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

MD 6.6	REGULATORY GUIDES	DT-16-16
Volume 6:	Internal Management	
Approved by:	Michael Weber, Director Office of Nuclear Regulatory Research	
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Issuing Office:	Office of Nuclear Regulatory Research Division of Engineering	
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EXECUTIVE SUMMARY

Management Directive 6.6, "Regulatory Guides," is recertified as accurate and up to date and is being republished as part of the NRC Plan to Update Management Directives. This revision reflects organizational changes and minor editorial changes.

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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 that—

- Activities are undertaken in an open and transparent manner.
- Staff decisions are sound and consider the need for and impact of proposed actions.
- Regulatory guidance will be provided to identify acceptable methods for applicants and licensees to meet applicable laws and regulations, when needed.

II. OBJECTIVES

- Identify a consistent process for the development and processing of regulatory guides (RGs) and ensure statutory requirements are met.
- Ensure the efficient use of staff resources in developing guidance to applicants and licensees.
- Ensure coordination among offices during the development of guidance.
- Ensure that stakeholders (e.g., licensees, applicants, and members of the public and Agreement States) and individuals and offices within NRC all 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.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Office of Nuclear Regulatory Research (RES)

1. Has overall responsibility to promulgate DGs and RGs. Coordinates with other NRC offices to prioritize DG and RG development and identify lead office and technical reviewers. Provides development tools, such as templates, for consistency.
2. Manages the DG and RG concurrence process in accordance with the procedures of Directive Handbook 6.6.
3. Develops DGs and RGs, when appropriate, based on technical expertise.
4. Reviews DGs and RGs developed within RES as well as other NRC offices for policy considerations, technical correctness, consistency, and format. Provides comments to the lead technical reviewer (LTR).
5. Coordinates with the LTR and others to facilitate the contract management process when developing DGs and RGs needing contractor support.
6. Edits DGs and RGs, prepares *Federal Register* notices, and after authorization to do so, arranges for DGs and RGs to be issued.

B. Office of Nuclear Reactor Regulation (NRR), Office of New Reactors (NRO), Office of Nuclear Material Safety and Safeguards (NMSS), and Office of Nuclear Security and Incident Response (NSIR)

1. Develop DGs and RGs in accordance with the policy and process described in Management Directive (MD) 6.6 to provide guidance to licensees and applicants on methods that are acceptable to the NRC staff in meeting its regulations.
2. Ensure that an LTR is assigned to develop regulatory guidance, coordinate with interested parties in the agency, and provide schedule feedback when designated as the lead office.
3. Ensure that the RGs comply with 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. Refer to MD 8.4, "Management of Facility-specific Backfitting and Information Collection," and the Committee to Review Generic Requirements (CRGR) Charter.
4. Cooperate and coordinate with other NRC offices, as appropriate, in developing guidance.
5. Review DGs and RGs developed by other NRC offices, as appropriate, for technical correctness and provide comments to the project manager.
6. Responsible for the control of Sensitive Unclassified Non-Safeguards Information (SUNSI), Safeguards Information, or Classified Information consistent with the scope of work performed.

C. Office of the General Counsel (OGC)

1. Reviews DGs and RGs to ensure they are consistent with applicable law, including current NRC regulations.
2. Determines that no legal objections exist to issuing a DG or RG.

D. Office of the Chief Information Officer (OCIO)

1. Approves or disapproves proposed information collections for submittal to the Office of Management and Budget (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 and oversight to ensure the NRC complies with best practices and applicable laws and regulations. These laws include but are not limited to the Government Paperwork Elimination Act (GPEA) (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.

E. Advisory Committees

The Advisory Committee on Reactor Safeguards (ACRS), the Advisory Committee on the Medical Uses of Isotopes (ACMUI), and the CRGR review and provide comments or recommendations for a DG, as appropriate. ACRS has the option of reviewing each DG and RG. ACMUI typically reviews DGs and RGs related to radiological health and safety. CRGR does not typically review DGs or RGs but should be consulted regarding any perceived backfitting issues.

