



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

RES OFFICE INSTRUCTION

Change Notice

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| Office Instruction No. | TEC-004, Rev. 0 (Was ADM-004, Revision 3) | Approved by: Brian Sheron Date: 05/10/2013 |
| Office Instruction Title | Regulatory Guide Review, Development, Revision, and Withdrawal Process | |
| Effective Date | May 10, 2013 | |
| Primary Contact | RES Web Listing of Primary Contacts | |
| Responsible Division | RES/DE | |
| ADAMS Accession No. | ML101750587 | |
| Training | None | |
| SUMMARY OF CHANGES: | | |
| <p>Replaces ADM-004, Revision 2. Changes include conforming changes to Management Directives 6.5, "NRC Participation in the Development and Use of Consensus Standards" and Management Directive 6.6, "Regulatory Guides," and changes to incorporate lessons learned from using Revision 2 of this procedure. The changes include clarifications and refinements of the draft regulatory guide (DG) and regulatory guide (RG) process, addition of appropriate guidance, and redistribution of responsibilities. In particular, the following changes were incorporated:</p> | | |
| <div><div>1.</div><div>Established the process for periodic review of RGs</div></div> <div><div>2.</div><div>Inserted duties and responsibilities section for RGDB Office Point of Contact</div></div> <div><div>3.</div><div>Established requirement for review to harmonize with international standards</div></div> <div><div>4.</div><div>Implemented a new administrative change process for RGs</div></div> <div><div>5.</div><div>Incorporated information from Management Directive 6.5, "NRC Participation in the Development and Use of Consensus Standards"</div></div> <div><div>6.</div><div>Incorporated information from Management Directive 6.6, "Regulatory Guides"</div></div> <div><div>7.</div><div>Established the Regulatory Analysis section as a stand-alone document that is referenced in both the draft and final RGs</div></div> <div><div>8.</div><div>Incorporated revised Implementation section in RGs to clarify their regulatory uses, backfitting, and issue finality considerations</div></div> <div><div>9.</div><div>Revised figure illustrating the regulatory guide process</div></div> <div><div>10.</div><div>Replaced sample documents with SharePoint locations and ADAMS Accession Nos.</div></div> <div><div>11.</div><div>Implemented minor "house-keeping" corrections</div></div> <div><div>12.</div><div>Incorporated a reference to the RGDB Desktop Procedure for Regulatory Guides</div></div> | | |

| Name | Action | Signature | Date |
|---------------------------------------|-------------------|--------------------|-----------------|
| Branch Chief | Concurrence | Tom Boyce | July 2, 2012 |
| D:DE | Concurrence | Michael Case | July 2, 2012 |
| D:DRA | Concurrence | Richard Correia | August 30, 2012 |
| D:DSA | Concurrence | Kathy Gibson | August 16, 2012 |
| D:PMDA | Concurrence | Teresa Grancorvitz | April 30, 2013 |
| RES Mailroom | Logging | Kevin Johnson | May 1, 2013 |
| D:RES | Approval | Brian Sheron | May 10, 2013 |
| Ha <u>Do</u> <u>OI Coordinator</u> | Follow-on Actions | Ha Do | May 10, 2013 |

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RES OFFICE INSTRUCTION
TEC-004, Rev. 0
REGULATORY GUIDE REVIEW, DEVELOPMENT, REVISION,
AND WITHDRAWAL PROCESS

1. PURPOSE

This office instruction (OI) provides guidance for use in reviewing, developing, revising, and withdrawing regulatory guides (RGs).¹ This document is intended for internal use by NRC staff and not for external distribution or use.

2. BACKGROUND

Management Directive (MD) 6.6, "Regulatory Guides," provides agency guidance for RGs, and assigns lead responsibility for these guides to the Office of Nuclear Regulatory Research (RES). The Regulatory Guide Development Branch (RGDB) in RES administers the agency program for RGs.

Regulatory guides are published to (1) assist stakeholders in understanding and (2) aid in complying with U.S. Nuclear Regulatory Commission (NRC) rules and regulations. Regulatory guides describe methods or processes the NRC staff has determined to be acceptable (but not required) for use in meeting specific requirements in the NRC's regulations (i.e., Title 10 of the *Code of Federal Regulations* (10 CFR)). Regulatory guides do not impose requirements. Licensees and applicants are free to use an alternative method, provided they demonstrate to the staff that the alternate method satisfies the underlying regulations. Use of RGs by licensees and applicants conserves staff resources and simplifies the approval process because the guides describe ways the staff has already determined to be an acceptable approach to meeting the regulations.

Regulatory guides may be reevaluated and updated at any time necessary. For example, RGs may be revised in response to licensee or applicant requests, or when the NRC determines the current guidance is no longer the best available method or technique for demonstrating compliance with the underlying regulations. Revised regulatory guides are normally considered to be forward fitting guidance documents; issuance of a revised or new RG is not – by itself – considered to be backfitting. When an RG is revised, current licensees whose licensing bases include the old version of the RG (or an approved alternate) are not required to use the new version of the RG. However, if licensees propose a change to their licensing basis that involves matters addressed in the old version of the RG, then the staff may review the proposed changes using the guidance in the new version of the RG. Where revised or new RGs provide implementing guidance for a new rule, the backfit considerations for the rule also include the RGs, so that separate consideration for the RGs is not necessary. Therefore, no backfitting consideration is usually needed for issuance of a revised or new RG. Detailed guidance on

¹ While this instruction provides the best information at a point in time, it should not be misconstrued to represent the only process that can be used. Exigent or other circumstances may necessitate significant variation from the process outlined here. Should this variation prove to be potentially beneficial for general use, its use should be continued and it should be identified for incorporation into this OI as part of a future revision.

implementation of an RG is contained in the Implementation section of each RG, which supports the staff's ordinary determination that revision of an RG does not constitute backfitting.

Management Directive (MD) 6.6 establishes the requirement for RGs to be periodically evaluated, typically every 5 years. The NRC lead technical office assigned for each RG performs the evaluation. Based on the results of the review, the NRC technical branch determines the appropriate action to be taken on the guide, with the concurrence of the RGDB. The appropriate actions are to declare the RG acceptable as-is, withdraw, revise, or administratively change the guide. In addition, the staff may determine that additional or new guidance should be developed. This periodic evaluation satisfies the underlying purpose of both Executive Order 13563 (76 FR 3821, January 21, 2011) and the direction in Executive Order 13579 (76 FR 41587, July 14, 2011) with respect to retrospective review of regulations.

Before revising an existing regulatory guide or issuing a new guide, the NRC normally issues the guide as a draft regulatory guide (DG) to solicit public comment and involve the public in developing the agency's regulatory positions. Draft regulatory guides have not received final NRC management review and approval; therefore, they do not represent official NRC staff positions. In finalizing a guide, the staff considers all comments received during the public comment period, and revises the regulatory guide as appropriate. Public comments and the staff responses are collated and made publicly available when the regulatory guide is finalized.

Regulatory guides may endorse consensus codes or standards, consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (NTTAA), and the Office of Management and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." Management Directive 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 its regulatory guidance with international standards. When existing regulatory guidance is being updated, international standards should be reviewed and considered when developing the guidance in RGs.

