

# POLICY ISSUE INFORMATION

March 30, 2012

SECY-12-0049

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 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-11-0046 dated March 31, 2011 (ML103430552). This paper contains no new commitments.

## BACKGROUND:

Prior to the RG update program, U.S. Nuclear Regulatory Commission (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 Consequently, many of the RGs became outdated, resulting in decreased public confidence in the RGs and increased potential of RGs containing inadequate or incomplete guidance. The infrequent revision of the outdated RGs also resulted in some program offices developing alternate means of providing current guidance to licensees, certificate holders, applicants, and staff.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. As part of the RG update program, the staff is reviewing the outdated RGs and, when practical, incorporating the guidance from various sources including NUREGs, ISGs, BTPs, and RISs. 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.

In a memorandum to the Chairman dated July 31, 2006, the staff outlined a plan to update the RGs within 3 years. The plan emphasized updating those RGs that directly impacted the support of new reactor applications (ML062120378).

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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 furthest into the future were typically those RGs that required a longer 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.

### **Purpose of RGs**

NRC uses RGs to inform the public and provide guidance to applicants, licensees, and certificate holders on 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 on a regulatory activity of interest to either NRC staff or licensees.

RGs 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 (SGI) or sensitive unclassified non-safeguards information (SUNSI).

### **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 an RG is normally the development of the technical basis by the responsible staff office or a contractor. 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. Once the internal review is completed, the draft RG is made publicly available in the Agencywide Documents Access and Management System (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, in response to the comments received, the original draft RG is substantially changed, it 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 RG undergoes a second review by the authoring program office, the ACRS, and OGC. When this is completed, 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, both the ACRS and OGC have two opportunities to review new or revised RGs, once before being issued as a draft 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 as necessary.

**DISCUSSION:**

In the annual status report in SECY 08-0105 dated July 17, 2008 (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 the Office of Nuclear Regulatory Research (RES) continues to work with the other program offices to address any delays as quickly as possible.

The following table (Table 1) summarizes the progress made by the staff in reviewing and revising the RGs originally identified to the Commission in 2006. The table does not include new guides or guides that were revised multiple times since the start of the Regulatory Guide Update Project.

<b>TABLE 1: ACCOMPLISHMENTS AS OF DECEMBER 2011</b>		
<b>Category</b>	<b>RGs in 2011</b>	<b>RGs to date</b>
RGs revised and issued	24	104
RGs found to be acceptable as written	38	53
RGs withdrawn*	2	40*
RGs in-process or deferred	-	182**
Total RGs (approximate)***	-	379***

\* Withdrawn RGs does not include 66 RGs withdrawn prior to the start of the update program.

\*\* Regulatory guides may be categorized as deferred if tied to an active rulemaking, the technical basis is under development, or for harmonization with codes or standards from external organizations.

\*\*\* Total does not include new RGs or RGs that have been revised multiple times since the start of the update program.

As of December 2011, a total of 197 of the original RGs have been revised, found to be acceptable-as-written, or withdrawn. This is approximately 52% of the total 379 RGs that were active at the start of the update program. Changes in staff assignments to support higher-priority tasks and a reprioritization of staff resources away from the regulatory guide update project have resulted in the deferral of 146 RGs. Completion dates for the deferred RGs are being scheduled according to the level of interest from stakeholders, the time required to develop and properly document the revised technical basis, the availability of technical staff to prepare the revision, and coordination with related activities (e.g., rulemaking or consensus standards development). The deferral of these RGs caused the completion of the regulatory guide update project to extend beyond the originally anticipated time frame.

Members of the RGDB periodically meet with key members of each program office to reassess the remaining RGs and develop a prioritized schedule based on the technical and regulatory issues to be addressed, the impact on stakeholders, and the availability of resources. Each program office has identified specific individuals to serve as the point-of-contact and to assist with the RG update process. The points-of-contact for the Offices of Nuclear Reactor Regulation (NRR) and New Reactors (NRO) routinely participate in the RGDB weekly staff meeting which helps resolve any issues or concerns in a timely manner. The RGDB staff works with the program offices to review and update the deferred RGs. If suitable, the guides are declared "Acceptable-As-Written" and entered into the continuous maintenance program.

## Continuous Maintenance Program

The staff is working to complete the updating of all of the RGs identified in the RES memorandum to the Chairman dated June 1, 2006, and to finalize all of the new RGs identified since the initiation of this project. In addition to completing the RGs under the original program, the RGDB staff has instituted a continuous maintenance review program for RGs that have been revised or found to be acceptable-as-written. This program provides for periodic review of all RGs to ensure they continue to provide updated and acceptable guidance and accurate information. Most of the RGs in the continuous maintenance program are scheduled to be reviewed every 5 years. Some RGs, such as those that address American Society of Mechanical Engineers Code Cases, are updated more frequently. Progress on this effort will be included in the annual RG status update provided to the Commission.

