

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

| MD 6.3 | THE RULEMAKING PROCESS | DT-19-08 |
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| <i>Approved By:</i> | Patricia K. Holahan, Director, Division of Rulemaking Office of Nuclear Material Safety and Safeguards | |
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| <i>Issuing Office:</i> | Office of Nuclear Material Safety and Safeguards Regulatory Analysis and Rulemaking Support Branch | |
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| EXECUTIVE SUMMARY | | |
| <p>Management Directive (MD) 6.3 is revised to incorporate the final rulemaking plan template as approved in SRM-COMSECY-16-0029 (ML19030A940). Additional information on how to use this Commission-approved template is available online at "The NRC Rulemaker" Web site (internal). This focused change affects only the MD 6.3 references section of this directive and the rulemaking plan section of this handbook. Broken links have been corrected throughout.</p> | | |

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For updates or revisions to policies contained in this MD that were issued after the MD was signed, please see the Yellow Announcement to Management Directive index ([YA-to-MD index](#)).

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I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission to develop high quality rules that are consistent with the requirements of all applicable laws and regulations and to conduct rulemakings using a process that is effective, efficient, and open. In all aspects of its rulemaking, the NRC is committed to making public participation as meaningful as possible.

II. OBJECTIVES

- The NRC gives the public and other interested stakeholders the opportunity for meaningful participation in rulemaking proceedings, including public meetings and opportunities for comment.

- The NRC gives Agreement States and Federally recognized Tribes the opportunity to comment on applicable preliminary rulemaking actions.
- Offices receive Commission approval before initiating a rulemaking action, unless an exception exists.
- Offices establish and meet schedules for rulemaking actions.
- Offices coordinate with each other so that staff resources are used efficiently during the development of rulemaking products.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Commission

1. Rulemaking authority for the NRC is vested in the Commission by the Atomic Energy Act of 1954, as amended (42 U.S.C. 2201). The Commission establishes rules and regulations to govern the civilian uses of nuclear materials and facilities in order to protect public health and safety, promote the common defense and security, and protect the environment.
2. The Commission is responsible for the following:
 - (a) Directing the initiation and prioritization of rulemaking activities, including through the review, approval, and denial of rulemaking plans;
 - (b) Approving, modifying, or denying each advance notice of proposed rulemaking, proposed rule (including supplemental proposed rules), final rule (including direct final rules and interim final rules), and action on a petition for rulemaking;
 - (c) Approving, modifying, or denying each issuance and revision to Commission policy statements, including the enforcement policy; and
 - (d) Ensuring that the NRC's regulations comply with the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), and the Congressional Review Act (5 U.S.C. 801-808).
3. The Commission has exclusive authority to issue rules concerning the following:
 - (a) A significant question of policy;
 - (b) Title 10 of the *Code of Federal Regulations* (10 CFR) Part 7, "Advisory Committees;" and 10 CFR Part 9, Subpart C, "Government in the Sunshine Act Regulations," concerning matters of policy; and
 - (c) Issuance and revision of policy statements.

4. A rule involves a significant question of policy and must be submitted to the Commission for approval and issuance if it—
 - (a) Represents a major change in existing Commission policy,
 - (b) Addresses a major new issue, or
 - (c) Would result in a major commitment of resources by a class of licensee.
5. In determining whether a rule involves a significant question of policy, the technical lead office for the rulemaking action should consider the following:
 - (a) The impact of the action on licensees and the public;
 - (b) The degree of controversy that could be associated with the action;
 - (c) The existence of significant public health, safety, environmental, common defense and security, or safeguards issues;
 - (d) The applicability of existing precedent; and
 - (e) Resources that will be required for implementation.
6. Delegations of Authority to the Executive Director for Operations (EDO)

The Commission has delegated the following rulemaking authority to the EDO.

 - (a) The Commission has delegated to the EDO the authority to ensure that the NRC's rules comply with the Regulatory Flexibility Act, Paperwork Reduction Act, and the Congressional Review Act (47 FR 11816; March 19, 1982; 50 FR 42145; October 18, 1985). The EDO may redelegate this authority, as appropriate.
 - (b) The Commission has delegated to the EDO the authority to initiate and issue rules explicitly delegated to the staff. The Commission specifically delegated to the staff the incorporation by reference of American Society of Mechanical Engineers (ASME) *Boiler and Pressure Vessel Code* (BPV Code) and *Operation and Maintenance of Nuclear Power Plants* (OM Code) in 10 CFR 50.55a, "Codes and standards"; revisions to certificate-of-compliance rules; and rules that make corrections or administrative changes. Therefore, these rules are exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#) and [SECY-10-0016](#)).
 - (c) The Commission has delegated to the EDO (47 FR 11816, March 19, 1982; 50 FR 42145, October 18, 1985) the authority to initiate and issue certain rulemaking actions that do not raise a significant policy issue or are corrective in nature or result in a rule of a minor, corrective, or nonpolicy nature that does not substantially modify existing precedent (i.e., the incorporation of ASME Code cases, certificates of compliance, and statutorily mandated rules

where there is no discretion). Therefore, these rules are exempt from the rulemaking plan requirement (see [SRM-COMSECY-17-0002](#), [SRM-SECY-15-0129](#), and [SECY-10-0016](#)).

- (d) The Commission has delegated to the EDO the authority to initiate and issue administrative rulemakings (such as updating addresses and phone numbers and correcting typographical errors). These administrative rules are exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#) and [SECY-15-0129](#)).

7. Delegations of Authority to the Chief Financial Officer (CFO)

The Commission has delegated certain rulemaking authority to the CFO.

- (a) The Commission has delegated to the CFO ([ML071830096](#)) the authority to initiate and issue a rule that revises the annual fee regulations in—
 - (i) 10 CFR Part 170, “Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended,” and
 - (ii) 10 CFR Part 171, “Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Material Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.”

Note: Because it is explicitly delegated to the staff, the annual fee rule is exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#)).

- (b) The Commission has delegated to the Chief Financial Officer (CFO) the authority to develop and promulgate rules needed to carry out the CFO’s responsibilities. The CFO’s rulemaking authority does not extend to the promulgation of a proposed or final rule that involves a significant question of policy ([ML022260125](#)). Policy matters associated with the fee rules are resolved through separate Commission direction before they are included in rulemaking. (See Section III.A.4 and Section III.A.5 of this directive for a description of what constitutes “significant questions of policy.”)
- (c) For any rule that is issued by the CFO, the CFO is required to obtain the EDO’s concurrence, a determination from the Office of the General Counsel (OGC) of no legal objection to the action, and, as appropriate, concurrence by the Chief Information Officer (CIO) ([ML022260125](#)).
- (d) If a rulemaking will be issued under the authority delegated to the CFO, then the Commission further delegates to the CFO the authority to ensure that the rule complies with the Regulatory Flexibility Act and the Congressional Review Act.

B. Executive Director for Operations (EDO)

The EDO has the following authority:

1. In accordance with Management Directive (MD) 9.17, "Organization and Functions of the Office of the Executive Director for Operations," the EDO ensures that all rulemaking is conducted in accordance with general policy guidance from the Commission.
2. As stated in Section III.A.6 of this directive, the Commission has delegated to the EDO the authority to initiate and issue certain rulemakings.