The RGDB developed more detailed implementing guidance for use by RGDB members that is in an RGDB Desktop Procedure that is maintained on the SharePoint site. Examples of areas for more detailed guidance are: 1) tracking DGs and RGs on SharePoint, 2) maintaining an organized record keeping system in ADAMS, 3) maintaining templates, 4) updating the NRC external web site, and 5) preparing DG and RG review packages.

3. DEFINITIONS

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| ADAMS | The Agencywide Documents Access and Management System (ADAMS) is the official recordkeeping and document storage system through which the NRC provides access to the collections of documents related to the agency's regulatory activities. |
| Advisory Committee on the Medical Uses of Isotopes (ACMUI) | Advises the Commission on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. Membership includes health care professionals from various disciplines who comment on changes to NRC regulations and guidance; evaluate certain non-routine uses of radioactive material; and provide technical assistance in licensing, inspection, and enforcement cases. |

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| Advisory Committee on Reactor Safeguards (ACRS) (includes functions of Advisory Committee on Nuclear Waste [ACNW]) | Reviews and advises the Commission with regard to the licensing and safety of nuclear production and utilization facilities, the adequacy of proposed reactor safety standards, technical and policy issues related to the licensing of plant designs, areas of health physics and radiation protection, issues associated with nuclear materials and waste management, and other matters referred to it by the Commission. Security related RGs are exempt from ACRS review. |
| Affected Offices | Offices that should review and concur on the technical content of an RG being developed. Regional offices should be included when appropriate. |
| Draft Regulatory Guide (DG) | A numbered, pre-decisional version of a new or revised regulatory guide during its internal and external review and concurrence cycle. |
| External Stakeholder for Sensitive Regulatory Guides | An external individual seeking to view and provide comments on a sensitive regulatory guide or draft guide (i.e. Official Use Only-Security Related Information (OUO-SRI), Safeguards Information (SGI), and classified information), whose need-to-know has been determined and whose security clearance, where applicable, has been granted by the NRC. |
| Lead Technical Office | The NRC program office that has the technical expertise and lead responsibility for the subject covered in a regulatory guide. |
| Non-publicly Available | Documents and records (or portions of them) protected from public disclosure because they are: <ol style="list-style-type: none">1. specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy;2. related solely to the internal personnel rules and practices of the agency;3. are specifically exempted from disclosure by statute such as trade secrets, commercial or financial information, and privileged or confidential data;4. inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency; or5. personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. |
| Office Liaison | Some program offices have identified office liaisons as a central point of contact (POC) to coordinate all actions submitted by RES regarding the review, development, revision, and withdrawal of RGs. |

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| Program Office | The Office of Federal and State Materials and Environmental Management Programs, (FSME), Office of Nuclear Materials Safety and Safeguards (NMSS), Office of Nuclear Reactor Regulation (NRR), Office of New Reactors (NRO), Office of Nuclear Security and Incident Response (NSIR), and Office of Nuclear Regulatory Research (RES) are the current program offices within the NRC. |
| Program Office Liaison | Staff members in program offices that serve as a central POC to coordinate actions regarding the review, development, revision, and withdrawal of RGs. |
| Publicly Available | Information that has been published or broadcast for public consumption, is available on request to the public, is accessible on-line or otherwise to the public, is available to the public by subscription or purchase, could be seen or heard by any casual observer, is made available at a meeting open to the public, or is obtained by visiting any place or attending any event that is open to the public. |
| Regulatory Guide Development Branch (RGDB) | The RGDB is the RES technical staff responsible for developing, revising, or withdrawing RGs. The RGDB staff works with other NRC staff to assist in formatting, technical editing, assembling the package for concurrence, issuing the DG for public comment, facilitating appropriate committee review(s), and issuing draft and final guides. |
| RGDB Office Point of Contact (POC) | The RGDB staff member responsible for coordinating the RG development and revision process with a single program office (i.e., FSME, NMSS, NRR, NRO, NSIR, and RES). The RGDB Office POC coordinates schedules and actions between the RGDB and the assigned program office liaison to ensure timely evaluation of guides and overall coordination of RGs from the program office. |
| RGDB Project Manager | The RGDB staff member responsible for coordinating the development and revision of individual guides. Once a draft guide is provided to the RGDB Project Manager, the RGDB Project Manager maintains control over revisions and versions of the document. The RGDB Project Manager is also the point of contact with the technical leads/program office liaisons in other NRC offices for assigned guides. |
| RGDB Regulatory Guide Specialist | The RGDB staff member responsible for providing administrative support and assistance to the RGDB staff. |
| RGDB SharePoint Site | A SharePoint site (http://portal.nrc.gov/edo/res/de/rgdb/default.aspx) administered by the RGDB to allow tracking and commenting on RGs by interested NRC staff. |
| Technical Lead | The technical lead is the technical staff member in the lead technical office responsible for developing the new or revised regulatory guide and its technical basis. The Technical Lead ensures that technical issues are coordinated with the appropriate program offices and addresses public comments on the draft regulatory guide. |

4 RESPONSIBILITIES AND AUTHORITIES

The duties and responsibilities in this section implement the organizational responsibilities and delegations of authority in MD 6.5 and MD 6.6. If there is any conflict, the guidance in the MDs governs.

4.1 Office of Nuclear Regulatory Research

- a. Develops and publishes RGs assigned to RES.
- b. Provides coordination and support for the review and publishing of RGs assigned to other NRC Offices.

4.1.1 The Director of the Division of Engineering (DE) reports to the Office Director of RES and has the following responsibilities:

- a. Approves issuance of DGs, RGs, and related Federal Register notices (FRNs).
- b. Coordinates interactions between RES/DE and other NRC divisions and offices when appropriate.

4.1.2 The Branch Chief of the Regulatory Guide Development Branch (RGDB) reports to the Director of DE and has the following responsibilities:

- a. Manages the process of developing, revising, and issuing RGs.
- b. Obtains resolution of policy issues.
- c. Coordinates and facilitates meetings, as needed, between affected offices.
- d. Briefs upper management, including interoffice management, on progress, status, and potential and current issues.
- e. Develops generic communications covering several or more RGs (e.g., generic FRNs).
- f. Coordinates efforts among the RGDB staff and provides guidance, as needed.
- g. Assigns specific RGDB Project Managers and POCs to coordinate with specific committees to ensure a uniform and consistent flow of information to and from the committees (i.e., a single POC).
- h. Responsible for the structure and content of the RGDB SharePoint site: (<http://portal.nrc.gov/edo/res/de/rqdb/default.aspx>) containing information on all RGs.
- i. Ensures adequate resources for RGDB.

4.1.3 The RGDB Office Point of Contact (POC) reports to the RGDB Branch Chief and has the following duties and responsibilities:

- a. All activities associated with programmatic responsibilities for RGs, but not those activities associated with the individual development of new or revised guides. The RGDB Office POC may also serve as the RGDB PM for individual guides assigned to an office.
- b. Coordinates and facilitates meetings, as needed, between affected offices. Manages periodic meetings with responsible individuals in assigned program office. As a minimum, this will be at the office liaison/RGDB office POC level.
- c. Briefs upper management, including interoffice management, on progress, status, and potential and current issues. Prepares and presents monthly status meetings to RES/DE Director and others as required.
- d. Maintains the status of all DGs and RGs assigned to their program office on the RGDB SharePoint site: (<http://portal.nrc.gov/edo/res/de/rgdb/default.aspx>).
- e. Provide input and updates to the RES Op Plan as needed. Coordinates Op Plan entries for significant RGs in RES and other NRC offices.
- f. Initiate periodic review of RGs.
- g. Develop infrastructure plans for assigned program office. Reviews emerging staff positions contained in documents such as generic communications and interim staff guidance, and recommends changes to NRC's regulatory infrastructure (Standard Review Plans (SRPs), RGs, inspection procedures, industry codes and standards, etc.).
- h. Proactively initiate revisions to RGs based on regulatory infrastructure plans and stakeholder feedback. Coordinates efforts among the RGDB staff and provides guidance, as needed.

