADAMS accession numbers. By not indicating a specific version, the staff intends to make the reference “dynamic,” meaning the user should refer to the latest version of the source material in order to use the most up to date guidance. If the staff intends the reference to be “static,” meaning that the user should refer to a specific version of the source material, then the reference should include the revision number and date.

Generally, references used in RGs should be available to the public. The source of each reference should be clearly identified. If the reference is not publicly available (e.g., if it is security related), then this should be indicated.

6.4.6. Glossary (Optional)

Because the agency uses many terms or phrases with specific, and not necessarily common, meanings, a glossary may be added to define such terms and phrases. This will be especially helpful for large guides. The glossary should follow the format in the DG template.

6.4.7. Abbreviations List (Optional)

If an RG contains many abbreviations, acronyms, or initialisms, the staff should consider including a list of such items.

6.4.8. Bibliography (Optional)

If the guide was developed using a number of documents that it does not reference, a bibliography may be included as an aid to the reader.

6.4.9. Appendices (Optional)

If the Discussion or Staff Regulatory Guidance section requires particularly detailed information, the TL and RG PM should consider relegating these details to separate appendices to increase the clarity and readability of the RG. Each appendix should be identified as being an extension of the Discussion or Staff Regulatory Guidance section and should be appropriately referenced in that section.

6.5. Instructions for Converting a DG to an RG

The RG PM and TL are responsible for converting a DG into an RG after the public comment period has closed.

The RG should be developed using the RG template. RGPMB maintains a sample template in ADAMS and updates it as needed.

6.6. Instructions for Writing a Federal Register Notice for a DG/RG

RGPMB has developed a template for FRNs. As noted in attachment 1, RGPMB maintains a sample template in ADAMS and updates it as needed.

The primary NRC contact for FRNs is the LRC in OGC. The LRC's role is as follows:

- The LRC provides a SharePoint site where users can enter specific information into an online application and obtain a draft FRN in the latest acceptable format. The RG PM is encouraged to use this resource whenever practical, as the FRN will then be consistent with established templates. The link to the FRN generator is <https://intranet.nrc.gov/ogc/32869> or <https://frn.nrc.gov/>.
- The LRC transmits proposed FRNs from the NRC to the Office of the *Federal Register*.
- The LRC provides a [SharePoint](#) site where users can track FRNs.

Once the DG or RG has been made publicly available, the RG specialist or the PM sends the FRN to the LRC, who reviews it, makes any corrections, and sends it by email to the RG BC for signature. The RG BC digitally signs the FRN and sends the signed version back to the LRC by email.

The LRC transmits the FRN to the Office of the *Federal Register*, who publishes the FRN within 2–3 working days.

The email address where the LRC receives FRNs is Notice_Publish.Resource@nrc.gov.

6.7. Instructions for Performing Periodic Reviews

The appropriate LTO is responsible for supplying a PR for each RG within the 10-year review period. Expectations associated with PRs are derived from SRM-SECY-12-0076, “Staff Requirements—SECY-12-0076—Plan for Retrospective Analysis of Existing Rules,” dated August 15, 2012 (Package No. [ML112970155](#)). The initial plan described the NRC’s longstanding and recent efforts to (1) identify, simplify, and update outdated regulations to make them more effective and less burdensome, and (2) incorporate risk assessments into regulatory decision-making. The Commission approved the staff’s plans, which included the PR of RGs because they are considered implementing guidance for agency regulations.

The SRM was based upon the following executive correspondence:

- Executive Order 13563 states, in part, the following:

[T]he agency will periodically review its existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.
- OMB Memorandum M-11-10, “Memorandum for the Heads of Executive Departments and Agencies, and of Independent Regulatory Agencies,” dated February 2, 2011, addressing Executive Order 13563 instructs agencies to conduct periodic, retrospective reviews and analyses of existing regulations with an eye toward determining which, if any, “may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them ... so as to make the agency’s regulatory program more effective and less burdensome in achieving regulatory objectives.”

The format for PRs is implemented through the use of templates, which can be obtained from ADAMS ([ML14303A139](#)) or by contacting the RG PM. The ADAMS package contains instructions (ML14302A412) as well as templates for the memorandum (ML14302A413) and evaluation (ML14302A414). The templates are guidelines; deviations from the templates should be discussed between the TL and the RG PM.