IV. APPLICABILITY

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

V. DIRECTIVE HANDBOOK

Directive Handbook 6.6 describes the requirements and NRC's basic internal procedures for issuing DGs and RGs.

VI. REFERENCES

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

E.O. 12889, "Implementation of the North American Free Trade Agreement," dated December 28, 1993.

E.O. 13563, "Improving Regulation and Regulatory Review," dated January 18, 2011.

Nuclear Regulatory Commission Documents

Committee to Review Generic Requirements Charter (http://www.nrc.gov/about-nrc/regulatory/crgr.html).

Management Directives—

1.1, "NRC Management Directives System."

3.5, "Attendance at NRC Staff-Sponsored Meetings."

6.3, "The Rulemaking Process."

8.4, "Management of Facility-specific Backfitting and Information Collection."

Memorandum to J. L. Uhle from J. E. Lyons, Subject: Request to Waive CRGR Review of Regulatory Guides, dated August 18, 2008 (ML082250687).

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," June 21, 2004.

NUREG-1379, Revision 2, "NRC Editorial Style Guide," May 2009.

RES Office Instruction, TEC-004, "Regulatory Guide Review, Development, Revision, and Withdrawal Process," available at http://fusion.nrc.gov/res/team/pmda/Lists/OI%20Listing/AllItems.aspx.

SECY-R-577, "Regulatory Guides," November 20, 1972.

Internal NRC Regulatory Guide Web Site: http://fusion.nrc.gov/res/team/de/rgdb/default.aspx.

Federal Register

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

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

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).

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I. INTRODUCTION

A. Procedures for the Regulatory Guides

1. This handbook outlines the process the U.S. Nuclear Regulatory Commission staff will follow when developing and issuing regulatory guides (RGs).

2. RGs are documents in which the NRC staff describes an acceptable method for meeting specific provisions of the NRC's regulations, techniques used by the staff for evaluating specific problems or postulated accidents, or data needed by the staff for reviewing applications for permits and licenses. They are also used to endorse standards where appropriate.

3. 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 drafts are issued as final (or effective) RGs. Both the request for public comment on the DG and the issuance of the RG are made by notice published in the *Federal Register*. A small number of RGs are not publicly available due to inclusion of Sensitive Unclassified Non-Safeguards Information (SUNSI), Safeguards Information, or Classified Information. These RGs are processed accordingly with controlled distribution to cleared stakeholders for DGs and cleared recipients for users of the final RGs. Whenever possible, a redacted version of the RG is provided to the public for those RGs that include sensitive information.

4. "Trial Use" RGs are intended to allow early use on a pilot basis to gather experience and feedback prior to general implementation.

5. "Administratively Changed" RGs are those issued as revisions but, having no substantive difference in the established staff position, 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 of review and its issuance is made by notice published in the *Federal Register*.

6. RGs are issued in the following 10 broad 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, and (10) general.

B. Usage of the Regulatory Guides

1. RGs do not impose requirements. The methods, techniques, or data described in an RG are acceptable to the NRC staff for meeting NRC regulations. However, applicants or licensees may use alternatives as long as sufficient information is provided that demonstrates the requirements in NRC's regulations are satisfied. Using the methods, techniques, or data described in an RG relieves the applicant or licensee of this burden.

2. The use of RGs by applicants and licensees also conserves staff resources and simplifies licensing because the methods, techniques, and requested data described in RGs are known to meet the stated regulations.

II. REGULATORY GUIDE FORMAT

A. Required Sections

Each RG deals with a specific, limited topic and is divided into the sections listed below. The RG specialist (RGS) or the Office of Nuclear Regulatory Research (RES) Project Manager (PM) will provide a template for standardization and consistency.