4.1.4 The RGDB Project Manager (PM) reports to the RGDB Branch Chief and has the following duties and responsibilities:

- a. Coordinates the development and review of assigned individual RGs with appropriate technical leads/program office liaison. Serves as the POC for questions on assigned RGs with affected offices to keep them informed of progress and to ensure uniformity of the information being provided and requested.
- b. Reviews guides for format, administrative issues, technical, legal, and regulatory correctness. Works with the technical leads/program office liaison and RGDB POC to improve the quality of the guide and assists the technical leads/program office liaison as needed.
- c. Reviews reference and bibliographic information for accuracy. Verifies that internal documents are available in ADAMS and external documents are publicly available.

- d. Collects and verifies that all public and stakeholder comments are assembled into a public comment template (non-public for sensitive comments and documents) and coordinates development of responses with the technical lead (within the Secure Local area network Electronic System (SLES) for SGI).
- e. Works with the technical lead to convert DG to RG format and revise guidance in response to internal and external comments.
- f. Provides final editing of RG (including format and content).
- g. Coordinates with the technical leads/program office liaison to ensure sensitive unclassified non-safeguards information (SUNSI) reviews are conducted on new or revised material or references, and provides review documentation when requested. See MD 12.6, "NRC Sensitive Unclassified Information Security Program" and MD 12.7, "NRC Safeguards Information Security Program" for additional information.
- h. Develops draft language for transmittal and concurrence memoranda, FRN, and other supporting documents.
- i. Prepares the review package for the draft final RG and distributes the package electronically to the appropriate review office(s) and committee(s) upon approval by management. Collects comments and secures needed approvals and concurrences. [NOTE: applies to publically available information and sensitive information (i.e., OUO-SRI and SGI). Classified documents are excluded and are the responsibility of the technical lead.]
- j. Maintains a file for each RG under their purview. File should contain the DG, RG, documentation of SUNSI review, approval (or waiver) from the appropriate committee(s), public comment/staff response document, and other documents deemed important to tracking the development of the RG from draft to final published version. Delivers completed package to the RGDB Regulatory Guide Specialist after Federal Register Notice announcing release of final RG is published. [NOTE: The technical lead should maintain a similar file for correspondence, comments and documents designated as Safeguards in SLES. Files related to classified documents, comments and correspondence will be maintained by the technical lead.]
- k. For all regulatory guides under their purview, updates and maintains the RGDB SharePoint site: (<http://portal.nrc.gov/edo/res/de/rqdb/default.aspx>) with the current status of each regulatory guide.
- l. Prepares descriptive paragraphs highlighting branch accomplishments when DG is issued for public comment or RG is released as final. After review by the RGDB Branch Chief, the highlight paragraph is sent to the RES/DE Technical Assistant for incorporation into the RES weekly summary report. Highlight paragraphs are available to RGDB staff on the RES G:/ drive at: [G:\DE\1-Regulatory Guide Program\Periodics and Highlights\Highlights](#).

4.1.5 The RGDB Regulatory Guide Specialist reports to the RGDB Branch Chief and has the following duties and responsibilities:

- a. Provides administrative support and assistance with the updating of the RGDB SharePoint Web site; (<http://portal.nrc.gov/edo/res/de/rgdb/default.aspx>) in support of branch activities.
- b. Provides administrative support to maintain and update the DG and RG records in ADAMS in support of branch activities.
- c. Coordinates technical editing of draft and final regulatory guides.
- d. Prepares memos and notices including FRNs, GAO-001 forms, "Submission of Federal Rules under the Congressional Review Act," forms, and related documents announcing the availability of a guide, withdrawal of a guide, and the opportunity for stakeholders to submit related comments.
- e. Coordinates with technical leads in the transmittal and distribution of sensitive documents (i.e. OUO-SRI and SGI to cleared stakeholders for comment. Classified document are excluded and remain the responsibility of the technical lead.
- f. Arranges for the guides to be distributed and displayed on appropriate NRC Web sites.
- g. Coordinates publication and distribution with the Office of Administration (ADM) and Office of Information Services (OIS) as needed to assure that public and internal NRC Websites are revised promptly and the draft and final regulatory guides are available at the appropriate time.
- h. Distributes any internal and external comments and information on specific DGs and RGS to the appropriate RGDB PM.

4.2 Lead Technical Office

For RGs designated in their area of responsibility or expertise on the SharePoint site for RGs, the Lead Technical Office (LTO) performs the following activities:

- a. Identifies a Technical Lead (TL) to be the POC with the RGDB Project Manager.
- b. Conducts periodic review of RGs and recommends appropriate agency actions.
- c. Develops technical bases for new RGs or revisions to RGs.
- d. Coordinates new or revised technical positions with other program offices, as needed, while ensuring technical consistency of agency positions. Coordination typically is needed when developing a draft guide, and when addressing comments from the public and stakeholders, Office of General Counsel (OGC), and special NRC committees.

- e. Coordinates within the SLES for documents, correspondence and comments designated as Safeguards.
- f. Reviews international standards for applicability and incorporation into regulatory guides to demonstrate harmonization with international standards.
- g. Reviews voluntary consensus standards for applicability and use in RGs. See MD 6.5 for additional information.
- h. Develops DGs with support from the RGDB Project Manager.
- i. Develops the regulatory analysis (and backfit analysis if required).
- j. Verifies that reference and bibliographic information are correct and publicly available.
- k. Obtains initial technical editing of draft regulatory guide and related documents. See <http://www.internal.nrc.gov/ADM/techedit/techedit.html> for ADM support information.
- l. Makes presentations and provides technical support for all meetings (e.g., ACRS, ACMUI, workshops, and public meetings).
- m. Reviews all comments (internal and public), responds, and revises the documents, as warranted.
- n. Prepares a document listing all public comments (or accurate summaries of similar comments) and staff responses which are clear, concise, and responsive to the comment.
- o. Coordinates with the RGDB PM to ensure that SUNSI reviews of new or revised material or references is conducted, and provides review documentation to the RG PM. See MD 12.6 for additional information.
- p. Coordinates with the RGDB Office POC or PM to ensure that any potential issues or areas that should be considered for future revisions to a RG are documented in the SharePoint site for that RG.
- q. Coordinates with the RGDB Office POC or PM in determining cognizant internal and external stakeholders for sensitive and classified documents.

4.3 Affected Offices

- a. Review the DGs or RGs sent to them for concurrence. As stated in MD 6.6, 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, and

3. Agrees that the material for which the office has a programmatic basis for judgment is factual and accurate.
- b. Concur (or concur with comment) on the authorization memorandum for publication of the guide. Concurrence on the authorization memorandum signifies concurrence and agreement with all of the associated documents within the authorization to publish the package (e.g., the guide, regulatory analysis, transmittal memoranda, etc.).
- c. Provide the necessary concurrence from the Division Director, or designee, for publishing a DG for public comment or trial use, as described in MD 6.6.