Note: The Commission's delegation to the EDO includes the authority to issue preliminary proposed, draft proposed, and final versions of these rulemaking actions. See Exhibit 1 of this handbook for clarification of the terms "preliminary proposed," "draft proposed," and "final."

3. Before promulgating a proposed or final rule within the scope of Section III.A.6 of this directive that modifies 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," the EDO obtains the determination of no legal objection from OGC and concurrence from the Office of Commission Appellate Adjudication and the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel. If any office fails to concur, the proposed action is to be referred to the Commission.
4. The EDO monitors the progress of rulemakings that are within the scope of the EDO's signature and/or concurrence authority. For these rulemakings, the EDO resolves issues preventing office concurrence.
5. The EDO monitors the progress of petitions for rulemaking.
6. After the Commission approves the rulemaking plan, the EDO may release preliminary proposed rule language and preliminary regulatory basis documents for public review or comment. The staff must notify the Commission before publicly releasing preliminary proposed rule language for a proposed rule that has not been submitted to the Commission.
 - (a) The EDO may redelegate this authority, as appropriate, and has re delegated it to—
 - (i) The Director of the Office of Nuclear Material Safety and Safeguards (NMSS),
 - (ii) The Director of the Office of New Reactors (NRO), and
 - (iii) The Director of the Office of Nuclear Reactor Regulation (NRR).
 - (b) The Directors of NMSS, NRO, and NRR may redelegate this authority to the appropriate staff level.

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7. The EDO holds public interactions to obtain external stakeholder input.
- (a) The EDO holds public meetings, workshops, and Webinars to obtain informal public input. These interactions may include releasing preliminary versions of a regulatory basis, rule language, or statement of considerations for discussion at the meeting, following the provisions of Section III.B.6 of this directive.
- Note: The NRC will hold public meetings in accordance with MD 3.5, "Attendance at NRC Staff Sponsored Meetings," and the NRC's 2002 policy statement on enhancing public participation in NRC meetings (67 FR 36920; May 28, 2002). Formal notice and comment for proposed rules will be conducted in accordance with the Administrative Procedure Act and NRC requirements and procedures.
- (b) The EDO ensures that rules are compliant with the Regulatory Flexibility Act, Paperwork Reduction Act, and the Congressional Review Act.
- (c) The EDO may redelegate the authority to hold public interactions and obtain external stakeholder input, as appropriate, and has re delegated it to—
- (i) The Director of NMSS,
 - (ii) The Director of NRO, and
 - (iii) The Director of NRR.
- (d) The Directors of NMSS, NRO, and NRR may redelegate this authority to the appropriate staff level.
8. The EDO delegates to the Director of NRR the authority to approve the following:
- All rulemaking packages and associated Commission memoranda containing amendments to 10 CFR 50.55a, "Codes and Standards," pertaining to the incorporation by reference of the ASME BPV and OM Codes.
- (a) This delegation of authority only applies to recurring 10 CFR 50.55a rulemakings pertaining to Section III and Section XI of the ASME BPV Code, the ASME OM Code, and the related regulatory guides that approve or disapprove ASME Code cases (see [SECY-10-0016](#)). These rulemakings are exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#)).
- (b) The applicability will not extend to 10 CFR 50.55a(h), in which the NRC incorporates by reference Institute of Electrical and Electronics Engineers (IEEE) Standard 603, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations," pertaining to protection and safety systems.

- (c) The delegation of authority applies only to rulemakings that represent the updating of basic codes and standards previously approved by the Commission for incorporation by reference. In exercising this rulemaking authority, the Director of NRR shall seek the concurrences or the determination of no legal objection of all applicable NRC offices.
 - (d) The Director of NRR may not redelegate this authority.
 - (e) For additional details, see the February 5, 2010, memorandum from the EDO to the Director of NRR ([ML091730349](#)), [SECY-10-0016](#), and [SRM-SECY-15-0129](#).
9. The EDO designates NRO as the lead office for design certification and other rulemaking activities related to new and advanced reactors (see [COMSECY-09-0003](#) and [SRM-COMSECY-009-0003](#)).
 10. As delegated by the Commission, the EDO ensures that the NRC's regulations comply with the Regulatory Flexibility Act, the Paperwork Reduction Act, and the Congressional Review Act.
 11. The EDO redelegates to the Director of NMSS the authority to issue administrative rulemakings (for administrative changes, such as updating addresses and phone numbers and correcting typographical errors). These administrative rules are exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#)).
 12. Upon staff completion of a rulemaking action, the EDO—
 - (a) Transmits the rule for Commission action or notifies the Commission of the intent to issue a rule under the authority of the EDO.
 - (b) If necessary, returns the rule to the staff for modification or resolution of questions within a specified schedule.
 13. The EDO concurs on rules developed by OIP.
 14. The EDO concurs on rules developed by OGC, if appropriate.

C. Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration, and Human Capital Programs (DEDM)

Provides central coordination for the NRC rulemaking program by overseeing the rulemaking process for the EDO; ensures consistency in methods used to develop and issue rules; and oversees the development of rulemaking reports and their submission to the EDO.

D. Chairs, Advisory Committees

As appropriate, lead Committee review of rules of technical or safety significance and provide comments on rulemaking documents. The Advisory Committee on the Medical Uses of Isotopes provides comments to the Division of Materials Safety, Security, State, and Tribal Programs, NMSS. The Advisory Committee on Reactor Safeguards provides comments to the Commission. In both cases, the technical lead office receives the comments as well.

E. Chair, Committee to Review Generic Requirements (CRGR)

As appropriate, leads CRGR review of rules that involve backfitting or violation of the issue finality provisions in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," or that meet other criteria identified by the CRGR and communicated to the Commission ([SECY-16-0064](#)) and as contained in the current CRGR charter and procedure. Provides comments to the technical lead office and the Division of Rulemaking (DRM), NMSS.

F. General Counsel (GC)

1. Conducts rulemakings and submits them to the Commission or the EDO for review and approval.
2. Holds public interactions to obtain external stakeholder input.
 - (a) Holds public meetings, workshops, and Webinars to obtain informal public input. These interactions may include releasing preliminary versions of a regulatory basis, rule language, or statement of considerations for discussion at the meeting, following the provisions of Section III.B.6 of this directive.
 - (b) Ensures that rules are compliant with the Regulatory Flexibility Act, Paperwork Reduction Act, and the Congressional Review Act.
3. Designates a staff attorney to provide legal advice and support for each rulemaking action, which may include participation in a working group.
4. Analyzes each request for a rulemaking action for legal sufficiency.
5. Reviews and makes a determination of no legal objection on rulemaking plans before they are submitted to the Commission.
6. Reviews rulemaking actions to ensure compliance and consistency with the following:
 - (a) OGC office instructions;
 - (b) Applicable laws and regulations; and

- (c) Current rules and other authoritative statements of NRC policy, including consistency in the use of wording, terminology, definitions, backfitting, issue finality, and risk standards.
- 7. Forwards review comments on rulemaking documents to the NMSS rulemaking project manager (RM PM) or the Commission.
- 8. Consults with DRM on the processing of petitions for rulemaking, including determining whether the petition includes the information required in 10 CFR 2.802.
- 9. Determines whether agency documents under review should be considered final rules that are subject to the process dictated in the Congressional Review Act.