MD 6.6 establishes the requirement that the NRC review RGs periodically to evaluate their accuracy and continued applicability. At a minimum, the reviews need to be performed every 10 years, in accordance with Enclosure 1, “Longer-Term Efficiencies,” to SECY-16-0035, “Additional Re-baselining Products,” dated March 18, 2016 (Package No. [ML16077A184](#)), and as addressed by the related memorandum ([ML17047A723](#)). Every year, the RGPMB staff will identify the RGs for which 10-year PRs are due within the next 1–2 years, for all LTOs. However, in addition, RGs may be reviewed or re-evaluated at any time necessary using the PR process. For example, reviews may be needed because of changes in regulations, lessons learned, inspection results, changes in endorsed consensus codes, or revisions to standards developed by external organizations.

As stated above, RGs may be reviewed or re-evaluated at any time necessary. These reviews should be requested by TLs and their management and coordinated with the RG BC. RES-OI-PRM-001, “Process for Developing Work Requests and Coordination of Research Activities,” Revision 3, dated May 12, 2020 ([ML17040A032](#)), provides guidance on requesting RGPMB support for substantive technical reviews of RGs and for the technical development of RG revisions based on review findings.

6.7.1. Periodic Review Process

When a PR is to be performed, the RG BC will assign an RG PM to coordinate with the LTO, who will identify the branch that will support the PR. The LTO BC will designate a TL reviewer for the PR, and the RG PM will coordinate with the TL to arrange for a timely evaluation of the RG. In addition, the RG PM will provide the TL with a PR template, a PR memorandum template, and further guidance on best practices for performing a PR.

The TL conducting the PR will consider five questions to determine the current status of the RG:

- (1) the issues affecting the guide,
- (2) their significance,
- (3) the resources needed to address them,
- (4) the staff action needed,
- (5) a basic time frame for that action.

Based on the answers to these review questions, the TL BC should work with the TL to decide on the appropriate action to take and should discuss the action with their division director to gain alignment.

6.7.2. Review Decisions

There are four types of PR decisions:

- (1) reviewed with no issues identified,
- (2) reviewed with issues identified for future consideration,
- (3) revise based on issues identified,
- (4) withdraw based on issues identified.

The PR decision represents an agency decision on actions to take on an RG. Therefore, the TL should gain alignment on the decision within the LTO, up to the division director, before submitting the PR to RGPMB for review and publication. The LTO should consider the impact of the decision and gain alignment with other divisions and program offices that may have a significant stake in the RG (e.g., if the decision is to withdraw an RG that removes important guidance relied on by another division or program office). In addition, when performing a PR, the TL should consider and address the findings of previous PRs.

6.7.3. Periodic Review Submission Process

Before formally submitting a PR, the TL is encouraged to submit a draft PR for initial feedback from the RG PM and BC. The formal PR submission is made by a memorandum from the TL division director to the DE director. After the submission of the PR, the RG PM and BC will be part of the concurrence process, along with the TL, the TL BC, and their division director. To facilitate this process, the RG PM will work with the RG specialist to create the ADAMS files, obtain concurrences, and finalize the PR for publication on the existing public web page for the RG.

6.8. Instructions for Making Administrative Changes to RGs

Allowing administrative changes to RGs eases the burden of staff reviews for nonsubstantive matters and improves the workflow process.

An RG may be revised to make nonsubstantive changes (e.g., to correct typographical errors or change formatting) without going through the normal review process if the revision makes no substantive difference to the established staff positions in the guide.

Administrative changes are processed as follows: The RG revision is prepared by the TL or the RG PM. The appropriate BCs then review it to verify that the administrative changes have not resulted, directly or indirectly, in any substantive change to the staff regulatory guidance. After the RG is edited, OGC reviews it and provides an NLO determination. When the review is completed, the RG is issued as a final RG. The RA and FRN announcing the administrative change will include a summary of why the RG was issued as a direct-to-final RG, as well as instructions for submitting comments if desired.