## Distribution of Regulatory Guides

The priority for updated RGs is determined by the needs of internal and external stakeholders in various areas of the nuclear industry. While the RGDB coordinates the overall regulatory guide update program, the various NRC program offices assess the needs of stakeholders on an ongoing basis, and serve as the technical leads for their respective guides.

The following table (Table 2) shows the status of all guides in the regulatory guide update program (both original and maintenance programs) as of December 2011. Table 2 includes new guides and guides that have been revised multiple times since the start of the Regulatory Guide Update Project but it does not include RG withdrawn prior to the start of the project.

<b>Program Office</b>	<b>Completed</b>	<b>In-Process</b>	<b>Deferred</b>	<b>Total</b>
ADM	-	1	-	1
FSME	31	3	5	39
NMSS	28	4	58	90
NRO	10	8	7	25
NRR	46	6	23	75
NSIR	29	10	1	40
RES	80	30	52	162
<b>TOTAL*</b>	<b>224*</b>	<b>62*</b>	<b>146</b>	<b>432*</b>

Completed – RGs that are new, updated, withdrawn, or found to be acceptable-as-written

In-Process – RGs currently being revised or reviewed by the RGDB, program office, ACRS, or OGC

Deferred – RGs not being worked on for a variety of reasons

\* 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.

## Improvements to the RG Program

The RG update process averages about 11 months from development of the technical basis to release of the final guide. In an effort to streamline this process, the ACRS has agreed to focus on draft guides that are either new guides or tied to an active rulemaking, and allow draft guides that are revisions to existing RGs to be issued for public comment without formal review from the ACRS. This improvement should reduce the time required to update a RG by 6 weeks or more. The RGDB staff continues to work with other review groups to expedite the internal RG review and concurrence process.

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 (ML110190027), the staff has revised the RG update process to improve collaboration among the program offices to develop RGs and other supporting documentation in parallel with new and revised rulemaking activities. This coordination of effort helps ensure that internal reviewers as well as external stakeholders will be able to review the proposed rule and the regulatory guidance at the same time.

### **Harmonizing Codes and Standards**

The staff is working to improve its process for harmonizing RGs with consensus standards and international standards. This is consistent with the findings of the International Atomic Energy Agency (IAEA) Integrated Regulatory Review Service (IRRS) mission to the U.S. in October 2010. Harmonization is being implemented in three ways. First, the staff issued Management Directive (MD) 6.6, "Regulatory Guides" in April 2011 to describe the need for harmonization with international standards and promote better understanding and consistency of the RG development process. Second, MD 6.5, "NRC Participation in the Development and Use of Consensus Standards" was revised and issued in December 2011 to better describe the staff's participation in the development of consensus standards, as well as NRC use of consensus standards. And third, the staff is a key participant in the Nuclear Energy Standards Coordination Collaborative (NESCC), a joint initiative of the NRC, American National Standards Institute (ANSI), National Institute of Standards and Technology (NIST), and the Department of Energy (DOE), to facilitate and coordinate standards to meet the needs of the nuclear industry. As part of the NESCC, the NRC is supporting the development of a database that will show the interconnection of NRC regulations and guidance documents with national and international standards developed by ANSI, NIST, American Society of Mechanical Engineers, Institute of Electrical and Electronics Engineers, and similar national and international organizations. This multi-organizational database will be usable by both NRC and industry and should improve the NRC staff's ability to identify applicable consensus and international standards.

### **Backfit and Regulatory Guidance**

The NRC staff is working to develop language that clarifies the intent and use of the RGs. In a letter to OGC dated June 4, 2010 (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. NRC responded in a letter dated July 14, 2010 (ML101960180), stating, in part, that OGC and NRC staff would examine the current backfitting language accompanying the issuance of RGs and provide clarification as needed. The RGDB staff and OGC worked for several months to revise the "Implementation" section of the RGs to resolve the issue. The CRGR reviewed and approved new text for the standard backfit language to be included in the "Implementation" section of revised RGs during a June 2011 meeting. NEI provided further comments on the revised language as it applied to new plants and, in response, OGC and RES are jointly evaluating the desirability of additional changes to the "Implementation" language. In addition, OGC believes that backfitting and issue finality matters associated with issuance of the RGs should be provided in the *Federal Register* notices announcing the draft RGs for comment, and in final form for use. The OGC is currently determining the best approach for developing that language.

RESOURCES:

This paper contains no new commitments and requests no additional resources. The staff performs most of the updates to RGs with contractor support used where needed for technical basis development. Resources are already included in the fiscal year (FY) 2012 and FY 2013 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. Additionally, the RG update program has budgeted \$266,000 in the FY 2012 Current Estimate and \$275,000 in the FY 2013 President's Budget in the Operating Reactor business line for contractor support. Resources for FY 2014 and beyond will be addressed in the Planning, Budgeting, and Performance Management process.

COORDINATION:

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

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