G. Inspector General (IG)

- 1. Reviews rules and regulations in conducting audits, investigations, and regulatory reviews.
- 2. Determines whether a rulemaking action should be reviewed by the Office of the Inspector General (OIG) before it is submitted to the Commission. If applicable, the Inspector General (IG) may provide comments concerning—
 - (a) The impact of the rulemaking on the economy,
 - (b) The efficiency of programs and operations administered or financed by the NRC, and
 - (c) The prevention and detection of fraud and abuse in the administration of these programs and operations.

H. Chief Financial Officer (CFO)

- 1. The Commission has delegated to the CFO the authority to develop and issue any rule that is necessary to revise the annual fee regulations in 10 CFR Parts 170 and 171 ([ML071830096](#)).
- 2. The CFO's rulemaking authority does not extend to the promulgation of a proposed or final rule that involves a significant question of policy ([ML022260125](#)). (See Section III.A.4 and Section III.A.5 of this directive for a description of what constitutes "significant questions of policy.")
- 3. Reviews and concurs on rulemaking plans and any subsequent changes to a plan that have significant resource implications.
- 4. For each rule that is issued by the CFO, the CFO is required to obtain the EDO's concurrence and a determination from OGC of no legal objection to the action.

5. Forwards review comments on final rules to the PM within OCFO.
6. Recommends that the Commission approve or deny each petition for rulemaking that falls within the scope of rulemaking authority delegated to the CFO.
7. If a rulemaking will be issued under the authority delegated to the CFO, the CFO directs the preparation of the rulemaking package and all required supporting documents.
8. If a rulemaking will be issued under the authority delegated to the CFO, the CFO ensures that the rule complies with the Regulatory Flexibility Act, Paperwork Reduction Act, and the Congressional Review Act.

I. Director, Office of Congressional Affairs (OCA)

1. Keeps Congress fully and currently informed of NRC rulemaking actions.
2. Ensures that NRC staff is aware of the specific congressional committees that should receive notification of NRC rulemaking actions by a congressional letter.
3. Signs and transmits congressional letters and Congressional Review Act forms ([Form GAO-001](#)) to Congress and the Government Accountability Office (GAO) in order to notify Congress of NRC rulemaking actions in compliance with the Congressional Review Act.

J. Director, Office of International Programs (OIP)

Conducts rulemakings related to 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material," and submits them to the Commission or the EDO for review and approval.

K. Director, Office of Public Affairs (OPA)

1. Evaluates whether a press release is advisable for a rulemaking action and proposes press releases for consideration by the Chairman.
2. If a press release is advisable, designates an OPA representative to prepare a preliminary press release for comment and review by the technical lead office.
3. Publishes the press release at the appropriate stage(s) of the rulemaking process, following appropriate processes for press releases.

L. Office of the Secretary (SECY)

1. Dockets public comments on advance notices of proposed rulemaking, draft regulatory basis documents, proposed rules, and petitions for rulemaking. Forwards the comments to the RM PM in coordination with technical lead office for review and

consideration, and forwards the comments to DRM for posting on the Federal Government's rulemaking Web site, [Regulations.gov](https://www.regulations.gov).

2. Transmits the Commission's staff requirements memoranda (SRM) on rulemaking actions (e.g., rulemaking plans, proposed rules, and final rules) to the staff.
3. Unless approval authority is delegated to another office, SECY validates the Commission's approval of the following by signing the *Federal Register* notice (FRN):
 - (a) An advance notice of proposed rulemaking,
 - (b) A proposed rule,
 - (c) A supplemental proposed rule,
 - (d) A direct final rule,
 - (e) A final rule,
 - (f) Petition documents (letter and FRN), and
 - (g) Policy statements.
4. Prepares certified indexes for rulemaking dockets as requested by OGC to support litigation.
5. Approves staff requests for extension of rulemaking schedule tasks in the Commission tracking system, after receiving Commission approval where necessary.
6. Processes requests for comment period extensions for requests for public comment issued through FRNs signed by the Secretary of the Commission.

M. Director, Office of Nuclear Material Safety and Safeguards (NMSS), for Centralized Rulemaking Services

Responsible for the planning, development, documentation, tracking, reporting, and implementation of policies and procedures for the NRC's rulemaking functions in the reactor and materials business lines ([ML17040A503](https://www.nrc.gov/reading-rm/doc-collections/ml17040a503)); delegates execution of these functions to the Director, DRM, NMSS.

1. Conducts project management for rulemaking activities associated with operating and new reactors; the nuclear fuel cycle; use, transportation, storage, or disposal of nuclear materials and waste; nuclear security; and certain administrative requirements. Coordinates with the technical lead office, identified in Section III.N of this directive, to ensure the timely completion of rulemaking actions, as well as related guidance.
2. Prepares regulatory analyses for rules and other regulatory actions, and develops guidance on the regulatory analysis process and topics such as economic consequences and labor rates.

3. Responds to petitioners on petitions for rulemaking that are deemed deficient, as described in 10 CFR 2.803(b)(2).
4. Reviews rulemaking actions to ensure agency staff prepare rulemaking documents that comply with the following:
 - (a) The Congressional Review Act (5 U.S.C. 801-808);
 - (b) The Administrative Procedure Act of 1946 (5 U.S.C. 551 et seq.);
 - (c) The Federal Register Act of 1935 (44 U.S.C. Chapter 15);
 - (d) The requirements of the Office of the Federal Register (1 CFR, "General Provisions; and 1 CFR Chapter I, "Administrative Committee of the Federal Register");
 - (e) The Plain Writing Act of 2010 (Pub. L. 111-274);
 - (f) The Paperwork Reduction Act (44 U.S.C. 3501 et seq.); and
 - (g) The Regulatory Flexibility Act (5 U.S.C. 601 et seq.).
5. The EDO has delegated to the Director of NMSS the authority to issue administrative rulemakings (for administrative changes, such as updating addresses and phone numbers and correcting typographical errors) ([ML17040A503](#)). These administrative rules are exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#)). The Director of NMSS redelegates the authority to issue administrative rulemakings to the Chief, Regulatory Analysis and Rulemaking Support Branch (RASB).
6. In consultation with OGC, processes petitions for rulemaking. Processing a petition includes the following:
 - (a) Receiving the referred petition from SECY (see Section III.L of this directive);
 - (b) Determining whether the petition includes the information required in 10 CFR 2.802;
 - (c) Requesting that SECY docket the petition upon making the determination that the required information is included or preparing a letter to the petitioner for signature by the Director, NMSS, if the required information is not included (i.e., non-acceptance);
 - (d) Preparing a notice of docketing to be published in the *Federal Register*;
 - (e) Reviewing and analyzing issues raised in the petition and any public comments, as applicable;
 - (f) Leading working group and Petition Review Board meetings; and

- (g) Preparing the rulemaking plan for petitions when staff recommends initiating rulemaking in coordination with the technical lead office.
- 7. Ensures that the rulemaking actions are consistent with current regulations and other agency policy, including consistency in the use of wording, terminology, and definitions.