6.9. Instructions for Writing Trial Use RGs (Pilot Use)

An RG may be issued for trial use to support new rulemaking actions or a new regulatory approach. Typically, a trial use RG does not establish the staff's position for the purposes of the backfitting rule and may continue to be revised in response to experience with its use. This will ensure that the final RG adequately addresses lessons learned from the regulatory review of pilot and follow-on applications, and that the guidance is sufficient to promote regulatory stability in the review, approval, and implementation of the proposed actions. The trial period should be limited, based on an achievable set of conditions. Once those conditions are achieved, the trial use RG will be reissued as a DG, and the process for final issuance of an RG will be followed. The process for preparation and issuance of trial use RGs is the same as for other RGs.

6.10. Instructions for Withdrawing an RG

RGs may be withdrawn when, for example, they no longer provide useful information, their guidance is superseded by changes in the regulations, or their guidance has been incorporated into a different guide.

Caution, as stated in MD 6.6, 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. New applications and applications for changes to existing licenses should use other regulatory guidance.

The process for withdrawing an RG is similar to the process for issuing a final RG. The withdrawal package is routed to the appropriate program offices, the ACRS, and OGC for review and concurrence before being announced in the *Federal Register*. The concurrence package needs to include responses to a set of standard questions that have been developed to explain the reason for withdrawing an RG.

The NRC website provides a link to the FRN announcing the withdrawal of the RG. The FRN explains to the public and stakeholders the staff's basis for withdrawing the RG. If an RG has been withdrawn and is not being replaced, then the FRN and the RG web page should indicate this and should explain the status of the withdrawn RG for existing licensees and users. If an RG has been withdrawn and will be replaced by either a newly created RG or a revision to an existing RG, then the FRN and the RG web page should (1) indicate that the RG is being withdrawn and provide a cross-reference to the replacement RG, and (2) explain the status of the withdrawn RG for existing licensees and users.

6.11. Instructions for Writing an RG Associated with Rulemaking Activities

As mentioned in section 5, in SRM-SECY-11-0032, the Commission directed several process enhancements to address the cumulative effects of regulation. Among these enhancements was the direction to publish draft guidance concurrently with proposed rules and to publish final guidance concurrently with final rules.

The Division of Rulemaking, Environmental, and Financial Support (REFS) in NMSS has policies and procedures for developing guidance associated with rulemaking. These policies and procedures are integrated with RGPMB procedures. The NMSS processes can be found in NMSS Policy and Procedures 6-10, "NMSS Procedures for Preparation and Review of Rulemaking Packages," Revision 4 issued March 29, 2021 ([ML20244A210](#)). Additional guidance for rulemaking processes is available on the REFS SharePoint site.

NMSS has established protocols for RG PMs for RGs supporting rulemaking efforts in the memorandum "Protocols for Regulatory Guide Project Managers for Rulemakings That Have Supporting Implementing Guidance," Revision 2, dated August 6, 2021 ([ML22042A416](#)).

RGs in support of a rulemaking should be prepared on the same schedule as the rulemaking. DGs and RGs in support of rulemaking should be scheduled for completion before the applicable draft or final rule is routed for internal reviews. This allows reviewers to verify that the guidance is consistent with the rest of the rule package. In all cases, the draft of the final guidance must be submitted with the rule, unless a waiver is obtained from the Office of the Executive Director for Operations. Details for this process are provided in NMSS Policy and Procedures 6-10.

6.12. Special Processes Supporting the Guidance Process

6.12.1. Determination of Whether Guidance Constitutes a Major or Non-major Rule under the Congressional Review Act

Before publication of an RG, the TL and the RG PM will work with NMSS/REFS/RASB to determine whether the RG constitutes a major rule under the CRA. This assessment will include any necessary review by the Office of Information and Regulatory Affairs within the OMB.

The CRA (5 U.S.C. 801–808) requires that Federal agencies, including independent regulatory agencies such as the NRC, submit copies of their "rules," and certain other information pertaining to each rule, to both houses of Congress and the Government Accountability Office

(GAO) before the rules can become effective. The term “rule” is broadly defined and can apply to NRC final rulemakings and to many other NRC final documents, including RGs.

To comply with the CRA’s requirements at 5 U.S.C. 801(a)(1)(A), final RGs that are determined to be rules under the CRA must be submitted to both houses of Congress and to the GAO (accompanied by three GAO-001 forms, which include the other information that the CRA requires agencies to provide in these submissions to Congress and GAO) before the RG can become effective. As a general matter, RGs are not expected to qualify as major rules under the CRA. If, however, an RG were determined to be a major rule under the CRA, that would require the NRC to delay the effective date of the RG for a minimum of 60 days after the copies of the RG and the GAO-001 forms are received by Congress.