5. INSTRUCTIONS

5.1 Scope of Regulatory Guides

The NRC's Regulatory Guides 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 Review²
10. General

5.2 Regulatory Guide Format

The NRC issues two different types of RGs: (1) substantive RGs providing technical and regulatory guidance for compliance with NRC requirements; and (2) standard format and content RGs to assist applicants with the format and content of applications. Both types of RGs may be issued first as a DG for review and comment and then as a final RG for use by stakeholders. Example templates and additional information is provided for each type on the RGDB Template [SharePoint Site](#) and in [ADAMS](#) (see below).

The use of templates on SharePoint implements the format for DGs and RGs. The templates are to be used for reviews and updates for all DGs and RGs. Deviations from the templates for individual guides should be discussed between the Technical Lead and the RGDB PM, and may be appropriate depending on the situation. Changes to the templates themselves are coordinated by RGDB members with the appropriate program offices and OGC, and approved by the RGDB branch chief before posting to the SharePoint site.

2 As of October 2007, all Division 9 regulatory guides have been withdrawn.

- a. Draft and final regulatory guide (DG & RG) template in [SharePoint](#) or ADAMS (See Attachment 1).
- b. Standard format and content DG & RG template and instructions in [SharePoint](#) or ADAMS (See Attachment 2).
- c. Flow chart of regulatory guide review and concurrence flow path for revising regulatory guides (See Attachment 3).
- d. Template for Section D – Implementation of DGs & RGs in [SharePoint](#) or ADAMS at Accession No. ML111460184.
- e. Regulatory analysis template in [SharePoint](#) or ADAMS (See Attachment 4).
- f. Sample Notice to be posted on Web Site in lieu of Regulatory Guides containing security-related or safeguards information (See Attachment 5)

As a general rule, each regulatory guide addresses a specific topic and is organized into the following sections.³

5.2.1 Introduction – Section A of each guide states the purpose of the guide and its scope, the applicable NRC regulation(s) which the guide supports, and any related regulations or regulatory guidance. The introduction also includes the following standard statements:

- a. The OMB statement on information collection activities and OMB clearance number applicable to the regulations that the guide supports.
- b. A standard sentence that OMB has not found the guide to be a major rule as designated in the Congressional Review Act.

For large documents (typically more than 30 pages), the introduction section may also include a table of contents, as shown in the draft and final regulatory guide templates.

For both the DG and RG, the explanatory footnote on the front page needs to identify the ADAMS accession number for the regulatory guide and regulatory analysis. The ADAMS accession number for the staff's response to public comments should be added to the explanatory footnote on the front page of final regulatory guides.

5.2.2 Discussion – For revisions to existing RGs, Section B typically begins with a short background discussion of the changes in this revision of the regulatory guide. New RGs should have an introductory paragraph discussing why a new RG is being issued. The section then outlines the subject addressed by the guide and briefly states the technical bases or rationales considered in developing the regulatory positions.

The discussion section does not provide regulatory positions and should not refer to an apparent position that is not otherwise specified in Section C. The last part of Section B should describe how the RG harmonizes with national or international consensus codes

3 Not all RGs fit into this format. For example, the standard format and content guides do not provide regulatory positions but provide applicants an example of the format that should be used and the information that should be provided in order to expedite review of the application.

and standards. In a standard format and content guide, the discussion section is replaced with the Standard Format and Content section.

- 5.2.3 Staff Regulatory Guidance – Section C of each guide describes the methods, techniques, or data that the staff considers acceptable for use in meeting the requirements of the NRC regulation(s) cited in Section A. The discussion of each regulatory position should be clear and concise. Clearly note that the methods, techniques, or data described in the regulatory position are not requirements and the use of the permissive “should” is preferred over the prescriptive “shall” unless the discussion is directly linked to a regulatory requirements. In standard form and content guides, the regulatory position is replaced with an implementation discussion.
- 5.2.4 Implementation – Section D provides information to applicants and licensees regarding the NRC staff’s plan for using the regulatory guide, and a discussion on compliance with the backfit rules applicable to various nuclear facilities.

Because regulatory guides normally describe methods the staff considers acceptable for use in implementing specific parts of the agency’s regulations, explain techniques the staff uses in evaluating specific problems or postulated accidents, or provide guidance to applicants, the OGC has determined that regulatory guides are not substitutes for regulations and compliance with them is not required. However, in some rare cases, it may be necessary to issue a regulatory guide describing methods or processes the NRC has determined are mandatory for existing licensees. Before such a mandatory regulatory guide can be issued, a backfit analysis must be completed and included as part of the regulatory guide package.

Both the Management Directive 8.4, “[Management of Facility-specific Backfitting and Information Collection](#),” and NUREG-1409, “[Backfitting Guidelines](#)” (ADAMS Accession No. ML032230247) provide additional guidance on backfitting.

The specific regulations for backfit concerns are found in the following regulations:

- a. Backfit for nuclear power plants, 10 CFR 50.109, “Backfitting”
- b. Backfit for special nuclear material, 10 CFR 70.76, “Backfitting”
- c. Backfit for the independent storage of spent nuclear fuel and high-level radioactive waste, and reactor-related greater than Class C waste, 10 CFR 72.62, “Backfitting,” and
- d. Backfit for Gaseous Diffusions Plants, 10 CFR 76.76, “Backfitting.”

New nuclear power plants are subject to the issue finality provisions in both 10 CFR 50.109 and in various provisions in 10 CFR Part 52. Some production and utilization licensees, such as medical licensees and research and test reactors, have no applicable backfit or issue finality rules.

The current guidance and language for Section D – Implementation is available in [SharePoint](#) or in ADAMS at accession No. ML111460184. As of the publication date of this procedure, the OGC has approved the language for nuclear power plants. Other

language is still under review and is subject to revision by OGC during their review of the draft or final guide.

- 5.2.5 Glossary – Because the agency uses many abbreviations and terms or phrases with specific (and not necessarily common) meanings, a glossary may be added to enable the reader to find frequently used abbreviations, terms, and phrases. This will be especially helpful for large guides. The glossary should follow the format in the draft regulatory guide template (Attachment 1).
- 5.2.6 References – If references are used, they should follow the format shown on pages 58 – 63 of Rev. 2 of NUREG-1379, “NRC Editorial Style Guide” (Available in ADAMS at Accession No. ML093280744 or on the NRC Web Site at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1379/r2/>). In accordance with this guidance, references to selected NRC regulatory guidance documents (RGs, Standard Review Plans, ASME and IEEE codes incorporated into 10 CFR 50.55a) should not include dates, version numbers, or ML numbers because this could confuse applicants on the appropriate guidance to follow, and potentially limit the NRC staff from using its latest guidance as reflected in these documents.

Note that all references cited in regulatory guides should be available to the public and the source should be clearly identified. A footnote should be used to identify how members of the public can access each of the referenced documents. References that are publicly available in ADAMS can be identified with a common footnote or by including the ADAMS accession number at the end of the reference citation. References to outside organizations should include the address, telephone, and Website information necessary to allow the reader to obtain the referenced material. A list of addresses for some external organizations is part of the RGDB SharePoint Web site. (<http://portal.nrc.gov/edo/res/de/rqdb/Templates/Forms/AllItems.aspx>).