N. Directors, Office of Nuclear Material Safety and Safeguards (NMSS), Office of Nuclear Reactor Regulation (NRR), and Office of New Reactors (NRO), as Technical Lead Offices

NMSS, NRR, and NRO have been delegated rulemaking authority ([ML17040A503](#)). The office director in each respective office is responsible for the following:

1. Leads the development and execution of all rulemaking activities related to areas of responsibility, applies appropriate resources, and monitors rulemaking schedules to ensure that rules are developed in the timeframe specified by the Commission.
2. Designates an office representative to participate in an NRC working group, as appropriate.
3. Coordinates, through NMSS, interaction with Agreement States and Tribes for applicable rulemakings, including review of preliminary documents (e.g., rule plan).
4. Holds public interactions to obtain external stakeholder input.
 - (a) Holds public meetings, workshops, and Webinars to obtain informal public input. These interactions may include releasing preliminary versions of a regulatory basis, rule language, or statement of considerations for discussion at the meeting, following the provisions of Section III.B.6 of this directive.
 - (b) Ensures that rules are compliant with the Regulatory Flexibility Act, Paperwork Reduction Act, and Congressional Review Act.
5. Develops the rulemaking plan for Commission review and approval, including any required resources, in coordination with DRM.
6. Develops the draft regulatory basis and regulatory basis, in coordination with DRM, and approves it for transmittal to OEDO and the Commission before publication by DRM.
7. Leads the development of implementing guidance in accordance with MD 6.6, "Regulatory Guides," and [SRM-SECY-11-0032](#), "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process." Draft proposed or draft final guidance should be completed before forwarding the rule package to the Commission. Draft guidance should be developed and reviewed/concurred in parallel with the rule to enable the staff to meet this schedule. Exceptions (i.e., guidance not being available concurrent with the rule package) should be extremely rare and

should be approved by the technical lead office and communicated to OEDO and the Commission offices, as appropriate.

8. Provides final office-level approval of rulemaking documents (e.g., rulemaking plans, Notes to Commissioners' Assistants associated with regulatory basis documents, draft proposed rules, draft final rules) before transmitting them to OEDO.
9. Coordinates with DRM on schedules, resources, and management of rulemaking projects.
10. Raises potential policy issues to the Commission as early as practicable in the rulemaking process, especially in those instances where leadership is not able to resolve significant differences in approach.
11. Submits data to the Common Prioritization of Rulemaking (CPR) Working Group related to the prioritization of rulemakings within their business lines, as well as new rulemakings to be included and rulemakings to be discontinued. Coordinates with the CPR Working Group, which creates an integrated prioritization list for all NRC rulemakings.
12. Ensures the timely completion of rulemaking actions, as well as related guidance.
13. Coordinates rulemaking actions with other Federal Government agencies, when appropriate, or when this coordination is required by statute or regulation.
14. Coordinates with OPA to determine the appropriate public and media outreach, including whether a press release is appropriate; provides OPA with information sufficient to conduct the outreach.
15. Ensures that rulemaking documents are properly managed and archived in the Agencywide Documents Access and Management System (ADAMS).
16. Solicits stakeholder participation and comments at various stages of the rulemaking process.

O. Director, Office of Enforcement (OE)

1. Determines, in consultation with OGC, whether changes to the [NRC Enforcement Policy](#) are needed because of the rulemaking action and initiates a request for Commission approval of changes as appropriate.
2. Determines, in consultation with OGC, whether a rulemaking action requires the amendment of a "Criminal Penalties" section in Title 10 of the *Code of Federal Regulations*.

P. Chief Information Officer (CIO)

1. Reviews and forwards comments to the RM PM on the following to ensure that the information technology effects of the rulemaking have been adequately evaluated and addressed. Ensures compliance with the information collection requirements of the Paperwork Reduction Act and the agency's policies and procedures governing information management.
 - (a) Rulemaking plans,
 - (b) Proposed rules,
 - (c) Direct final rules, and
 - (d) Final rules.
2. The CIO has delegated the authority described in Section III.T.3 of this directive to the NRC Clearance Officer.

Q. Directors, Sponsoring Offices

Offices without delegated rulemaking authority (e.g., the Office of Nuclear Security and Incident Response) may sponsor a rulemaking activity. The director of the sponsoring office is responsible for the following:

1. Leads the development of the rulemaking plan and regulatory basis (draft and final versions), including any resource requirements.
2. Ensures that the rulemaking plan is reviewed and concurred on by offices impacted by the rulemaking and by DRM. Ensures that OGC provides a no legal objection determination on the rulemaking plan.
3. Raises potential policy issues to the Commission as early as practicable in the rulemaking process, especially in those instances where leadership is not able to resolve significant differences in approach.
4. Leads the development of implementing guidance in accordance with MD 6.6 and [SRM-SECY-11-0032](#). Draft proposed or draft final guidance should be completed before forwarding the rule package to the Commission. Draft guidance should be developed and reviewed/concurred in parallel with the rule to enable the staff to meet this schedule. Exceptions (i.e., guidance not being available concurrent with the rule package) should be extremely rare and should be approved by the technical lead office and communicated to OEDO and the Commission offices, as appropriate.
5. Designates an office representative to participate on the rulemaking working group and additional key supporting staff, as needed.
6. Participates in and contributes to internal and external meetings set up by DRM or the technical lead office.

7. Assists in drafting staff responses to public comments.
8. Reviews and provides office concurrence on rulemaking documents.
9. Coordinates with the technical lead office to ensure all responsibilities under Section III.N of this directive are executed.

R. Rulemaking Coordinating Committee (RCC)

1. The RCC is a standing interoffice group with representatives from OGC and the technical lead offices: NRO, NRR, and NMSS (chair). Other offices, including OCIO, NSIR, OIP, OCFO, and RES, regularly participate in RCC meetings.
2. The RCC's focus is to ensure consistency in methods used to develop and promulgate rules and to initiate and implement improvements to the rulemaking process.

S. Directors, Concurring Offices

1. Designate an office representative to review and provide comments on each rulemaking action.
 - (a) Indicate whether the representative is authorized to provide office concurrence while participating as a member of the working group.
 - (b) Designate other key staff, as necessary, to assist in developing documents necessary for the rulemaking.
2. Respond to the technical lead office with any questions or concerns regarding the rulemaking action.
3. Review rulemaking actions to ensure that they are technically sound and consistent with the authority and responsibility of the office.
4. Forward comments on rulemaking packages to the technical lead office and the RM PM.
5. Forward comments on rulemaking plans and draft technical bases to the technical lead office and the RM PM.