6.12.2. Review of Guides Incorporating Controlled Unclassified Information, Sensitive Unclassified Nonsafeguards Information, Safeguards or Classified Information

The program office TL is responsible for performing reviews related to controlled unclassified information (CUI), sensitive unclassified nonsafeguards information (SUNSI), safeguards information, and classified information, consistent with the scope of work performed. The TL should maintain awareness of all CUI/SUNSI and classified information associated with the DG. The RG PM will ensure that a CUI/SUNSI review is completed and documented before transmitting the DG or RG for concurrence. A CUI/SUNSI review should be performed in accordance with MD 3.4, “Release of Information to the Public,” before preliminary guidance is released to the public or published in the *Federal Register*.

Requests to obtain sensitive documents should be directed to the Public Document Room staff at <http://www.nrc.gov/reading-rm/contact-pdr.html>. Requests from international partners should be directed to the NRC Office of International Programs at <http://www.nrc.gov/about-nrc/ip/contact-ip.html>. Requests for classified documents should be directed to the TL.

Unless the guide contains proprietary, Official Use Only, safeguards, or classified information, new and proposed revisions to every RG should be issued to the general public in the form of a DG to allow an opportunity for public comment.

Independent review of DGs allows individuals other than the authors to review, comment on, and concur (when appropriate) on the documents before they are finalized. When guides containing proprietary, Official Use Only, safeguards, or classified information are sent out for comment, they are controlled by the regulatory office to ensure that only personnel with a need to know are given the opportunity to review them. Such documents may be sent to stakeholders once the lead technical branch and the ADM, Division of Facilities and Security, Personnel Security Branch, have verified their need to know and access authorization or security clearance, as applicable. Additional information can be found at http://www.internal.nrc.gov/ADM/security/pers_sec/personnelmain.html and <https://drupal.nrc.gov/ocio/catalog/61197>.

6.12.3. Technical Editing

Prior to submitting a DG or a substantively revised RG to the RG PM for concurrence routing, the TL submits the document for technical editing. The TL normally arranges for this review at the point of development when the TL and the RG PM are unlikely to make any further

substantive changes to the DG or RG. Technical editing fees are usually the burden of the office developing the guidance.

6.12.4. Contractor Support in the Development of Guidance

If a contractor prepares a technical basis document, the TL is responsible for revising and reviewing the monthly letter status reports, approving payment vouchers, and using the technical basis to develop a DG. The TL should interact with the RG PM as required to facilitate contract verification.

6.12.5. Release of Draft Guidance to Public

As mentioned in section 5, in SRM-SECY-11-0032, the Commission directed several process enhancements to address the cumulative effects of regulation. Among these enhancements was the direction to publish draft guidance concurrently with proposed rules and to publish final guidance concurrently with final rules. In the spirit of issuance of guidance documents for public comment, the NRC issues new and revisions to existing RGs as DGs for public information and an opportunity for public comments.

DGs are announced as publicly available for comment through an FRN.

A DG or RG will not normally be released to the public until the required approvals are completed. However, if advance discussion would facilitate the development of the DG or RG (e.g., by the ACRS or in another meeting open to the public), further public understanding of the related rulemaking, or allow for affected licensees to plan in advance for implementation, then the staff can make the preliminary draft document publicly available after consultation with the technical offices involved and with RGPMB and OGC.

It is not necessary to include "Pre-decisional" watermarks on working copies of a DG, or on a DG that is being routed internally to the NRC for concurrence. The same applies to all other internally routed documents that will eventually become publicly available (e.g., memoranda, SECY papers, management directives).

When a DG is made publicly available for advance discussion (e.g., for an ACRS meeting), the ADAMS version that is publicly available should include a "Pre-decisional" watermark to indicate that the guidance is not final. The staff should remove the watermark when preparing the guide for publication in the *Federal Register* as a DG for comment or as a final RG for use.

It is the responsibility of the office releasing the preliminary or draft guidance to perform a CUI/SUNSI review before making the document public. These reviews are performed in accordance with the guidance in MD 12.6, "NRC Sensitive Unclassified Information Security Program."

