



## **POLICY ISSUE** **(Information)**

September 26, 2019

SECY-19-0094

FOR: The Commissioners

FROM: Margaret M. Doane  
Executive Director for Operations

SUBJECT: ANALYSIS OF THE FREQUENCY FOR UPDATING REGULATORY  
GUIDANCE

### PURPOSE:

The purpose of this paper is to inform the Commission of the results from the staff's analysis of the frequency for updating agency regulatory guidance documents. This paper does not include any new staff commitments.

### BACKGROUND:

Staff Requirements Memorandum M180118, "Briefing on Strategic Programmatic Overview of the Decommissioning and Low-Level Waste and Spent Fuel Storage and Transportation Business Lines," dated February 1, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18032A209), directed the U.S. Nuclear Regulatory Commission (NRC) staff to "look at the frequency for updating guidance documents, and consider how best to balance the value of incorporating lessons learned in periodic updates with maintaining the stability of the program, as well as consideration of the resources required from both staff and stakeholders. Staff should inform the Commission of the results of this analysis."

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Subsequently, the Executive Director for Operations issued a tasking memorandum titled, "U.S. Nuclear Regulatory Commission Guidance Update Frequency Tasking," dated August 9, 2018 (ADAMS Accession No. ML18218A354 (not publicly available)), that directed the staff to form a working group (WG) representing the NRC's program offices (i.e., the Offices of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, New Reactors, Nuclear Security and Incident Response, and Nuclear Regulatory Research) to address the Commission's information request. The staff's analysis and the results are summarized and discussed below.

#### DISCUSSION:

The WG initiated its analysis of the frequency of updating the agency's regulatory guidance by identifying the drivers for the updates of various types of regulatory guidance. The WG found that the need to update guidance is traditionally driven by several categories of activities, including the following:

- Commission direction, including rulemakings;
- licensing activities (e.g., precedents set in licensing activities; lessons learned from operating experience; lessons learned from responses to generic communications; incorporation of temporary guidance, such as branch technical positions and interim staff guidance; and lessons learned from relief requests);
- inspection activities (e.g., lessons learned from operating experience, inspector feedback, external stakeholder input from frequently asked questions);
- advances in technology (e.g., as described in NUREG-series reports and industry technical literature); and
- industry demands and inputs (e.g., white papers, Nuclear Energy Institute documents, Electric Power Research Institute reports, industry or stakeholder requests and comments, topical reports, changes to the Standard Technical Specifications, new or revised consensus standards).

In addition, there have been other drivers external to the agency that initiated changes to guidance, such as preparations for new reactor reviews in 2007, security enhancements following the terrorist attacks on September 11, 2001, and lessons learned from the March 11, 2011, accident at the Fukushima Dai-ichi nuclear power plant.

The WG then identified the frequency of updates for various types of guidance documents, as practiced by the staff. The WG focused its efforts on those that are frequently used in licensing and inspections of various types of facilities and applicants.<sup>1</sup> The WG cataloged the inventory of documents, the frequency of scheduled updates, the governing instructions, and the basis for changes to the update frequency. The enclosure, "Summary of Regulatory Guidance Update Frequency," summarizes this information.

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<sup>1</sup> In determining which guidance documents to include in this task, the WG applied experience related to the definition of "rule" from the Congressional Review Act (CRA) (5 U.S.C. §§ 801–808) as it pertains to any "agency statement of general applicability ... and future effect designed to implement, interpret, or prescribe law or policy." The WG did not include all documents that would be covered by the CRA's definition of rule because the WG did not consider some to be commonly used for regulatory guidance (e.g., final rules, NRC policy statements).

The WG assessed the frequency of updates in the governing instructions for the associated guidance documents, the benefits of updates to stakeholders, the resource implications for the updates, and the staff's approach for considering whether to update its guidance. The WG found that, while the staff engages in ongoing reviews of its guidance, it has flexibility to decide whether and when an update is needed. In particular, the WG observed that there is no overall agency directive that specifies the frequency of reviews and updates for all guidance documents. While many of the individual guidance documents have governing instructions, they may not specify the frequency for reviews or updates.