T. NRC Clearance Officer, Office of the Chief Information Officer (OCIO)

1. In accordance with MD 3.54, "NRC Information Collections Program," the NRC Clearance Officer reviews the following:
 - (a) Rulemaking plans,
 - (b) Proposed rules,
 - (c) Supplemental proposed rules,

- (d) Direct final rules,
 - (e) Final rules, and
 - (f) Regulatory guides.
2. The NRC Clearance Officer—
 - (a) Ensures compliance with the information collection requirements of the Paperwork Reduction Act,
 - (b) Coordinates the review of the information technology impacts of the rulemaking by OCIO, and
 - (c) Coordinates OCIO's review of the rulemaking for compliance with the NRC's policies and procedures governing information management.
 3. Certifies that information collections contained in NRC rulemakings adhere to the Paperwork Reduction Act.
 4. Submits the information collections associated with NRC rules to the OMB for review and approval.

U. Director, Division of Rulemaking, NMSS

1. Responsible for all rulemaking and petition for rulemaking activities for the materials, new reactors, and operating reactors business lines, including administrative rules and rulemaking infrastructure, including executing the functions delegated in Section III.M of this directive. Directly supports NMSS, NRO, and NRR by managing the development of rulemakings for each office's respective business line(s).
2. Responsible for designating the Liaison Officer to the Office of the Federal Register.
3. Signs FRNs for regulatory bases and regulatory analyses.
4. Designates an RM PM to work with the lead technical office for the development of rulemaking plans, draft regulatory basis documents, and regulatory basis documents to support a specific rulemaking activity. The RM PM—
 - (a) Coordinates the rulemaking and lead the working group developing a proposed or final rule, in accordance with NMSS Policy and Procedures 6-10, "NMSS Procedures for Preparation and Review of Rulemaking Packages" ([ML17257A004](#)).
 - (b) Determines the offices from which concurrence will be requested on the rulemaking actions.
 - (c) Ensures that OGC provides a determination of no legal objection on the rulemaking actions.

-
- (d) Ensures the review and, if necessary, update of references to standards that have been incorporated by reference.
 - 5. Establishes and chairs a steering committee, as appropriate, to oversee rulemaking and petition for rulemaking activities and to obtain alignment on technical and legal issues.
 - 6. Leads NMSS staff to provide the following centralized rulemaking support services:
 - (a) Chairs meetings of the RCC.
 - (b) Assigns the regulation identifier number (RIN) and the NRC Docket ID.
 - (c) Maintains NRC rulemaking Web sites.
 - (d) Forwards the monthly Congressional Review Act report to the Office of Management and Budget (OMB).
 - (e) Forwards review comments on rulemaking actions to the technical lead office, identified in Section III.N of this directive, for review and consideration.
 - (f) Forwards public comments on petition for rulemaking actions to the technical lead office and to the petitioner.
 - (g) Serves as the Agency Administrator for the Federal Docket Management System, FDMS.gov.
 - (h) Posts rulemaking documents on the Federal Government's rulemaking Web site, Regulations.gov.
 - (i) Maintains agency historical documents related to rulemaking, tracks rulemaking activities, issues rulemaking reports, and conducts reviews, including the following:
 - (i) The Annual Rulemaking Report to the Commission;
 - (ii) The Unified Agenda of Federal Regulatory and Deregulatory Actions;
 - (iii) The annual Statement of Regulatory Priorities (formerly the Regulatory Plan) submitted to OMB as required by Executive Order 12866;
 - (iv) The Plan for Retrospective Analysis of Existing Rules, which the NRC will periodically update on a voluntary basis, in response to Executive Order 13579;
 - (v) The retrospective review of administrative regulations; and
 - (vi) *Ad hoc* reports, as requested by senior management.
 - (j) Provides centralized support for cost analysis for rules, including actions considered to be rules under the Congressional Review Act. Provides agency guidance on cost/benefit analysis.

- (k) Reviews the electronic compilation of 10 CFR Chapter I, "Nuclear Regulatory Commission," which appears on the NRC's public Web site.

V. Chief, Regulatory Analysis and Rulemaking Support Branch (RASB), DRM, NMSS

The Director of NMSS has redelegated to the Chief, RASB, the authority to issue administrative rulemakings (for administrative changes, such as updating addresses and phone numbers and correcting typographical errors). These administrative rules are exempt from the rulemaking plan requirement (see [SRM-SECY-15-0129](#)).

IV. APPLICABILITY

The policy and guidance in this MD apply to all NRC employees who are involved in the rulemaking process.

V. DIRECTIVE HANDBOOK

Directive Handbook 6.3 describes the actions involved in the developing and processing of a rulemaking and provides guidelines for NRC offices for coordinating, concurring, and reporting on rulemakings. For information on the legal and format requirements applicable to the preparation of rulemaking documents, see the Web resource for agency staff, "The NRC Rulemaker," located on the internal Web site at <https://usnrc.sharepoint.com/teams/NMSS-The-NRC-Rulemaker>.

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U.S. NUCLEAR REGULATORY COMMISSION DIRECTIVE HANDBOOK (DH)

| DH 6.3 | THE RULEMAKING PROCESS | DT-19-08 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------|
| <i>Volume 6:</i> | Internal Management | |
| <i>Approved By:</i> | Patricia K. Holahan, Director, Division of Rulemaking Office of Nuclear Material Safety and Safeguards | |
| <i>Date Approved:</i> | July 3, 2019 | |
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| <i>Issuing Office:</i> | Office of Nuclear Material Safety and Safeguards Regulatory Analysis and Rulemaking Support Branch | |
| <i>Contact Name:</i> | Helen Chang | |
| <p>EXECUTIVE SUMMARY</p> <p>Management Directive (MD) 6.3 is revised to incorporate the final rulemaking plan template as approved in SRM-COMSECY-16-0029 (ML19030A940). Additional information on how to use this Commission-approved template is available online at “The NRC Rulemaker” Web site (internal). This focused change affects only the MD 6.3 references section of this directive and the rulemaking plan section of this handbook. Broken links have been corrected throughout.</p> | | |

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I. OPENNESS AND TRANSPARENCY

The Commission is committed to maintaining an effective and efficient regulatory process that is open and transparent. Through its existing rulemaking processes, the U.S. Nuclear Regulatory Commission identifies, simplifies, and updates outdated regulations to make them more effective and less burdensome for internal and external stakeholders.

A. Memoranda from the Office of Management and Budget (OMB)

The NRC voluntarily complies with the following memoranda from the Office of Management and Budget (OMB):

1. Memorandum (M-07-13) from Rob Portman, "Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices," April 25, 2007 (<https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2007/m07-13.pdf>).
2. Memorandum (M-10-06) from Peter R. Orsag, "Open Government Directive," December 8, 2009 (https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf).
3. Memorandum (M-11-15) from Cass Sunstein, Office of Information and Regulatory Affairs (OIRA), "Final Guidance on Implementing the Plain Writing Act of 2010," April 13, 2011 (<https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2011/m11-15.pdf>).
4. Memorandum (M-11-19) from Cass Sunstein, OIRA, "Retrospective Review of Significant Regulations," April 25, 2011 (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2011/m11-19.pdf>).
5. Memorandum (M-11-28) from Cass Sunstein, "Executive Order 13579, Regulation and Independent Regulatory Agencies," July 22, 2011 (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2011/m11-28.pdf>).
6. Memorandum from Cass Sunstein, OIRA, "Cumulative Effects of Regulation," March 20, 2012 (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/inforeg/cumulative-effects-guidance.pdf>).
7. Memorandum from (M-11-10) Cass Sunstein, OIRA, "Reducing Reporting and Paperwork Burdens," June 22, 2012 (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2011/m11-10.pdf>).