6.12.6. Public and Internal Comment Resolution Documentation

RGPMB maintains templates in ADAMS that provide recommended formats to aid in the development of comment resolution documents ([ML14302A388](#) or [ML15264A835](#)). The RG PM should consult with the assigned attorney to determine which format would be more appropriate

to use. MD 6.6 states that the RG PM and TL will compile summaries of the public comments. These summaries can be used in either format.

The TL has the primary responsibility for completing the comment resolution document.

6.13. Committee Reviews and Approvals

The concurrence process can be completed by paper copy, email, or e-concurrence through the following link: <https://adamsicm.nrc.gov/ccr/>. E-concurrence is now the preferred method.

DGs and RGs should receive internal review and concurrence before being released to the public. Specifically, DGs should be routed to the appropriate program offices, advisory committees, and OCIO for concurrence and to OGC for NLO determination, then issued for public comment. The TL provides the proposed list of concurrences in the program offices for DGs.

In some cases, the program office may send the DG to regional offices or Agreement State representatives, or both, for their review and comment. When sending DGs and similar documents by email for review and comment, the sender should put "ACTION REQUESTED" or similar wording in the email header to alert the receiver that the email may require action on their part.

RGs dealing with the medical uses of radioactive material in diagnosis and therapy should be reviewed by the ACMUI in lieu of the ACRS. The TL and NMSS should request a review by ACMUI as necessary.

For RGs that may require consultation with or outreach to States or Tribes (e.g., RGs related to siting, environmental reports, and emergency planning), the TL, in consultation with the RG PM, will determine whether the RG is likely to affect or be of interest to States or Tribes and will coordinate with NMSS as appropriate.

Availability of the DGs should be announced in the *Federal Register* for public comment. If the DGs contain CUI/SUNSI, safeguards information, or classified information, then stakeholders with appropriate clearance and need to know may contact the NRC for access to the DGs. RES has delegated authority to the RGPMB branch chief to sign out FRNs. If a DG undergoes substantive revision in response to public comments, then the final guide should be routed to the same offices and committees that reviewed the DG.

After the public comments are resolved, the documents are again routed to the appropriate program offices, advisory committees, and OCIO for concurrence and to OGC for NLO determination. Upon concurrence, the NRC issues the final RG(s). The specific routing of a final RG depends on the changes made to the guide in response to the public comments. However, the final RG should be routed to the same program offices as the DG.

If the DG remains substantively unchanged after the comment period, then the final RG does not require a second review by the program offices; it should be sent only to the ACRS, OCIO, and OGC for review before being issued for use. The TL is responsible for determining whether the revisions are substantive.

Office concurrence means the following:

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

6.13.1. Reviews by the Advisory Committee on Reactor Safeguards

Note: The ACMUI typically reviews DGs and RGs related to radiological health and safety.

The TL prepares all presentation materials, provides them to the RGPMB, and makes the presentation to the ACRS. The RG PMs provides coordination with the appropriate ACRS PMs and committees, as needed.

The ACRS has the option of reviewing each DG and RG. The RG PM offers the ACRS the opportunity to review the DG before issuance for public comment and again after all of the public comments have been addressed and the final RG is ready for publication. The ACRS has adopted internal procedures stating that in general, the ACRS need not review DGs before they are issued for public comment unless the DGs are new guides or support a proposed rule. The ACRS chooses the most significant guides to review before their publication as final RGs.

RGs related to physical security are typically exempt from ACRS review. Further information is available in the memorandum “Procedure for ACRS Review of Regulatory Guides,” dated August 10, 2011 ([ML11216A100](#)), and the memorandum of understanding “Advisory Committee on Reactor Safeguards Review of U.S. Nuclear Regulatory Commission Technical Matters,” dated March 31, 2021 ([ML21025A349](#)).

6.13.2. Committee to Review Generic Requirements—Backfitting, Forward Fitting, and Issue Finality Reviews

The CRGR does not typically review DGs or RGs. Nevertheless, the staff should be diligent in recognizing that backfitting, forward fitting, and issue finality concerns may be raised during staff or stakeholder review. When those concerns are raised, the RG PM should consult with the NRC’s Backfitting Community of Practice to determine the legitimacy of the concerns. The RG PM also may need to engage the CRGR. The CRGR Charter provides the following regarding when to engage the CRGR:

The 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.