1. Introduction

   This section states the purpose of the RG and identifies the specific regulations to which the RG is directed or related. This section also includes the relevant Office of Management and Budget (OMB) statement on information collections and the appropriate OMB clearance numbers.

2. Discussion

   This section 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. Appendices are used to provide detailed information, if needed. The discussion section may contain an analysis or may discuss the technical methods. In a DG, comments may be requested on specific aspects of the proposed guidance.

3. Staff Regulatory Guidance

   This section of the RG contains the methods, techniques, or data that are acceptable to the staff for meeting the regulations cited in the introduction. Staff positions described in this section must be clear and concise with little accompanying discussion. The methods, techniques, or data described in the staff regulatory guidance section are methods acceptable to the staff, not requirements. The requirements are contained in the Commission's regulations. Licensees may propose methods different from the stated staff position if they can justify that they meet the pertinent regulations. As a result, the word "should" is generally appropriate for use in this section. "Shall" (or "must") will be used only in an attributed quotation or direct reference to a regulation. Staff positions in this section should be clearly identified in consecutively numbered, organized paragraphs. New or changed staff positions in the staff regulatory guidance section are addressed in the implementation section.

4. Implementation

   (a) This section describes the staff's plan and the potential licensee application of the RG. The licensee submittals to be reviewed against the RG are specified, as appropriate. If a date or schedule is specified in the regulations for compliance with a staff position cited in the RG, the date or schedule should be included in the implementation section.

   (b) Since the staff positions in RGs do not constitute requirements, a backfit is not imposed simply by issuing an updated RG. However, in some revisions, the staff position is presenting information in a new or different fashion from the previously applicable staff position. In these cases, the difference between the current staff position and the proposed staff position (or the newly written staff position) should be considered and the rationale for consideration of the backfit rule should be summarized. For example, a change is not considered a backfit if it is intended to be applied to future applicants or to license amendments that are voluntarily submitted by licensees. When a staff position is revised in an RG, the staff's acceptance of licensee compliance with the regulations remains valid as documented in the licensing basis. However, the staff position in the revised RG will be used in evaluating compliance with the applicable regulations for license applications or license amendment requests unless applicants or licensees propose alternatives. Relaxations of staff positions are not considered backfits if the implementation of the relaxation is voluntary (Management Directive (MD) 8.4, "Management of Facility-specific Backfitting and Information Collection"). Administrative, recordkeeping, reporting, and statutory changes are not considered backfits.

(c) Occasionally, new or different requirements are promulgated in rulemaking and implemented using an RG to describe methods acceptable to the staff. In these cases, the implementation section will summarize the analysis of the backfit from the rulemaking package, or provide the link or reference, where the analysis may be found. The staff is expected to be diligent in recognizing backfit concerns raised during the review and comment period. If a legitimate backfit concern is raised, the Committee to Review Generic Requirements (CRGR) should be engaged.

B. Regulatory Analyses

1. Regulatory analyses explain the basis for the agency's decisions and show that a systematic process is being followed. DGs should be supported by a regulatory analysis to support openness and transparency. If an existing analysis was prepared for a previous version of the RG (or was prepared for a related rule that is still valid and includes consideration of the impacts associated with the DG), a new, separate analysis is not needed. In such cases, the existing regulatory analysis is referenced.

2. A brief summary of any changes made as a result of public comment or final review that may have affected the regulatory analysis or backfit considerations discussed in the DG should be included for the final RG. Often a brief statement can be used, such as "None of the changes made between the DG and the RG affected the conclusion of the regulatory analysis or backfit considerations." This statement should be included in the implementation section and/or in the *Federal Register* notice (FRN) of availability for the RG. Likewise, an ACG should provide a brief explanation of the rationale for issuing a revision having only nonsubstantive changes in the implementation section or in the FRN.

3. The regulatory analysis is identified for the reader and can be located by reference to its Agencywide Documents Access and Management System (ADAMS) accession number in the footnote on the cover page of the DG and the RG.