B. Presidential Memorandum and Executive Orders

The NRC also voluntarily complies with the following Presidential Memorandum and Executive Orders:

1. Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (September 30, 1993) (<https://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>).
2. Executive Order 13258, "Amending Executive Order 12866 on Regulatory Planning and Review," 67 FR 9385 (February 26, 2002) (<https://www.gpo.gov/fdsys/pkg/FR-2002-02-28/pdf/02-5069.pdf>).
3. Presidential Memorandum (M-09-12) for the Heads of Executive Departments and Agencies, "Transparency and Open Government," January 21, 2009 (<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2009/m09-12.pdf>).
4. Executive Order 13579, "Regulation and Independent Regulatory Agencies," 76 FR 41587 (July 14, 2011) (<https://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>).

II. CUMULATIVE EFFECTS OF REGULATION (CER)

- A. Cumulative Effects of Regulation (CER) describes the challenges that licensees, or other impacted entities such as Agreement 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 significant number of new and complex regulatory actions stemming from multiple regulatory actions, 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 duties that ensure safety or security. CER can be aggravated if the new requirements lack clarity.
- B. The NRC's rulemaking process enables explicit consideration of CER by—
 1. Encouraging interaction with outside stakeholders throughout the rulemaking process in order to resolve issues that can lead to implementation challenges and contribute to CER; and
 2. Soliciting feedback on CER concerns to increase stakeholder awareness and enable the NRC to make better-informed decisions on how to mitigate CER.

- C. Two CER process improvements require that NRC staff (1) prepare a regulatory basis and guidance for most rulemaking activities and (2) interact with external stakeholders during the development of these documents. For additional information on CER, see the Commission paper designated as Office of the Secretary (SECY) SECY-11-0032 (Agencywide Documents Access and Management System (ADAMS) Accession No. [ML110190027](#)) and the Staff Requirements Memorandum (SRM) SRM-SECY-11-0032 ([ML112840466](#)). Both documents are entitled “Consideration of the Cumulative Effects of Regulation in the Rulemaking Process.”

III. COMMISSION CONSIDERATION OF A RULEMAKING ACTION

- A. Under [SRM-SECY-15-0129](#), a rulemaking plan is required for all rulemakings, except those that the Commission has explicitly delegated to NRC staff as a staff-delegated rulemaking (see SRM-COMSECY-17-0002 ([ML17059D045](#)) and Section III.A.6 of this directive). Commission approval of the rulemaking plan is required before the staff may initiate rulemaking activities. (See Section V of this handbook for more information about rulemaking plans.)
1. The staff must submit to the Commission a rulemaking plan for a proposed or direct final rulemaking action for Commission review and consideration.
 2. The rulemaking action is submitted to the Commission through the Executive Director for Operations (EDO), the General Counsel (GC), the Chief Financial Officer (CFO), or the Director, Office of International Programs (OIP).
 3. The Commission may take one of the following actions:
 - (a) Approve the rulemaking action as submitted,
 - (b) Approve the rulemaking action subject to specified changes,
 - (c) Disapprove the rulemaking action entirely, or
 - (d) Direct that the rulemaking action be revised and issued or revised and resubmitted to the Commission for reconsideration.
- B. SECY schedules meetings on significant or controversial rulemaking actions, or items of interest to the Commission, at the request of the Commission. Commission meetings on these matters are open to the public in accordance with the Government in the Sunshine Act (5 U.S.C. 552(b)). The meeting must be closed to the public if classified, sensitive, or safeguards matters are involved.
- C. The Commission’s decision on a direct final rule or a final rule is affirmed by each Commissioner in a public meeting.

- D. The Commission's decision is then reflected in an SRM issued by SECY. If the Commission directs changes to be made in the rulemaking action, the SRM describes these changes and may request resubmission of the rulemaking action for Commission review and approval before publication.

IV. RULEMAKINGS UNDER THE AUTHORITY OF THE EXECUTIVE DIRECTOR FOR OPERATIONS (EDO) OR THE CHIEF FINANCIAL OFFICER (CFO)

A. Forwarding Rulemaking Actions to the EDO Through Memorandum

1. If a rulemaking action falls within the scope of the EDO's delegated rulemaking authority, then the director of the technical lead office must forward the action to the EDO by memorandum. See the available templates for rulemaking actions on the internal Web site "[The NRC Rulemaker](https://usnrc.sharepoint.com/teams/NMSS-The-NRC-Rulemaker)" at <https://usnrc.sharepoint.com/teams/NMSS-The-NRC-Rulemaker>.
2. The memorandum must explain the basis and purpose of the rulemaking action.

B. Notifying the Commission of the Exercise of the Rulemaking Authority

1. Proposed Rules Issued by the EDO or the CFO
 - (a) Before the EDO or the CFO issues a proposed rule for publication in the *Federal Register*, they must notify the Commission.
 - (i) For each proposed rule for EDO issuance, the Division of Rulemaking (DRM) rulemaking project manager (RM PM) in consultation with the technical lead office prepares a draft EDO Daily Note that describes the intent of the EDO to issue the proposed rule. The draft EDO Daily Note is an enclosure to the memorandum forwarding the proposed rule for signature by the EDO. Staff in the Office of the Executive Director for Operations (OEDO) will publish the EDO Daily Note the day before the rule is signed. See OEDO Procedure 0350, "NRC Daily Notes and One-Week Look Ahead," available on the OEDO Procedures SharePoint site at http://fusion.nrc.gov/edo/team/Lists/OEDO_Procedures/Type_View.aspx.
 - (ii) For each proposed rule for CFO issuance, the OCFO prepares a memo that describes the proposed rule and describes the intent of the CFO to issue the proposed rule.
 - (b) After the proposed rule has been signed by the EDO or the CFO, the RM PM forwards the completed rulemaking package for publication in the *Federal Register* to the Regulatory Analysis and Rulemaking Support Branch (RASB), DRM, Office of Nuclear Material Safety and Safeguards (NMSS).

2. Final Rules Issued by the EDO or CFO

Before forwarding a final rule for publication in the *Federal Register*, the EDO and the CFO must notify the Commission.

(a) The RM PM, in coordination with the technical lead office, prepares the following:

(i) A draft EDO Daily Note for EDO-signed rules, or a memorandum for CFO-signed rules, that describes the intent of the EDO or CFO to issue the final rule, and

(ii) A Notice of Signed Final Rule, which is a memorandum to the Commission.

(b) The technical lead office includes the draft EDO Daily Note (or memorandum from the CFO) and Notice of Signed Final Rule with the memorandum forwarding the final rule for the signature of the EDO or the CFO.