6.13.3. Office of the General Counsel

OGC reviews the documents and provides an NLO determination. An NLO determination is a finding by OGC 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.

The TL must consult with the NRC's OGC to ensure that the requirements of the CRA are followed. OGC's CRA review is conducted as part of its NLO review of a final RG. OGC is responsible for determining whether an RG qualifies as a "rule" under the CRA's broad statutory definition. If OGC has determined that an RG, or RG revision, is a rule under the CRA, the TL would coordinate with NMSS/REFS/RASB regarding whether the RG is also a major rule under the CRA. See section 6.12.1 for more information.

In addition, OGC verifies that the implementation section appropriately describes how the NRC staff will comply with applicable backfitting and issue finality provisions in the *Code of Federal Regulations* and the Commission's forward fitting policy in MD 8.4.

6.14. Schedules for Tracking RGs

RGPMB has created scheduling templates to capture important milestones in the RG process, specifically where the responsibility for completing the next milestone changes hands. RGPMB has created schedules for completing the RG process within 6 months, 9 months, and 11 months. RG PMs are responsible for creating, updating, and posting in SharePoint the schedules for new and revised RGs, except for RGs associated with rulemaking, which follow the rulemaking schedule.

The first milestone is the date on which a complete draft of the DG is submitted to RGPMB by the TL after being reviewed and approved by the TL's management. The RG PM uses this date to initiate the scheduling process and develops an appropriate schedule based on input from the TL. The RG PM distributes the schedule to the lead program office, OGC, and the ACRS (or other appropriate review committee). Using the initial submittal date, the SharePoint software schedules follow-on dates for the important milestones and expected completion of the RG process.

As the DG/RG continues through the RG process, the RG PM updates SharePoint with actual completion dates for each important milestone and enters the completion date when the final RG is issued.

Appendix 1 explains where to find templates for the 6-month, 9-month, and 11-month schedules.

6.15. Authorization, Printing, and Distribution

RGPMB maintains in ADAMS the record copies of each RA, DG, public comment resolution document, FRN, and RG in the appropriate package, and also as standalone documents where appropriate. The final RAs, DGs, public comment resolution documents, and RGs are generally classified as publicly available in ADAMS, unless they are security related. RGs that contain safeguards information are maintained on the SLES network. RGPMB maintains associated links to the DG and RG on the NRC public website under "Document Collections."

RGPMB maintains templates in ADAMS for the development of documents associated with DGs/RGs for all NRC users.

RGPMB transmits a package to the Office of Congressional Affairs, which provides appropriate copies to Congress to meet the requirements of the CRA.

For each DG/RG, RGPMB prepares a concurrence package for signature by the DE director and for follow-on concurrence by the division directors of any required program offices, as well as OCIO and OGC. Issuance of the final RG does not require subsequent concurrence from the program offices after the public comment period unless the DG has undergone substantive changes as a result of input received during the comment period.

7. PERFORMANCE MEASURES

RGPMB monitors existing processes to manage performance measures for RGs. The RG SharePoint site has an RG Dashboard that provides data used for performance monitoring, including the following:

- The RG Dashboard's schedule tracker tab measures the time remaining to complete the revision or issuance of an RG. The schedule tracker can monitor individual milestones in the process to identify milestones those that are taking more time than scheduled and are slowing down the process.
- The RG Dashboard provides data on the number of DGs and RGs that are in progress and completed.
- The RG Dashboard provides data on completed PRs, PRs that are overdue, and PRs that will be due within the next few months.

As directed by [RES-OI-PRM-008](#), "RES operating Plan (OpPlan)," RGPMB should enter activities for the RG process into the RES Operating Plan, as appropriate, to monitor significant activities and identify areas for improvement.

8. REFERENCES

Code of Federal Regulations

Available at <https://www.govinfo.gov/help/cfr>.

- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, “Backfitting.”
- 10 CFR 70.76, “Backfitting.”
- 10 CFR 72.62, “Backfitting.”
- 10 CFR 76.76, “Backfitting.”

