

POLICY ISSUE **(Information)**

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SECY-13-0031

FOR: The Commissioners

FROM: Brian W. Sheron, Director
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SUBJECT: STATUS OF REGULATORY GUIDE UPDATE PROGRAM

PURPOSE:

This paper provides the Commission with the annual status of the Regulatory Guide (RG) update program as directed in a memorandum from Chairman Diaz entitled, "Chairman Approval of an Acquisition for the Office of Nuclear Regulatory Research (RES), 'Technical Support for Revision of Regulatory Guides'," dated June 15, 2006. This paper updates the previous annual status report to the Commission in SECY-12-0049 dated March 30, 2012 (U.S. Nuclear Regulatory Commission's (NRC) Agencywide Documents Access and Management System Accession No. ML120200045). This paper contains no new commitments.

BACKGROUND:

Prior to the commencement of the RG update program in June 2006, NRC staff reviewed RGs on an infrequent basis and revised them as resources were available. Consequently, many of the RGs became outdated, resulting in decreased public confidence in the RGs and the increased potential for RGs to contain inadequate or incomplete guidance. The infrequent revision of the outdated RGs also resulted in some program offices developing alternate means of providing current guidance to licensees, certificate holders, applicants, and staff. These alternate means included NUREGs, Interim Staff Guidance (ISG), Branch Technical Positions (BTPs), Regulatory Issue Summaries (RISs), and similar documents.

In response to industry plans to submit a number of new applications, the staff initiated a Regulatory Guide Update Program so that new license applications could reflect the latest staff guidance. As part of the Regulatory Guide Update Program, the staff is reviewing the outdated RGs and, when practical, incorporating the guidance from various sources including NUREGs, ISGs, BTPs, RISs, and Codes and Standards. In addition to determining the usefulness of existing RGs and withdrawing RGs that are no longer relevant, the staff is addressing gaps in existing regulatory guidance by authoring new RGs to meet licensing and oversight needs in areas that have not previously been addressed.

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In a memorandum to former Chairman Klein dated July 31, 2006, the staff outlined a plan to update the RGs. The plan emphasized updating those RGs that directly impacted the support of new reactor applications (ADAMS Accession No. ML062120378). In the initial RG update plan, the library of RGs was divided into groups based on priority and available resources. The highest priority RGs were those needed to support new plant licensing; these were completed by March 31, 2007. The remaining RGs were prioritized based on the complexity of the update and the anticipated availability of technical staff. These RGs were scheduled to be completed between mid-2007 and the end of 2010. The RGs deferred the longest were typically those RGs that required significant time to develop a technical basis, depended on related activities such as rulemaking, or had difficulty, in light of competing demands, making technical staff available to revise them sooner. Since the initial plan was developed, the agency has continued to update the RGs considering their priority and available agency resources.

Purpose of RGs

The NRC uses RGs to inform the public and to provide guidance to applicants, licensees, and certificate holders of acceptable methods for complying with the Commission's rules and regulations. In addition, some RGs identify acceptable techniques to be used to evaluate specific problems or postulated accidents, while others provide standard formats that applicants and licensees can follow when submitting documents to the Commission. The use of the methods, processes, and formats identified in RGs can substantially reduce the time spent reviewing a license application or a license amendment.

Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Licensees, certificate holders, and applicants may propose alternate approaches; however, additional staff time may be required to review an alternate methodology. Most RGs are publicly available, but certain security RGs may be restricted if they contain safeguards information or sensitive unclassified non-safeguards information.

Summary of RG Development Process

The RG update program is an agencywide process involving the program offices, the Office of the General Counsel (OGC), the Advisory Committee on Reactor Safeguards (ACRS), and the Office of Administration (ADM). The first step in the creation or revision of a RG is normally the development of the technical basis by the responsible staff office. The staff uses the technical basis to develop a draft RG (also known as a draft regulatory guide or DG) for internal review and concurrence by the appropriate program offices and OGC. Once the internal review is completed, the draft RG is made publicly available in the ADAMS, and a notice is published in the *Federal Register* announcing the availability of the document and requesting public comments. The public comment period is typically 60 days. If staff receives public comments that warrant substantial changes in the original draft RG, the RG receives a second round of internal review and concurrence and may be re-issued for public comment. If little or no change is made in response to comments, the draft RG undergoes a second review by the authoring program office, the ACRS, and OGC. When this is completed, the Regulatory Guide is finalized, and the final document is released to the public, announced in the *Federal Register*, and sent to Congress.

With the exception of some security-related regulatory guides, the ACRS has the opportunity to review draft guides before they are issued for public comment and again before being issued as a final guide. Regulatory Guides applicable to medical licensees are provided to the Advisory Committee on the Medical Uses of Isotopes for their review and comment. In addition, the

Committee for Review of Generic Requirements (CRGR) is consulted for potential backfit concerns if necessary.