C. References, Bibliography, and Glossary

RGs should be supported by references, bibliography, and glossary information, as appropriate. References should be used only when they are available to the public.

D. Appendices

The information provided in an RG can be supported by an appendix or attachment, where useful, to convey information in an efficient manner. Tabular data are normally provided in an appendix. To facilitate the staff regulatory guidance section 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

within 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

Key points in the development and revision process for an RG are described in the following sections. Detailed instructions for processing an RG are found in RES Office Instruction TEC-004, "Regulatory Guide Review, Development, Revision, and Withdrawal Process."

A. Need for Guidance Identified

The need for a new RG or revision, or withdrawal of an existing RG, is usually identified by one of the technical offices or is necessary as a part of a periodic update process. RGs may be needed to (1) support a new regulation or rulemaking, (2) incorporate advances in technology or operating experience, (3) incorporate staff positions from generic communications or licensing reviews, or (4) endorse new, revised, or reaffirmed domestic and international standards.

B. Trial Use Guides (Pilot Use)

The issuance of an RG for use on a pilot basis may be performed to support new rulemaking actions. Typically, a trial use RG does not establish the staff's position for purposes of the backfitting rule. The use of an RG in this category is intended to enhance regulatory stability in the review, approval, and implementation of the proposed actions. The process for preparation and issuance of a trial use RG is the same as other RGs.

C. Harmonization to International Standards

Endorsement of international standards is an important element in providing harmonization of 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 and/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 also 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 where the staff could explain how the RG meets the intent of the international standard.

D. Periodic Update Process

The RES Regulatory Guidance and Generic Issues Branch (RGGIB) will work with program offices periodically to evaluate whether a revision should be pursued or if the guidance should be withdrawn. The review should support considerations required by Executive Order 13563, "Improving Regulation and Regulatory Review." RGs will typically be evaluated every 5 years. The RGGIB PM alerts the lead technical branch when an evaluation is due. The lead technical branch will then review the RG to determine if the guidance is current or if a revision is needed. If a revision is not needed or a withdrawal is not recommended, a memorandum or e-mail (entered into ADAMS) from the reviewing organization(s) is sufficient for RES to update the database with the recommendation. If the lead technical branch determines that a revision to the RG is appropriate, the lead technical branch prepares a DG. If the revision will have no substantive changes and no change to the staff regulatory guidance section, the revision is processed as an ACG. The review of the DG and issuance of an ACG should be identified on the internal NRC Regulatory Guide Web site to communicate the ongoing availability of the RG to stakeholders (http://fusion.nrc.gov/res/team/de/rgdb/default.aspx). If withdrawal is recommended, the process simply requires notice in the *Federal Register* of the action. A withdrawal does not change licensee commitments to the document. The notice announces that the withdrawn RG will not be available for use in the future. The Web site will identify current RG status.

E. Development of the Draft Guide (DG)

1. The Lead Technical Reviewer (LTR) is responsible for performing necessary research to develop the guidance: writing the DG and the RG, writing or identifying the associated regulatory analysis, and obtaining the appropriate level of agreement needed to support issuance of the RG. The LTR should determine if any domestic or international standards exist that can be used in support of the RG, and ensure the staff's position on any standard is fully understood and factored into the staff's regulatory guidance. RGs in support of new rulemakings should be prepared on the same schedule as the rulemaking. RG revisions or RGs in support of existing rules should be scheduled for completion within 2 years. This 2-year timeframe applies whether it is a proposed revision of an existing RG or a new RG. The RG will normally be issued as a DG to allow for public comment. For DGs, public comments are requested by a specific date, which is stated on the DG and in the published FRN. The comment period is typically 60 days. However, the comment period may be shortened or lengthened when justified. If the DG is determined to be a technical regulation in accordance with E.O. 12889 (which implements the North American Free Trade Agreement), then a 75-day comment period is required. In addition to meeting the 75-day comment period, if required by E.O. 12889, the comment period for a DG should conform to the comment period of any related rulemakings or other actions.