- 5.2.7 Bibliography – If the guide was developed using a number of documents that are not referenced in the guide, a bibliography may be included as an aid to the reader. The bibliography should follow the form in Rev. 2 of NUREG-1379.
- 5.2.8 Appendices – If the guide uses extensive details for the Discussion or Staff Regulatory Guidance sections, the PM should consider developing separate appendices to enhance the clarity and readability of the RG. Each appendix must be clearly identified as being an extension of the Discussion or Staff Regulatory Guidance and must be appropriately referenced in those sections.
- 5.2.9 Regulatory Analysis – The regulatory analysis (see ADAMS Accession No. ML102390356) is a separate document that travels as part of the regulatory guide review and concurrence package and is referenced in each draft and final regulatory guide. The regulatory analysis describes why the regulatory guide is being changed (or created) and identifies what is being changed in a revised guide. It also evaluates the need and consequences of the proposed revision to the guidance. The development and issuance of regulatory guides are supported by regulatory analyses. NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission” (ADAMS Accession No. ML003738939) contains information on the content and format of the Regulatory Analysis document.

If there is an existing analysis for a previous revision of the guide (or one that was prepared for a related rule) that is still valid and includes consideration of the impacts associated with the proposed guide, there is no need for a separate regulatory analysis. In such cases, this section should simply reference the existing regulatory analysis, which must be publicly available. If no valid analysis exists, the technical lead, in cooperation with the RGDB project manager should prepare the regulatory analysis as part of the draft guide review and concurrence package.

5.3 Regulatory Guide Review

- 5.3.1 Periodic Review – Management Directive 6.6 establishes the requirement that RGs be reviewed periodically to evaluate their accuracy and continued applicability. The reviews are typically performed every 5 years. The RGDB Office POC is responsible for identifying RGs requiring periodic review and coordinating with the program office to ensure a review by the appropriate lead technical branch. When the technical lead branch designates a technical lead reviewer for a RG, the RGDB Project Manager assigned to the individual RG is responsible for liaison with the technical lead to ensure an evaluation of the RG is conducted.

An evaluation by the technical lead consists of addressing several questions intended to determine the issues affecting the guide, their significance, and the resources needed to address them. These questions may be answered directly in SharePoint by the technical leads or may be communicated to the RGDB Project Manager. The questions are as follows (Note: sources of information to review to help answer these questions can be found in the RGDB Desktop Guide on SharePoint):

1. What are the known technical or regulatory issues with the current version of the RG?
2. What is the impact on internal and external stakeholders of not updating the RG for the known issues, in terms of licensing and inspection activities?
3. What is an estimate of the level of NRC effort needed to address the identified issues in terms of FTE and contract dollars?

Based on the answers to the above three questions, the branch chief for the technical lead should decide the appropriate action to take on the RG, as described in Section 5.4 below, and provide a plan to accomplish the action to RGDB. The RGDB branch chief should concur in this decision.

- 5.3.2 For Cause Review – Regulatory guides may be reviewed or reevaluated at any time necessary. Changes in regulations or endorsed consensus codes or standards developed by external organizations may result in the need to review or revise existing RGs. These reviews should be requested by the technical leads and their management and coordinated with the RGDB Branch chief. The guidance in RES Office Instruction PRM-001, “Process for New Work Requests: Responding to Informal Assistance, Research Assistance and User Need Requests” should be followed to request RGDB support for intermittent review of RGs.
- 5.3.3 Review Decision– Based on the results of the evaluation, the Technical Lead works with the RGDB Project Manager to determine the appropriate action to be taken on the guide,

which can be one of the four actions as discussed in Section 5.4. The agency decision regarding which action to take should have the concurrence of the branch chiefs of both the technical lead and RGDB.

5.4 Regulatory Guide Actions

In general, the Technical Lead office should develop a tangible plan to accomplish the actions listed below. The Technical Leads should work with the RGDB PMs to document information relevant to these plans, as appropriate. Examples of this information are described in the RGDB Desktop Guide, and include items such as the scope of technical changes, applicability to reactor or facility types, contracts required, industry needs and timing, etc.

- 5.4.1 Declaring a Regulatory Guide Acceptable-As-Is – A RG that is still applicable and useable by NRC staff, licensees, and applicants may be determined to be “Acceptable-As-Is.” The technical lead branch should communicate the evaluation and decision to the RGDB PM. Both the branch chiefs of the lead technical branch and RGDB should concur in the action. This determination is an agency decision. Documentation should contain sufficient information to explain why the guide was considered acceptable (typically, answers to the 3 questions in 5.3.1), and to capture key information about the guide to transfer this knowledge to future reviewers and management.
- 5.4.2 Withdrawing a Regulatory Guide – Regulatory guides may be withdrawn when 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. When an existing regulatory guide is withdrawn, current licensees may continue to use it, as the withdrawal does not affect any existing licenses or agreements. Withdrawal means that the guide should not be used for future NRC licensing activities. Changes to existing licenses or new application reviews should use other regulatory guidance.

The process for withdrawing regulatory guides is similar to the method used to process a final regulatory guide. The withdrawal package is routed to the appropriate program offices, 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 the guidance document. The questions are available on the RGDB SharePoint Website at: (<http://portal.nrc.gov/edo/res/de/rqdb/Templates/Forms/AllItems.aspx>).

A link is provided on the NRC’s web page for the withdrawn RGs to the Federal Register Notice (FRN) announcing the withdrawal. The FRN describes the staff’s basis for withdrawing the RG so that this information is made available to the public and stakeholders. If a RG is withdrawn and not being replaced, then the Federal Register notice and the regulatory guide Web page indicate that the RG is being withdrawn with no replacement, and explain the status of the withdrawn RG for an existing licensee or user. If an RG is withdrawn and being replaced by either a newly-created or revisions to an existing RG, then the FRN and the regulatory guide Web page: (i) indicate that the RG is being withdrawn with cross references to the replacement RG, and (ii) explain the status of the withdrawn RG for an existing licensee or user.

- 5.4.3 Revising a Regulatory Guide – A RG that is needed for licensing, oversight, or inspection activities, but should incorporate new guidance, address changes in

regulations, modify existing technical positions, or other issues, should be revised. This process is described in more detail in Section 5.5 below.

Regulatory guide revisions follow a standard review and concurrence process to help assure that all interested NRC offices and committees, licensees, applicants, and the public are given the opportunity to review and comment on the guide. A flow chart of the step-by-step process for developing and issuing a new or revised regulatory guide is shown later in this office instruction, on the RGDB [SharePoint Web](#) site for templates, and in ADAMS at Accession No. ML121070115.

Unless the guide contains proprietary, Official Use Only, safeguards, or classified information, new and proposed revisions to every regulatory guide should be issued to the general public as a draft guide to allow an opportunity for public comment. Independent review of a draft regulatory guide allows individuals, other than the authors, to review, comment, and when appropriate, concur on the documents before they are finalized. Documents designated or classified as proprietary, Official Use Only, safeguards, or classified information may be sent to stakeholders once their need-to-know and access authorization or security clearance, when applicable, has been verified by the lead technical branch and the ADM, Division of Facilities and Security (DFS), Personnel Security Branch. Additional information in the regard can be found at: http://www.internal.nrc.gov/ADM/security/pers_sec/personnelmain.html

- 5.4.4 Administrative Change Guide – A regulatory guide may be revised for the purpose of correcting typographical errors or format changes without going through the normal review process if, and only if, the revision results in no substantive difference in the established staff position. Allowing administrative changes to regulatory guides eases the burden of staff reviews for non-substantive matters and improves the work flow process.