Executive Orders

- Executive Order (EO) 12889, “Implementation of the North American Free Trade Agreement,” December 28, 1993:
<https://www.archives.gov/files/federal-register/executive-orders/pdf/12889.pdf>.
- EO 13563, “Improving Regulation and Regulatory Review,” January 18, 2011 (76 FR 3821; January 21, 2011):
<https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>.
- EO 13579, “Regulation and Independent Regulatory Agencies,” July 11, 2011 (76 FR 41587; July 14, 2011):
<https://obamawhitehouse.archives.gov/the-press-office/2011/07/11/executive-order-13579-regulation-and-independent-regulatory-agencies>.
- EO 13610, “Identifying and Reducing Regulatory Burdens,” May 10, 2012:
<https://www.whitehouse.gov/omb/information-regulatory-affairs/regulatory-matters>.

Management Directives

Available at <https://www.nrc.gov/reading-rm/doc-collections/management-directives/index.html>.

- Management Directive (MD) 1.1, “NRC Management Directives System.”
- MD 3.4, “Release of Information to the Public.”
- 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 6.5, “NRC Participation in the Development and Use of Consensus Standards.”
- MD 6.6, “Regulatory Guides.”
- MD 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.”

- MD 12.2, “NRC Classified Information Security Program.”
- MD 12.6, “NRC Controlled Unclassified Information (CUI) Program.”
- MD 12.7, “NRC Safeguards Information Security Program.”

NRC Documents

- Congressional Review Act SharePoint site (not publicly available): <https://usnrc.SharePoint.com/teams/NMSS-Congressional-Review-Act>.
- Office of Nuclear Material Safety and Safeguards (NMSS) Policy and Procedures 6-10, “NMSS Procedures for Preparation and Review of Rulemaking Packages,” March 2021 ([ML20244A210](#)), not publicly available.
- NMSS protocol, “Protocols for Regulatory Guide Project Managers for Rulemakings That Have Supporting Implementing Guidance,” Revision 2 , dated August 6, 2019 ([ML22042A416](#)).
- SRM-SECY-11-0032, “Staff Requirements—SECY-11-0032—Consideration of the Cumulative Effects of Regulation in the Rulemaking Process,” October 11, 2011 ([ML112840466](#)).
- “Identifying the Effects of Commission Direction on Preparing Guidance Documents and Recommending Best Practices for Publication of Guidance Documents,” August 14, 2012 ([ML12227A355](#)), not publicly available.
- J.E. Lyons, memorandum to J. L. Uhle, “Request to Waive CRGR Review of Regulatory Guides,” August 18, 2008 ([ML082250687](#)), not publicly available.
- R. Furstenau, memorandum to M. Sampson, “Using a Qualitative Approach for Performing Regulatory Analysis for Non-rulemaking Regulatory Guides,” May 5, 2023 ([ML23033A392](#)), not publicly available.
- “Charter, Committee to Review Generic Requirements,” Revision 9, June 2018 ([ML17355A532](#)); <https://www.nrc.gov/about-nrc/regulatory/crgr.html>.
- NUREG/BR-0053, “United States Nuclear Regulatory Commission Regulations Handbook,” Revision 6, September 2005 ([ML052720461](#)). (has been discontinued)
- NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Final Report” ([ML19261A278](#)).
- NUREG-1379, Revision 3, “NRC Editorial Style Guide,” April 2022 ([ML22115A119](#)).
- NUREG-1409, “Backfitting Guidelines,” Revision 1, March 2021 ([ML21006A433](#)).
- SECY-12-0076, “Plan for Retrospective Analysis of Existing Rules,” August 15, 2012 ([ML122280346](#)).