2. The LTR must consult with the NRC's Office of the General Counsel (OGC) to ensure that the requirements of the Congressional Review Act (CRA) are followed. OGC's CRA review is conducted as part of OGC's overall legal sufficiency review (i.e., during the no legal objection (NLO) review). The CRA requires that Federal agencies, including independent regulatory agencies such as the NRC, submit their proposed rules to both houses of Congress for review. The term "rule" is broadly defined, and could include an RG or a revision to an RG. The CRA has additional requirements if a rule is determined by OMB (OIRA) to be a "major rule" (see Section IV, Glossary).
3. The LTR is responsible for addressing and resolving any public comments and advisory committee review comments before issuance of the RG.
4. If a contractor prepares a technical basis document, the LTR is responsible for revising and reviewing the monthly letter status reports, approving payment vouchers, and using the technical basis to develop a DG. The LTR should interact with the PM as required to facilitate contract verification, scheduling, and publication of notice of the DG and the RG in the *Federal Register*.

F. Administratively Changed Guide (ACG)

When an RG is updated for the purpose of correcting typographical errors or format changes and has no substantive difference in the established staff position, the RG may be processed as an ACG. The ACG is intended to ease the administrative burden of staff review of nonsubstantive matters. The ACG is prepared by the PM or the LTR and reviewed to ensure that no substantive change has been made to the staff regulatory guidance directly or indirectly as a result of the administrative changes. Following editing, the ACG is reviewed by OGC to obtain a no legal objection determination, and the Advisory Committee on Reactor Safeguards (ACRS) is provided an option to review the RG. When the review is completed, the RG is issued and notice of the issuance is published in the *Federal Register*. The ACG will include a summary of the rationale behind the decision to issue without the draft review.

G. Withdrawal of a Regulatory Guide

When an RG has become outdated or is otherwise no longer needed, it may be withdrawn. Withdrawal of an RG does not change its application by existing users. Withdrawal is taken to signal that the document no longer reflects the preferred method of meeting the regulatory need that the document originally met. A justification should be prepared and incorporated into the FRN announcing the action. The withdrawal concurrence process includes all affected participants as required for a new RG or revision. The RG is considered withdrawn either on the date of publication of the FRN or an alternate date if provided within the FRN.

H. Release of Pre-decisional Regulatory Guide Language

1. RGs are not considered final until the effective date indicated in the FRN providing notice of the issuance of the RG. For the purpose of developing guidance, licensee stakeholders and members of the public are invited to participate in development during the public comment period. When supporting new rulemaking, elements of the staff guidance are prepared and issued in the FRN publishing the proposed rule. Any meetings held during the public comment period should be Category 3 to facilitate full participation by the public. (See MD 3.5, "Attendance at NRC Staff-Sponsored Meetings.") The staff will undertake public meetings, as needed, to solicit feedback regarding the proposed rulemaking.

2. A DG or RG will not normally be released to the public until the required approvals are completed as described within this MD. However, if advance discussion of regulatory guidance facilitates the development of the DG or RG and furthers public understanding of the related rulemaking, or allows for advanced implementation planning by affected licensees, the PM or RGS can change the document availability to "publicly available" after consultation with the affected technical offices and OGC (see TEC-004, Section 5.6.2). The draft document should be promptly placed on the Web site to ensure wide access to all stakeholders.

3. The proposed guidance should incorporate a watermark on the document. Before availability is noticed in the *Federal Register*, staff should mark all DGs and RGs as predecisional to identify that they are not final. This marking will be included for published DGs, and removed by the RGS during preparation of the RG and final *Federal Register* notice.