DISCUSSION:

In the annual status report in SECY-08-0105 dated July 17, 2008 (ADAMS Accession No. ML073340245), the staff informed the Commission of delays in the RG update program and the reasons for the delays, including changing priorities and revisions in staff resource allocations. The Regulatory Guide Development Branch (RGDB) in RES continues to work with the other program offices to review and update the RGs as quickly as possible. Table 1 summarizes the progress made by the staff in reviewing and completing the RGs originally identified to the Commission in 2006. As of December 2012, about 67 percent (284) of the total 426 RGs that were active at the start of the update program has been completed.

TABLE 1: Status of Regulatory Guides		
Category	RGs Completed in 2012	RGs to date
RGs Completed		
- RGs revised and issued	14	91
- RGs found to be acceptable as written	20	110
- RGs issued new	1	19
- RGs canceled ¹	19	19
- RGs withdrawn ²	5	45
Subtotal	59	284
RGs in active review or development		
- RGs in progress ³	-	40
- RGs under development ⁴	-	11
- RGs deferred ⁵	-	25
Subtotal		76
RGs delayed⁶	-	66
Total RGs in 2006 original program	-	426

Progress has been steady; averaging about 20 revised and issued guides (including new guides) per year since the start of the program. The number of “acceptable as written” guides

¹ RGs “Canceled” was proposed guidance from when the RG update program was initiated. Upon re-evaluation it was determined that they were not needed and ultimately were not issued.

² RGs “Withdrawn” do not include 66 RGs that were withdrawn prior to the start of the RG update program in 2006.

³ RGs “In Progress” are draft guides that have been delivered by the technical leads in NRC offices to RGDB for formal review by the program offices, OGC, and ACRS, and publication for public comment.

⁴ RGs “Under Development” are draft guides that are under active development by the technical leads in NRC offices and are expected to be delivered to RGDB in the near-term. .

⁵ RGs “Deferred” are draft guides that are tied to separate processes that are actively developing issues related to the RG. These activities include rulemaking, technical basis development by a contractor, or codes or standards under near-term development by standards development organizations.

⁶ RGs “Delayed” are guides that have not been reviewed for an update since 2006 because of insufficient resources and/or low priority.

has increased through the years due to implementation of the 5-year periodic review of RGs starting in 2012. As a result of higher-priority tasks, the agency has delayed completion of 66 RGs. Prioritization considers the needs of the stakeholders, the time and effort required to develop a technical basis for a revised guide, the availability of technical staff to prepare the revision, and coordination with related activities (e.g., rulemaking or consensus standards development).

Improving the Agency Regulatory Guidance Infrastructure

The staff has instituted several activities to further improve the effectiveness and efficiency of the RG program infrastructure. The staff has instituted an ongoing review program for RGs to help the agency to maintain its infrastructure. As reflected in Management Directive (MD) 6.6, "Regulatory Guides," this program requires a periodic review of all RGs (typically every 5 years) to ensure that the RGs continue to provide up-to-date information and guidance. Based on the results of the review, each program office decides whether or not to revise a RG. Many RGs are considered to be acceptable as-written based on the review. However, some higher-priority RGs, such as those that address American Society of Mechanical Engineers Code Cases, are updated more frequently than every 5 years. Each program office has identified points-of-contact to facilitate the RG review and update process with the RGDB. The RGDB conducts regular meetings with the program office contacts to coordinate reviews of RGs and to resolve issues in a timely manner.

In response to Commission direction in the Staff Requirements Memorandum for SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process" dated March 2, 2011 (ADAMS Accession No. ML110190027), the staff has revised the RG update process to improve collaboration among the program offices and to develop RGs and other supporting documentation in parallel with new and revised rulemaking activities. This coordination of effort helps to ensure that regulatory guidance accompanies the proposed rule in cases that a RG has been determined to be the appropriate regulatory guidance tool.

The RGDB staff is developing a process to collaborate with NRO (Standard Review Plan lead) to link the Standard Review Plan update program with the RG update program. This allows for updates to both regulatory documents at the same time, which results in resource savings and facilitates technical consistency across agency offices. The RGDB staff also participates in activities such as Fukushima Near-Term Task Force efforts and rulemakings for § 50.55a of Title 10 of the *Code of Federal Regulations*, "Codes and standards," to incorporate emerging guidance into its regulatory infrastructure where possible.

The staff is enhancing stakeholder involvement in its processes. For example, the staff is adding older versions of RGs on the external website for stakeholders that still reference them. A total of 173 documents have been profiled and put on the external website since mid-2012 (135 RGs and 38 DGs). In addition, external stakeholders are encouraged to provide input to the staff for consideration during its periodic review of RGs. To facilitate this input, the RGDB has established a new Web comment form⁷, available from the public NRC Library Web site. This input helps the agency prioritize its future updates to its regulatory infrastructure. The Web comment form supplements the normal agency process of publishing a notice in the *Federal Register* seeking comments on draft RGs, which are staff-proposed revisions to RGs. Links to all draft RGs that are open for comment are available from a "Documents for Comment" Web page.