(c) The EDO or the CFO must then—

(i) Publish the EDO Daily Note (or memorandum) on the day before the rule is signed;

(ii) Forward the Notice of Final Rule and a copy of the final rule to SECY for distribution to the Commission; and

(iii) Return the signed rule to the RM PM.

3. A rule signed by the EDO or the CFO must not be forwarded to the Office of the Federal Register (OFR) for publication any earlier than 10 working days after the rule's signature date (unless the Commission specifies a different period). A different review period applies to the fee rule, which has an expedited schedule: the CFO must not forward the proposed and final fee rule for publication any earlier than 5 working days. This practice provides the Commission with an opportunity to review the action before it is transmitted to OFR for publication. Once the 10-working-day period (or 5-working-day period for the fee rule) has elapsed, the technical lead office must forward the completed rulemaking package to RASB for publication in the *Federal Register*.

V. RULEMAKING PLAN

A. Purpose of the Rulemaking Plan

The rulemaking plan provides a preliminary outline of the scope and impact of the contemplated action sufficient for the Commission to determine whether the contemplated rule is needed. Commission approval of the rulemaking plan is required before the agency expends significant resources on the contemplated action.

B. Rulemaking Plan Requirement

Under [SRM-SECY-15-0129](#), a rulemaking plan is required for all rulemakings, except those that the Commission has explicitly delegated to the staff as a staff-delegated rulemaking. The Commission-approved template (see [SRM-COMSECY-16-0029](#)) for the rulemaking plan can be found at the "[The NRC Rulemaker](#)."¹

C. Rulemakings Exempt from the Rulemaking Plan Requirement

The following rulemakings are exempt from the rulemaking plan requirement because the Commission has delegated them to the staff as staff-delegated rulemakings:

1. The annual Revision of Fee Schedules rulemaking is delegated to the CFO.
2. Certificates of compliance for spent fuel storage casks rulemakings are delegated to the EDO.
3. Recurring rulemakings for incorporation by reference of American Society of Mechanical Engineers standards and related documents into Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.55a, "Codes and Standards," are delegated to the Director of the Office of Nuclear Reactor Regulation (NRR) as defined in Section III.B.8 of this directive.
4. Administrative rulemakings (for administrative changes, such as updating addresses and phone numbers and correcting typographical errors) are delegated to the EDO and redelegated to the Director of NMSS and the Chief, RASB.
5. Rulemaking plans do not need to be prepared for rulemakings that are mandated by statute or implement U.S. Government policy on export licensing controls, and involve no discretion as to the content of the rule. The Commission has not approved delegating to the staff the authority to initiate rulemaking for matters that require a limited exercise of discretion. To proceed with a rulemaking on these matters involving the exercise of minor levels of discretion, the staff must request Commission approval to proceed with rulemaking by submitting a short paper (not a rulemaking plan), in accordance with SRM-COMSECY-17-0002 ([ML17059D045](#)). For matters where more significant discretion exists, normal rulemaking plan requirements must be followed.
6. Periodic updates of the civil penalty amount (e.g. 10 CFR 2.205(j)).

¹ See Commissioners' Assistant Note, "Update on Plan to Enhance Commission Involvement in the Early Stages of Rulemaking," June 16, 2016 ([ML16153A356](#)) (nonpublic).

D. Concurrence on a Rulemaking Plan

Before submitting a rulemaking plan to the EDO, the technical lead office, which is responsible for the rulemaking plan, must obtain concurrence or a determination of no legal objection from—

1. The OCFO (indicating that the OCFO has no resource-related objection to the rulemaking action);
2. OCIO;
3. OGC (determination of no legal objection);
4. The Director of DRM, NMSS; and
5. Other NRC organizations to be affected by the rulemaking action from a technical standpoint, based on their designated areas of responsibility (e.g., OE or the regions). If formal concurrence is not necessary from certain affected offices or regions based on the significance of the activity, they should be included on distribution.

VI. REGULATION IDENTIFIER NUMBER (RIN) AND THE UNIFIED AGENDA**A. What is the RIN?**

The Regulation Identifier Number (RIN) is a unique number that the NRC assigns to each rulemaking activity either—

1. When the Commission approves the associated rulemaking plan or
2. When staff initiates a Commission-delegated rulemaking that does not require a rulemaking plan. (See Section V.C of this handbook.)

B. How is the RIN Used?

The RIN is used to identify the rulemaking action in the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda), available at <https://www.reginfo.gov/public/do/eAgendaMain>.

VII. DOCKET ID**A. What is a Docket ID?**

The Docket ID allows the public to search for related documents on [Regulations.gov](https://www.regulations.gov).

B. When is the Docket ID Assigned?

RASB assigns the Docket ID when—

1. SECY docket a petition for rulemaking (PRM),

2. The Commission approves the associated rulemaking plan, or
3. The staff initiates a Commission-delegated rulemaking that does not require a rulemaking plan.

VIII. WORKING GROUPS FOR RULEMAKING

A. Members

Working groups will be formed, if appropriate, for specific rulemaking actions. Working groups may include the following members:

1. An RM PM from DRM, NMSS, who is responsible for the development of the rule.
2. Member(s) from the technical lead office and sponsoring office, if applicable—generally, a primary technical contact for the rule and additional staff as needed.
3. Cost/benefit analyst.
4. A member from OGC to provide legal advice and support.
5. A member from RASB to provide input on the Regulatory Flexibility Act, the Congressional Review Act (CRA), plain language, and formatting requirements of the OFR. In addition, RASB provides support for drafting and editing rulemaking documents, including the comment summary and response section, the section-by-section analysis, amendatory instructions, and codified text of proposed and final rules, as appropriate.
6. A member from the Information Services Branch, Governance and Enterprise Management Services Division, Office of the Chief Information Officer (OCIO), to provide advice on information collection requirements and to coordinate any additional reviews by other organizations with OCIO. This member will recommend the temporary inclusion of other OCIO staff into the working group, as needed.
7. An Agreement State representative, as appropriate.
8. A member from the technical office (supporting office) developing the guidance if the issuance of the rule will require new or updated guidance, and a guidance project manager (PM) (when applicable). For example, a member of the Regulatory Guidance and Generic Issues Branch (RGGIB), Office of Nuclear Regulatory Research (RES), is assigned as a guidance PM when a regulatory guide is updated or a new guide is developed. The guidance PM supports the development of the guidance, the Federal Register notice (FRN), and the regulatory analysis.
9. Staff from other offices or regions, as appropriate.