I. Reviews and Approvals

1. The LTR solicits input from other technical offices and circulates the proposed changes or the DG in advance of finalizing the RG. Typically, when reviews are complete, the LTR transmits the DG (or the RG, in those instances in which a DG is not prepared) via cover memorandum signed by the LTR's division director and addressed to the RES division director responsible for RGs. ADAMS-archived mail (e.g., email) is acceptable as well. For DGs and RGs that do not change a staff position, branch chief approval is acceptable.

2. The PM will review the draft for policy considerations, content, and conformity to the template, and then submit the draft for technical editing. Following the editing process, the PM and RGS prepare a package for concurrence. The PM circulates the DG or RG for concurrence. Normally, OGC reviews the DG or the RG following the technical office concurrence; OGC provides a no legal objection (NLO) if OGC determines the DG or RG to be legally sufficient. Parallel concurrence may be acceptable and used on a case-by-case basis.

J. Advisory Committee Review

1. The LTR and PM coordinate actions in advance of submittal for advisory committee review.
2. The CRGR review is typically not required because RGs are considered voluntary. Often, changes in staff positions do not have backfit implications because they are forward fitting. However, topics that are promulgated using an RG that could create a backfit implication should be reviewed in advance by the CRGR. The staff is expected to be diligent in recognizing that backfit concerns may be raised during internal staff review, advisory committee review, or stakeholder review. If a review raises any legitimate concern at any point, CRGR will be engaged for further evaluation.
3. The ACRS is offered a chance to review both DGs and RGs prior to publication in the *Federal Register*. Any ACRS comments are then considered and any changes resulting from the ACRS comments are included prior to publishing the DG or RG.
4. The PM obtains documentation of CRGR or ACRS review either by e-mail or memoranda. The documentation should be kept in the same file as the concurrence package (either electronic or hard copy).

K. Security Review

The LTR should maintain awareness of all sensitive or classified information associated with the DG. The LTR will ensure that a SUNSI review is completed and documented prior to transmitting the DG or RG to RES.

L. Review of Guides Incorporating Sensitive Unclassified Non-Safeguards Information (SUNSI), Safeguards Information, or Classified Information

A small number of RGs are not publicly available due to inclusion of SUNSI, Safeguards Information, or Classified Information. These RGs are processed accordingly 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 provided in the NRC Security Program. Safeguards Information guides will be retained on the NSIR computer system (Safeguards Local Area Network and Electronic Safe (SLES)). Interaction and comment will be undertaken with selected cleared stakeholder representatives arranged by NSIR. Issuance of RGs is specific to selected, cleared stakeholders. When possible, redacted versions of DGs and RGs should be made available for the public.

M. Editing

Both DGs and RGs are submitted for technical editing by the PM just prior to concurrence review and issuance. Technical editing is normally arranged by RES at the point of development when the LTR or PM is unlikely to make any further substantive changes to the DG or RG. The technical editor reviews the DG or RG and ensures that it is in the correct format, is grammatically correct, written in plain language, and conforms to the NRC editorial style in NUREG-1379, Rev. 2, "NRC Editorial Style Guide." The RGS checks all citations and references for accuracy and for public availability. In addition, the RGS issues DG and RG numbers.