For example, Revision 1 of Regulatory Guide 5.66, “Access Authorization Program for Nuclear Power Plants,” dated July 2009 was classified as a Security Related – Official Use Only document because it included an attachment containing security-related information. By removing the attachment the NRC staff was able to re-designate the guide and issue Revision 2 of Regulatory Guide 5.66 in October 2011 to the general public. The revision of Regulatory Guide 5.66 was completed using the administrative change process because the removal of the attachment did not modify the NRC staff position.

Administrative changes are processed in the following manner: The RG revision is prepared by the technical lead or the RGDB POC or PM and is reviewed by the appropriate branch chiefs to verify 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 RG is reviewed by the OGC to obtain a No Legal Objection (NLO) determination, and the ACRS is provided an option to review the RG. When the review is completed, the RG is issued as a final RG. The Regulatory Analysis and Federal Register Notice announcing the administrative change will include a summary of the rationale behind the decision to issue without the draft review, as well as instructions on submitting comments if desired. However, the administrative changed guide will be issued as a final RG at that time.

5.5 Development of New or Revised Regulatory Guides

5.5.1 Identifying the Need for New Guidance – Identification of the need for a new regulatory guide or revision to an existing guide can come from a variety of sources. Typical sources for new or revised information include:

- a. a new or revised regulation may precipitate the need for new or revised guidance (in general, regulatory guides developed to support new or revised rulemaking 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 (ADAMS Accession No. ML12227A355))
- b. standards development organizations or international organizations may release new or improved standards;
- c. emerging staff positions (e.g., generic communication, interim staff guidance, licensing and inspection activities, etc.);
- d. input from external stakeholders (e.g., incorporate advances in technology or operating experience), typically submitted as comments to a draft guide or final RGs on the agency's Web site.

Once the need for new or revised guidance has been articulated, a lead technical office is identified and that office identifies a technical lead. Upon receiving a request from the lead technical office, the RGDB Branch Chief assigns responsibility for the guide to the RGDB Office POC or PM.

5.5.2 Development of the Technical Basis – The technical lead/office liaison is responsible for formulating the technical basis for a new or major revision to an existing regulatory guide. The technical basis may include a set of references, consensus standards, operational or regulatory experience, or a separate technical basis document (TBD) such as a NUREG. The format and content of the TBD can be similar to the technical portion of the draft regulatory guide for efficiency, and will normally be used by the technical lead to prepare the draft regulatory guide.

Development of the technical basis can be done in-house by NRC staff or by using contract support. Contract support is normally funded by the technical lead office, although in some cases, the RGDB may be able to provide funding. Funding from either the lead technical office or RGDB may be applied to the existing technical support contract administered by RGDB. In this case, the RGDB PM would be the Project Officer for the contract, and the technical lead would be the Technical Monitor.

5.5.3 Development of the Draft Regulatory Guide – Both a new regulatory guide and a revision to an existing regulatory guide (other than an Administrative Change) begin as a DG. The format for a draft regulatory guide is available on the RGDB [SharePoint Web](#) site and in ADAMS at Accession No. ML080380163. Simple revisions can begin with the existing regulatory guide; however, complex revisions or new regulatory guides should be developed from a TBD. The Technical Lead should informally coordinate new or revised technical positions with other program offices, as needed, while ensuring technical consistency of agency positions. Coordination typically is needed when

developing a draft guide before delivering it to RGDB, as well as when addressing comments from stakeholders, the public, OGC, and special NRC committees during the RG development process. This coordination facilitates the formal concurrence process between offices that is facilitated by the RGDB PM.

- 5.5.4 Development of Supporting Documents – The Technical Lead/program office liaison and the RGDB Office POC or PM cooperate in the development of documents supporting the draft regulatory guide. The RGDB provides the most current approach and template language for the regulatory analysis (as needed), backfit analysis (as needed), and SUNSI review documentation, and the Technical Lead provides the technical discussion for these documents. This cooperative development of the draft regulatory guide package helps assure that the document is properly formatted and contains the most current template language.

- 5.5.5 Addressing the Cumulative Effects of Regulations - The Cumulative Effects of Regulation (CER) describes the challenges that licensees, or other impacted entities such as State partners, face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a number of complex regulatory positions, programs, or requirements within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security.

The Commission directed several process enhancements to address CER in its SRM on 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 concurrent with proposed rules and to publish final guidance concurrent with final rules.

In light of the Commission direction to publish guidance with rules, it is imperative that the RGDB project manager and the rulemaking project manager communicate which guidance documents are clearly linked to rulemaking in order to ensure both documents are developed and published concurrently.

- 5.5.6 Technical Editing – The technical lead office is normally responsible for the technical editing of the guide for format, spelling and punctuation, grammar and syntax, clarity and plain language, availability of references in the public domain, and inclusion of required standard text. The RGDB Office POC or PM may opt to send draft or final guides to technical editing if, in their opinion, the guides should be edited to improve syntax and language. Because RGs being revised or developed by RES use the same technical editing staff as the RGDB, they can be sent to editing by either the technical branch or the RGDB. Guides developed by other offices should undergo a technical edit by the developing organization.

5.6 Internal and External Review of New or Revised Guides

- 5.6.1 Review Package Development – Before issuing the draft or final regulatory guide for review and comment, the RGDB project manager reviews the guide for quality, completeness, and usability, including the following:

- a. Technical Aspects
 1. The technical basis for the revision is complete, correct, and accurate.
 2. The reason for the change is properly explained in the Discussion section.
 3. The RG wording agrees with the intent and technical basis of the guide.
 4. The responses to stakeholder and public comments have the appropriate technical basis.
 5. Endorsement of voluntary consensus standards and harmonization with international standards has been appropriately considered.
- b. Regulatory Aspects
 1. The Regulatory Analysis and the RG Introduction section properly explain why the RG is being changed.
 2. The regulations are correctly identified and quoted in Section A, Introduction.
 3. The revision is in accordance with the applicable regulations.
 4. The revision and FRN are consistent with regulatory processes, particularly backfitting and issue finality considerations.
 5. The guide and FRN use the current format and template language.
 6. Relationships to other regulatory guidance, particularly SRPs and inspection procedures, have been considered and are consistent with the RG.
 7. Staff positions and endorsements of standards are clear and unambiguous.
 8. The Implementation Section is correct and appropriate to the topic of the RG.
 9. The responses to public and stakeholder comments fully address the comments and are understandable.
- c. Administrative Aspects
 1. The RG is formatted and dated correctly, and reads smoothly.
 2. The RG references are publicly available and properly formatted.
 3. ADAMS accession numbers are included with references whenever possible.
 4. The supporting documents (memos, transmittal sheets, Regulatory Analysis, etc.), are complete and agree with the discussion in the RG.

Once the RGDB project manager is satisfied with the guide package, the RGDB project manager works with the RGDB Regulatory Guide Specialist to prepare the review package and electronically distribute the concurrence package.

- 5.6.2 Routing the Review Package – Draft and final regulatory guides should receive internal review and concurrence before being released to the public. Draft regulatory guides are routed to the appropriate program offices and comments are resolved, then the draft guides are routed to the ACRS or ACMUI⁴ and the OGC before being issued for public comment. Routing of final regulatory guides is dependent upon the changes made to the guide in response to the comments.