⁷

Web comment form link <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html>

The NRC agreed with recommendations from the 2010 Integrated Regulatory Review Service Mission to further harmonize guidance in the NRC's Operating Reactor program with International Atomic Energy Agency's (IAEA) Safety Standards. The NRC is actively working to implement these recommendations as NRC regulations and RGs come up for periodic review. The NRC has established policy guidance in MD 6.6, which directs the staff to consider IAEA standards as a point of reference when drafting or revising regulatory documents and to consider direct endorsement of the IAEA standards where appropriate. As a result of this directive, NRC has published 13 new or revised RGs and issued for public comment 10 draft Regulatory Guides that harmonize with or reference IAEA safety standards that have been issued in the past 2 years.

The NRC staff has continued to refine language that clarifies the intent and use of the RGs. In a letter to OGC dated June 4, 2010 (ADAMS Accession No. ML101970353), the Nuclear Energy Institute (NEI) presented the opinion that publication of RGs does not comply with the agency's stated backfit policy because NRC does not provide backfit analyses when issuing interpretive guidance. The NRC responded in a letter dated July 14, 2010 (ADAMS Accession No. ML101960180), stating, in part, that OGC and NRC staff would examine the current backfit language accompanying the issuance of RGs and provide clarification as needed. The RGDB staff and OGC developed a set of templates to address backfit issues generically in the "Implementation" section of the RGs to address the comments. The NEI has provided further comments on the backfit language for specific RGs, and OGC and RES have continued to refine the "Implementation" language in response. The revised language has been incorporated into all appropriate documents associated with the RGs revision process.

Ongoing Reviews and Updates of Regulatory Guides

The RGDB coordinates the regulatory guide program agency wide. However, the priority for updating RGs is determined by the various NRC program offices based on assessment of the needs of their stakeholders and available staff resources. Staff in the program offices and RES serve as the technical leads for their respective guides and are responsible for developing the technical content and basis for the RGs.

Program Offices	Completed 2012	Active Review	Delayed Guides	Completed to Date	Guides Assigned
ADM	-	1	-	-	1
FSME	4	2	-	38	40
NMSS	8	7	47	35	89
NRO	6	11	1	21	33
NRR	8	10	9	53	73
NSIR	2	13	-	33	41
RES	14	59	10	94	163
TOTAL ⁸	42	103	67	274	440

Table 2 shows the status of all guides in the Regulatory Guide Update Program as of December 2012. It includes new guides (not part of the original program) and guides that have been revised multiple times since the start of the Regulatory Guide Update Program, but it does not

⁸ Total includes all RGs identified at the start of the Update Project as well as new RGs and RGs that have been revised multiple times during the life of the project.

include RGs withdrawn prior to the start of the program. Table 2 includes RGs that have been completed in 2012 (revised, declared acceptable as written, withdrawn, or issued new); RGs that are in the review process (in progress, under development, or deferred); delayed guides completed to date; and the total number of guides that are assigned per office.

The number of delayed RGs decreased from 146 guides in 2011 to 67 guides in 2012. A significant number (27) of the current delayed guides are related to material control and accounting systems (MC&A). The NMSS staff plans to rewrite and consolidate these guides into eight RGs, and a number of contractors completed the draft technical basis. The NMSS staff has initiated significant efforts to complete the technical basis and deliver the draft RGs to RGDB by the end of 2013. In addition, 19 guides are related to reprocessing facilities. These documents were developed in 1970s. Review of these documents is being delayed until resources are budgeted.

RESOURCES:

No additional budgetary resources are requested to complete this report.

This paper contains no new commitments and requests no additional resources. The staff performs the updates to RGs, with contractor support used where needed for technical basis development. Resources are already included in the fiscal year (FY) 2013 and FY 2014 budgets, primarily in the Operating Reactor and New Reactor business lines. Staff efforts are estimated to be 19 full-time equivalents (FTEs) per year in the Operating Reactor business line, 4 FTEs in the New Reactor business line, and 3 FTEs spread across the remaining business lines. In addition, the RG update program has budgeted \$340,000 in the FY 2013 Current Estimate and \$340,000 in the FY 2014 President's Budget in the Operating Reactor business line for contractor support. Resources for FY 2015 and beyond will be addressed in the Planning, Budgeting, and Performance Management process.

COORDINATION:

This Commission paper was reviewed by OGC and they have no legal objection. The Office of the Chief Financial Officer reviewed this paper for resource implications and has no objections.

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