The staff's review of guidance includes consideration of additional burdens that may result from updates. The potential for additional burdens on licensees is addressed in two ways. First, licensee adoption of updated guidance is voluntary unless the staff takes additional action in compliance with the backfitting regulations and policy and the NRC's forward fitting policy. The WG did not attempt to assess the resources that licensees may need to voluntarily adopt updated guidance. Second, NRC policy for updating guidance provides external stakeholders an opportunity to provide comments, including on the potential for additional burden. The staff notes that updates to guidance often provide greater flexibility, particularly updates driven by advances in technology. On the other hand, if guidance is not updated, but the issue arises in a license application review, the staff considers whether the issue is directly related to the application and essential to the staff's safety determination, in accordance with agency procedures for backfitting and forward fitting. A determination that the issue should be addressed as part of the staff's review could cause delays in the review.

The WG found that establishing clear and comprehensive guidance in updated guidance documents results in a more effective and efficient licensing review process, which can significantly benefit the agency and external stakeholders. The quality and completeness of licensee submittals are improved, reducing the need for and number of requests for additional information (RAIs) and saving resources for both the staff and applicants. Fewer RAIs may also result in an overall improvement in licensing review timeliness. Clear guidance also enhances regulatory predictability during inspections of facilities. In addition, updates help to manage and transfer knowledge among industry, the public, and NRC staff, which is important in light of personnel turnover. Capturing this knowledge can shorten the time needed for future licensing reviews and make the agency more agile in responding to new or different applications. Guidance updates enhance reliability and regulatory predictability for external stakeholders and reduce agency enterprise risk from both a technical and regulatory perspective.

The WG determined that a significant factor in determining the frequency of updates is the availability of staff resources. Specifically, guidance updates have traditionally been prioritized lower than many other staff functions (e.g., rulemaking, licensing, inspection, enforcement), and fewer available resources have resulted in less frequent updates. Although the staff does not explicitly track the resources necessary to update all types of guidance documents in the NRC program offices (summarized in the enclosure), the WG believes that it can be a sizable effort, which includes functions such as developing a technical basis, updating the guidance, conducting public meetings and resolving comments, and writing safety evaluation reports. As a result, the availability of staff resources impacts the predictability and timeliness of updates to guidance.

The WG believed that not having a consistent and documented approach for assessing whether and when to update all of the types of guidance documents discussed in the enclosure can affect regulatory program stability. The WG concluded that having an effective project management system improved the consistency of updates and enhanced regulatory program

stability. The WG further concluded that periodic reviews of all types of guidance, similar to the process used for regulatory guides, would also enhance consistency and stability. The periodic reviews provide a flexible approach for each type of guidance document that would allow the program offices to determine whether an update is appropriate. Such reviews would be routinely informed by a wide range of activities as discussed above, and these activities would be a major factor when determining the frequency for updates.

For regulatory guides, the staff records the decision to update the document and, unless the review contains sensitive information, makes the review available to internal and external stakeholders on the NRC's Web site, which the WG considers to be a best practice. Whether or not the staff decides an update is appropriate, documenting the results of a review can reduce the enterprise risk of outdated infrastructure, capture knowledge of the issues, identify resource requirements, and improve transparency for internal and external stakeholders. The WG concluded that effective project management of guidance documents, coupled with the use of periodic reviews to inform the need for guidance updates, can appropriately balance maintenance of program stability with stakeholder impacts and resources.

#### CONCLUSIONS:

The staff concluded that the drivers for the various types of regulatory guidance contribute significantly to the frequency of updating the guidance, and that the NRC does not have a specified frequency of updating all guidance documents. Nonetheless, the staff believes that updates to guidance are necessary for enhancing efficient and effective licensing and oversight processes and for informing both internal and external stakeholders. The staff has traditionally updated its guidance in response to various drivers, but a limiting factor for updates is the availability of staff resources, and an important factor in ensuring consistent updates is effective project management. The staff concludes that the NRC needs to continue to periodically review its guidance to appropriately balance the value of incorporating lessons learned in periodic updates with maintaining the stability of the program, as well as consideration of the resources required from both staff and stakeholders. The staff plans to develop appropriate procedures to implement a more consistent approach and incorporate best practices for reviews and updates of agency regulatory guidance.

#### COORDINATION:

The Office of the General Counsel has reviewed this package and has no legal objection.



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for Operations

Enclosure:  
Summary of Regulatory Guidance  
Update Frequency

SUBJECT: ANALYSIS OF THE FREQUENCY FOR UPDATING REGULATORY GUIDANCE  
 DATED: SEPTEMBER 26, 2019

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**ADAMS Accession No.: Pkg. ML19151A557      SRM-M180118      \*via email**

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