4 Regulatory guides dealing with the medical uses of radioactive material in diagnosis and therapy should be reviewed by the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in lieu of the ACRS.

Special Committees (e.g., ACRS and ACMUI) are offered the opportunity to review the guide before issuance for public comment and again after all of the public comments have been addressed and the guide is ready for final publication. The ACRS has adopted internal procedures that state, in general, the ACRS need not review draft regulatory guides before issuing them for public comment unless the draft guides are new guides or support a proposed rule. The ACRS chooses the most significant guides to review before publication as final regulatory guides. The technical lead prepares all presentation materials, provides them to the RGDB, and makes the presentation. The RGDB provides coordination with the committees as needed.

In some cases, the draft regulatory guide may be sent to the regional offices and/or agreement state representatives for their review and comment. When sending draft regulatory guides and similar document for review and comment, the sender should put "ACTION REQUESTED" or similar wording in the header of the e-mail to alert the receiver that the e-mail may require action on their part.

An exception to obtaining internal review and concurrence prior to release to the public is where a preliminary draft RG is being issued for information only on regulations.gov and/or the NRC public website, to assist the NRC in developing a draft RG for comment. In such cases, concurrence need not be obtained, but the preliminary draft RG must be clearly marked as such, a cover page must be included as part of the file of the preliminary draft RG indicating the preliminary nature of the document, and the website must set forth the same disclaimer alerting the reader to the preliminary nature of the document.

If the draft regulatory guide undergoes substantive revision in response to the comments, then the final guide should be routed to the same offices and committees that performed the review of the draft guide. If the draft regulatory guide remains substantively unchanged after the comment period, then the final guide does not require a second review by the program offices and should only be sent to the ACRS and OGC for review before being issued for use. The technical lead is responsible for determining if the revisions are substantive.

- 5.6.3 Federal Register Notice – Publishing an announcement in the *Federal Register* provides official notice of a document's existence, content, and legal effect. Draft regulatory guides are announced with a federal register notice (FRN) to alert stakeholders and the general public of their opportunity to comment on the draft guide. The comment period is normally 60 days but can vary between 45 and 90 days. An FRN is also issued to announce the withdrawal of a regulatory guide or the issuing of a new or revised guide. [NOTE: FRNs are used to announce draft regulatory guides for publically available information and sensitive information (i.e. OUO-SRI and SGI only. No FRN is issued for guides containing classified information.)]

A format of the FRN is available on the RGDB [SharePoint site](#).

- 5.6.4 Comment Review – Following the comment period, the technical lead and RGDB project manager consider all comments received and prepare a document that includes all comments and the staff's responses. Both the RGDB project manager and the technical lead should review the comments and responses to verify that each staff response fully addresses the comment and clearly describes the corrective action or reason for non-

action on the part of the agency. If any public comments indicate the RG is a backfit, the RGDB PM should consult with OGC and consider referral of the comments to the NRC's Committee to Review Generic Requirements.

A template for comment responses is available on the RGDB [SharePoint site](#).

The technical lead makes any necessary changes in the regulatory guide and supporting documents and, in conjunction with the RGDB project manager, converts the draft guide to the final guide format. The revised set of documents is sent to the RGDB project manager who is responsible for assembling the final approval package and routing it to the appropriate offices for review, comments, and concurrence. Formal concurrence from the program offices on the final regulatory guide is not necessary if there are no substantive changes between the draft and final documents.

- 5.6.5 Final Technical Editing – After all comments are addressed and the guide is ready for release, the RGDB should perform a final technical editing of all documents to ensure appropriate consistency of presentation and content. Suggested changes should be reviewed by the technical lead before issuing the documents.
- 5.6.6 Sensitive Document Processing – Some regulatory guides contain sensitive information (i.e., OUO-SRI and SGI; classified information is excluded) that should not be release to the public. These guides require special handling and their processing should be done on a case-by-case basis.

The number, title, and sensitivity level of such documents may be released in an FRN and on the public web page. Classified documents (e.g., Confidential and higher) shall not be released in an FRN nor the RES web page. The technical lead shall be contacted regarding the release of such documents. To obtain sensitive documents, requests shall 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 shall be directed to the technical lead.

5.7 Publication of Final Regulatory Guide

- 5.7.1 Release of Final Document – The RGDB Program Analyst is responsible for preparing and issuing the final package for the guide. The final issuance package normally contains:
- a. A memorandum from the RGDB Branch Chief to the Branch Chief of the Rules, Announcement, and Directives Branch, Division of Administrative Services, RADB/DAS/ADM announcing the availability of the final guide and requesting publication of the FRN,
 - b. a draft FRN,
 - c. a memorandum to the Office of Congressional Affairs (OCA) transmitting the completed Congressional Review Act (CRA) forms,

- d. 3 copies of the completed CRA form, and
 - e. a copy of the final RG (publicly availability must be carefully determined).
- 5.7.2 Publication - The RGDB Program Analyst initiates the declaration of the FRN and the guide as “Official Agency Records;” coordinates electronic publishing with the Web Content Services Team in the Office of Information Services (OIS), Information Services Branch; provides the FRN to the RADB/DAS/ADM; transmits 3 copies of the CRA to the OCA; and subsequently verifies that the official agency records match the approved documents. (The process stops at this point for issuance of the final RG, for withdrawing a RG, and when the RG is sensitive.) If the RG is being issued in advance of the rule it implements, the web site should state the relationship to the rule and the effective date of the guidance. If the RG is sensitive it will not be available via the web site. The web site link will direct the reader to a memorandum indicating that the document is not publicly available due to its sensitivity. The Notice should follow the format in the Notice template (Attachment 5).
- 5.7.3 Late Comments – Comments received after the close of the comment period or after publication of the final regulatory guide should be reviewed by the technical lead and RGDB Project Manager. If the comments are substantive, the technical lead may opt to undertake another revision of the regulatory guide. If the comments are not substantive they should be retained in the ADAMS file for reference during the next review cycle of the guide.

6. PERFORMANCE MEASURES

Existing processes will be used to manage performance measures for regulatory guides. Specifically, activities for individual guides may be entered into the RES Operating Plan as appropriate. These activities will be assigned E-, O- or Division-level milestones in accordance with RES OI PRM-008, “RES Operating Plan.” Success of regulatory guide processing will be measured through the existing performance measurement processes outlined in the Operating Plan.

7. REFERENCES

U.S. Nuclear Regulatory Commission (NRC), "NRC Regulations Handbook," NUREG/BR-0053, Rev. 5, March 2001, is available at:
<http://www.internal.nrc.gov/NRC/NUREGS/BR0053/R5> .

NRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 4, September 2004, is available at:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/>.

NRC, "NRC Editorial Style Guide," NUREG-1379, Rev. 2, May 2009, is available at:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1379/r2/>.