- Office of Nuclear Regulatory Research (RES) Office Instruction PRM-001, “Process for Developing Work Requests and Coordination of Research Activities,” Revision 3, May 12, 2020 ([ML17040A032](#)), not publicly available.
- RES Office Instruction PRM-008, “RES Operation Plan (OpPlan),” Revision 3, May 19, 2020 ([ML102790457](#)), not publicly available.
- RES Office Instruction TEC-004, “Regulatory Guide Review, Development, Revision, and Withdrawal Process,” Revision 0, May 10, 2013 ([ML101750587](#)).
- RES Office Instruction, RES OI ADM 001, “Preparing and Maintaining RES Office Instructions,” April 17, 2023 ([ML15217A296](#)), not publicly available.
- SECY-R-577, “Regulatory Guides,” November 20, 1972 (Package No. [ML21341A024](#)), not publicly available.
- SRM-SECY-12-0076, “Staff Requirements—SECY-12-00796—Plan for Retrospective Analysis of Existing Rules,” August 15, 2012 ([ML112970155](#)).
- internal NRC regulatory guide website:
<https://usnrc.sharepoint.com/teams/RES-RGPMB>.
- external NRC regulatory guide website:
<https://www.nrc.gov/reading-rm/doc-collections/reg-guides/>.
- controlled unclassified information (CUI) policies and procedures:
<https://drupal.nrc.gov/cui>.
- Congressional Review Act Sharepoint site:
<https://usnrc.sharepoint.com/SitePages/Congressional-Review-Act.aspx>

Federal Register

- “Notice of Development of New Guide Series,” December 27, 1972 ([37 FR 28544](#)).
- “Notice of Early Comment Period for Regulatory Guides,” June 12, 1974 ([39 FR 20628](#)).
- “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,’” January 27, 2016 ([81 FR 4673](#)).
- “Nuclear Regulatory Commission International Policy Statement,” July 10, 2014 (79 FR 39415) ([ML14132A317](#)).
- “Tribal Policy Statement,” January 9, 2017 ([82 FR 2402](#)).

United States Code

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

- Paperwork Reduction Act of 1995 ([44 U.S.C. 3501 et seq.](#)).
- National Technology Transfer and Advancement Act of 1995 ([15 U.S.C. 272](#)).
- Congressional Review Act of 1996 ([5 U.S.C. 801–808](#)).

Other Documents

- IAEA-NS-IRRS-2010/02, “Final IRRS Mission Report to the United States of America,” March 1, 2011 ([ML110630400](#)).
- Office of Management and Budget (OMB) M-19-14, “Memorandum for the Heads of Executive Departments and Agencies, Guidance on Compliance with the Congressional Review Act” Executive Office of the President, April 11, 2019:
- OMB Memorandum M-11-10, “Memorandum for the Heads of Executive Departments and Agencies, and of Independent Regulatory Agencies,” February 2, 2011, https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2011/m11-10.pdf.
- National Technology Transfer and Advancement Act of 1995 (NTTAA) ([5 U.S.C. 801–808](#)).
- OMB Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” January 27, 2016 ([81 FR 4673](#)).

Attachment 1: Templates

- Up-to-date templates related to regulatory guides (RGs) and draft regulatory guides (DGs) can be found in the Agencywide Documents Access and Management System (ADAMS) in the folder “RES/Regulatory Guides/Templates/New Templates.” The Regulatory Guide and Programs Management Branch maintains an internal agency [SharePoint page](#) with links to the associated documents in ADAMS.
- Discontinuance of RGs Template ML16061A458 (package)
- Draft RG Documents ML140303A137 (package)
- Executive Director for Operations (EDO) Note Templates
 - DG EDO Daily Note ML21081A311
 - RG EDO Daily Note ML21081A310
- *Federal Register* Notice—All Templates
 - Administrative Change ML15133A194
 - DG Discontinuance ML16078A252
 - DG Nonrulemaking ML22272A504
 - Public Meeting ML14302A252
 - Requesting Extension of Comment Period ML14302A255
 - RG Template ML14302A394
 - Template for RG Final (OUO-SRI, SGI) ML17111A647
 - Withdrawal ML14302A407
- Implementation Section ML20293A415 (package)
- Periodic Review Instructions and Templates ML14303A139 (package)
- Public Comment Tables
 - Alternative Public Comment Resolution Table ML15264A835
 - Public Comment Template (Abbreviated Table) ML14302A388
- Regulatory Analysis Template ML14302A258
- Regulatory Guide Documents (for a New or Revised Guide) (package) ML14303A142
- Schedule Templates
 - RG 11-Month Implementation Schedule ML22227A169
 - RG 9-Month Implementation Schedule ML22227A170
 - RG 6-Month Implementation Schedule ML22227A171
- Withdrawal Package Documents
 - One-Pager for Withdrawal of Regulatory Guides ML14240A599
 - Withdrawal Package Template ML14303A204 (package)

Nonrulemaking Regulatory Guide Process

Regulatory Guide Development Process