N. Authorization, Printing, and Distribution

1. The PM for a DG or RG will process the guide as indicated in TEC-004, which includes ensuring that OGC provided a no legal objection (NLO) and that the DG or RG has been revised in accordance with OGC revisions and comments. Any changes made to the DG or RG package after OGC's NLO must be brought to the attention of OGC to ensure that new legal issues are not raised or that the changes do not undermine OGC's previous bases for providing the NLO. The PM shall ensure that the NLO is included within the concurrence package. The package will be forwarded to the RGS for authorization, printing, and distribution.
2. The RGS prepares a package concerning the issuance and availability of the DG or RG. The package consists of an FRN and a memorandum to the Office of Administration to have the FRN published. The FRN announces the availability of the DG or RG. If there have been public meetings, workshops, or the issuance of draft language on the Web in advance of the FRN publishing the DG for public comment, this should be set forth in the FRN. When the FRN is providing notice of the issuance of an RG, it should include a specific reference to the FRN requesting public comments on the DG, the comments received, and the staff's response, if applicable. The FRN provides the ADAMS accession number for the DG or RG, but does not contain the DG or RG itself.
3. The RGS prepares the package for transmittal to the Office of Congressional Affairs, who provides the appropriate copies to Congress to meet the goals of the CRA.
4. Concurrence packages for DGs are signed by the division director responsible for RGs and by the required concurring offices.
5. For RGs, the concurrence package is signed by the Director of the Division of Engineering, RES. Concurrence from the program offices is not required for issuance of the RG unless substantive changes have been made during the public review and comment period.
6. When the DG or RG has been approved for issuance, the RGS prepares a camera-ready copy of the DG or RG. The RGS determines the number of printed

copies of the DG or RG to order. The RGS prepares an NRC Form 20, “Request for Printing and Copying Services,” specifying the number of copies for NRC and for the National Technical Information Services and all other pertinent details.

7. The RGS enters the DG or RG into ADAMS as a stand-alone document with its own accession number made publicly available. The ADAMS templates for the development of new guides are available on the RES Web site.
8. The RGS coordinates the immediate release and issuance of the DG or RG and posts on the appropriate Web sites (e.g., Document Collections). The RGS concurrently sends the FRN to the Government Publishing Office, where it is then published.

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, concurrence for each concurring office; documentation of the Office of the General Counsel’s statement of “no legal objection”; documentation of each appropriate advisory committee regarding its review; a statement on the security review of the regulatory guide; and any necessary companion documents.

Endorsement

In a regulatory guide, endorsement of a document, or part of a document, means that the staff has evaluated the material and has found that it is acceptable for use, either in whole or in part, and allowed for use by licensees as discussed within the RG. The endorsement must be discussed sufficiently to identify its limitations. To constitute endorsement, the subject document must be described in the staff regulatory guidance section. A document included as a listing in the reference or bibliography sections, or discussed outside of the staff regulatory guidance section, does not provide an endorsement.

Lead Office

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

Lead Technical Reviewer (LTR)

The person in the lead office acting as the point of contact for the regulatory guide (RG). The Lead Technical Reviewer (LTR) is responsible for developing, writing, and coordinating the RG with interested parties in the agency. The LTR obtains general agreement on the DG with other interested parties prior to the concurrence review.

Major Rule

Means a rule that 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 United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

No Legal Objection

Means that the document is not contrary to the law (statute or regulation) nor would it 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, and technical content as well as the resource impacts of the regulatory guide.
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.

Regulatory Guide Project Manager (PM)

The staff member with overall responsibility for coordination and issuance of a specific regulatory guide (RG) is organizationally assigned to the Office of Nuclear Regulatory Research (RES). The PM facilitates interoffice review by maintaining timeliness in processing. The PM secures office concurrence and approvals needed to publish an RG.

Regulatory Guide Specialist (RGS)

The Office of Nuclear Regulatory Research staff member assigned to assist in processing and publishing regulatory guides (RGs). The regulatory guide specialist provides expertise in preparing the RGs for issuance in the *Federal Register*.

Staff Position

A staff position is an explicit NRC staff interpretation of measures that, if taken, will satisfy the more generally stated, legally binding body of NRC regulations found in Title 10, Chapter 1 of the *Code of Federal Regulations*. In the context of regulatory guides (RGs), the staff positions are contained in the staff regulatory guidance section (previously regulatory position section), and the applicable regulations are discussed in the introduction section. The licensee has the benefit of knowing that the staff position stated in an RG has been vetted to be consistent with agency policy and acceptable staff positions stated in other documents. The revision to (or withdrawal of) an RG and the resulting change to the staff regulatory guidance does not affect the acceptability for use of a withdrawn or revised RG previously documented in the licensee's licensing basis.