NRC, U.S. NRC Management Directive and Handbook 6.5, "NRC Participation in the Development and Use of Consensus Standards," December 2011 available at:
<http://www.internal.nrc.gov/policy/directives/toc/md6.5.htm>

NRC, U.S. NRC Management Directive and Handbook 6.6, "Regulatory Guides," April 2011 available at: <http://www.internal.nrc.gov/policy/directives/toc/md6.6.htm>

NRC, U.S. NRC Management Directive and Handbook 8.4, "Management of Facility-Specific Backfitting and Information Collection," October 2004 available at:
http://www.internal.nrc.gov/ADM/DAS/cag/Management_Directives/md8.4.pdf

NRC, RES Office Instruction PRM-008, "RES Operating Plan," March 7, 2011, available at: <http://www.internal.nrc.gov/RES/policy/oi-Word-sources/oi-prm08-operating-plan-development.pdf>

NRC, SUNSI Policies and Procedures:
<http://www.internal.nrc.gov/RES/policy/sunsi/index.html>

NRC, U.S. NRC Management Directive 12.2, "NRC Classified Information Security Program," July 2006, available at:
http://www.internal.nrc.gov/ADM/DAS/cag/Management_Directives/md12.2.pdf

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NRC, U.S. NRC Management Directive 12.7, "NRC Safeguards Information Security Program," June 2008, available at:
http://www.internal.nrc.gov/ADM/DAS/cag/Management_Directives/md12.7.pdf

NRC, U.S. NRC Office Instruction PRM-001, "Process for New Work Requests: Responding to Informal Assistance, Research Assistance and User Need Requests," March 3, 2009. ADAMS Accession Number ML082610298,
<http://www.internal.nrc.gov/RES/policy/oi-Word-sources/oi-prm001-%20New%20Work%20Requests.pdf>

RES Office Instruction TEC-004
Attachment 1

Draft and Final Regulatory Guide Template

See ADAMS Accession No. ML13102A055
or go to the RGDB template page in [SharePoint](#).

RES Office Instruction TEC-004
Attachment 2

Standard Format and Content
Regulatory Guide Template
See

See ADAMS Accession No. ML071210010
or go to the RGDB [SharePoint](#) Website for Templates.

Instructions for Standard Format and Content guides:

1. Use the template for a DG (Attachment 1) or RG (Attachment 2), as appropriate, for Section A (Introduction).
2. Replace Section B (Discussion) with Section B, "STANDARD FORMAT AND CONTENT."

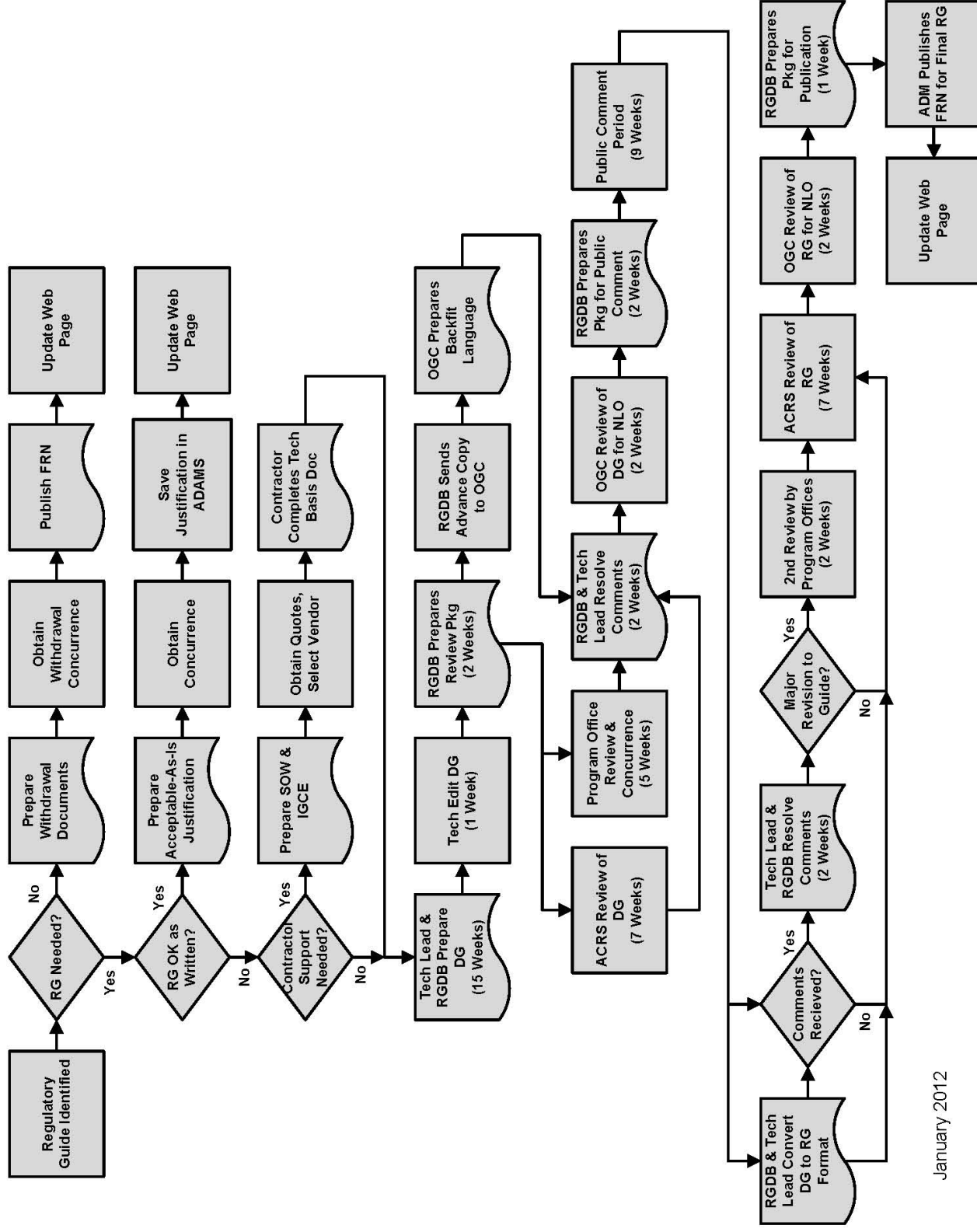
[The format of Section B – STANDARD FORMAT AND CONTENT should follow the intended format an applicant is expected to use in preparing an application. The Technical Lead should provide sufficient information for the reader to clearly understand what information is expected. All other sections should follow the DG/RG format.]

3. Rename Section D (Implementation) as Section C, "IMPLEMENTATION." Standard format and content guides will not have a Section D.

RES Office Instruction TEC-004
Attachment 3

Regulatory Guide Process Flow Chart
See
ADAMS Accession No. [ML121070155](#)

Regulatory Guide Development Process



RES Office Instruction TEC-004
Attachment 4

Sample Regulatory Analysis
See ADAMS Accession No. ML102390356
or go to the RGDB [SharePoint](#) Web site.

RES Office Instruction TEC-004 Attachment 5

Sample Notice for Regulatory Guides Containing Security-Related or Safeguards Information



NOTICE:

The document you have requested is not publicly available at this time.

The document may be Classified, contain Safeguards Information, or be marked "Official Use Only – Security-Related Information."

If you are an NRC applicant, licensee, or certificate holder and want to review this document, please contact your company's licensing manager, onsite NRC inspector, or NRC Project Manager to request a copy.

If you are not an NRC applicant, licensee, or certificate holder, and wish to obtain a copy of this document, please send a request to FOIA.Resource@nrc.gov, in accordance with NRC Management Directive 3.1, "Freedom of Information Act."

If you feel you have reached this page in error, please press the back button on your browser and try your selection again.