B. Responsibilities

A working group's activities include the following:

1. Assess the scope of the rulemaking action, identify the tasks necessary to complete the rulemaking action, identify members responsible for completing these tasks, and develop schedules and resource estimates for completing each stage of the action.
2. Interact with internal and external stakeholders during the development of—
 - (a) The draft regulatory basis and regulatory basis,
 - (b) The draft and final regulatory analysis,
 - (c) The proposed and final rule,
 - (d) Draft and final guidance for implementing the rule, and
 - (e) Any implementation and compliance dates in the final rule.
3. Solicit and consider stakeholder feedback on the CER related to the rulemaking, as applicable.
4. Prepare associated guidance, including licensing, inspection, and enforcement guidance, as appropriate (unless the guidance is prepared by a separate guidance working group).
 - (a) Ensure that any associated guidance is complete and referenced in the draft proposed rule and draft final rule packages, and developed in accordance with the [SRM on SECY-11-0032](#), "Consideration of the Cumulative Effects of Rulemaking," and any respective policy and procedures. For example, develop regulatory guides according to MD 6.6, "Regulatory Guides," and NUREGs according to MD 3.7, "NUREG Series of Publications."
 - (b) Coordinate with external stakeholders on the content of any guidance considered for endorsement or acceptance in the NRC's implementation guidance.
 - (c) The technical lead office is responsible for ensuring the guidance is revised and complete when the associated draft proposed rule or draft final rule package is provided to the Commission, in coordination with the guidance PM. Draft guidance should be developed and reviewed/concurred in parallel with the rule to enable the staff to meet this schedule. Exceptions (i.e., guidance not being available concurrent with the rule package) should be extremely rare and should be approved by the technical lead office and communicated to OEDO and the Commission offices, as appropriate (see [SRM on SECY-11-0032](#)). The guidance PM also must promptly inform the RM PM of any schedule change.

5. Assist the technical lead office in the preparation of rulemaking packages and supporting documents by providing necessary technical input.
6. Address public comments received, estimate the information collection burden, and prepare briefing materials. See Section XIII, "Public Participation," of this handbook for information on how to solicit and gather external stakeholder feedback.
7. Review contractor reports or monitor contractor effort if contract support is necessary.
8. Facilitate the concurrence process.
9. Apprise management of policy developments throughout the course of the rulemaking action.
10. Support the technical lead office in management briefings and public meetings.

IX. STEERING COMMITTEE FOR RULEMAKING

A. Responsibilities

A steering committee may be established for certain rulemakings, particularly those that are unusually controversial or complex and those for which the implementation responsibilities cut across several divisions or offices. The steering committee raises questions of policy for resolution by senior management or the Commission as appropriate, provides direction on significant technical issues, and facilitates concurrence on the rulemaking action.

B. Members

The steering committee is composed of the following members:

1. Senior managers from the affected offices (either the senior manager from (1) DRM, NMSS, or (2) the technical lead office serves as the committee chair), including the regions as appropriate;
2. A representative from OGC;
3. Agreement State representative(s), if appropriate; and
4. The Chief, RASB.

X. REGULATORY BASIS

A. Purpose of the Regulatory Basis

The technical lead office is responsible for developing the regulatory basis, in coordination with the RM PM. The regulatory basis often includes detailed information about the following:

1. Why a current regulation or policy needs to be changed;
2. Why alternatives to rulemaking are not the recommended options;
3. Different approaches to resolve the issue;
4. Supporting scientific, policy, legal, economic, or technical information;
5. Stakeholder interactions in developing the technical portion of the regulatory basis and stakeholder views;
6. Preliminary cost/benefit considerations;
7. Any backfitting or issue finality considerations, as appropriate; and
8. Any limitations on the scope and quality of the regulatory basis.

B. Responsibilities of the Technical Lead Office

1. Under [SRM-SECY-15-0129](#), the staff should provide (through a Note to Commissioners' Assistants (CA Note), or other appropriate communication, coordinated with OEDO) draft regulatory bases and regulatory bases to the Commission for all rulemakings that are not already explicitly delegated to the staff. The staff should send the CA Note no fewer than 10 business days before the publication of the draft regulatory basis or regulatory basis, to ensure that the Commission has an opportunity to assess whether additional involvement is warranted. See OEDO Procedure 0310, "Notes to Commissioners' Assistants," available on the OEDO Procedures SharePoint site at http://fusion.nrc.gov/edo/team/Lists/OEDO_Procedures/Type_View.aspx.
2. The staff will engage internal and external stakeholders during the development of the regulatory basis.
3. The staff will inform the Commission offices of significant stakeholder interactions through a CA Note or other appropriate communication.

XI. REGULATORY ANALYSIS PROCESS

- A.** The regulatory analysis process, an integral part of NRC decisionmaking, systematically provides complete disclosure of relevant economic information supporting a regulatory decision. The conclusions and recommendations included in a regulatory analysis are neither final nor binding, but are intended to enhance the soundness of decisionmaking by NRC managers and the Commission. The NRC conducts rulemaking regulatory analyses using cost-estimating best practices that include methods for the treatment of uncertainty and assessing factors that are difficult to quantify (see SECY-18-0042 ([ML17221A000](#))).

- B.** A regulatory analysis helps ensure that—
1. The NRC's regulatory decisions made in support of its statutory responsibilities are based on adequate information concerning the need for and consequences of proposed actions.
 2. Appropriate alternative approaches to regulatory objectives are identified and analyzed.
 3. No clear, preferable alternative is available to the proposed action.
- C.** For additional information on regulatory analysis, see the following documents:
1. NUREG/BR-0058 "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and
 2. NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook – Final Report."

XII. BACKFITTING AND ISSUE FINALITY

- A.** The NRC's regulations governing nuclear power reactors and certain nuclear materials licenses contain provisions that restrict the NRC's capability to impose new requirements on licensees or, in certain applications related to power reactors, to take a different position from a previous NRC position. These are denoted as backfitting and issue finality restrictions (issue finality is the terminology in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants").
- B.** Backfitting and issue finality restrictions applicable to nuclear power plants are contained in 10 CFR 50.109, 52.39, 52.63, 52.83, 52.98, 52.145, or 52.171, as applicable; and Paragraph VI in Appendices A through D to 10 CFR Part 52. Backfitting restrictions applicable to certain licensees possessing specified quantities of special nuclear material are in 10 CFR 70.76, "Backfitting." Backfitting restrictions applicable to independent spent fuel storage are set forth in 10 CFR 72.62, "Backfitting." Backfitting restrictions applicable to gaseous diffusion plants are set forth in 10 CFR 76.76, "Backfitting."
- C.** For additional information on backfitting and issue finality, see the following documents:
1. 10 CFR Part 50.109, "Backfitting," and related requirements for other classes of facilities;
 2. MD 8.4, "Management of Facility-Specific Backfitting and Information Collection"; and
 3. NUREG-1409, "Backfitting Guidelines."

XIII. PUBLIC PARTICIPATION

A. Administrative Procedure Act (APA) Requirements

1. The Administrative Procedure Act (APA) generally requires that an agency publish a notice of proposed rulemaking for most rules in order to provide an interested person with notice of the proceeding and an opportunity to comment on the contemplated action before the agency issues the rule in final form (see Section 553 of the APA for details).
2. The APA also requires that a final rule become effective at least 30 days after the final rule is published in the *Federal Register*, with limited exceptions (see Section 553 of the APA for details).
3. The NRC may waive the APA notice and comment requirement under the exceptions in 5 U.S.C. 553(b)(3)(A) or (B) and may waive the 30-day notice requirement under the exceptions in 5 U.S.C. 553(d).

B. Advance Notice of Proposed Rulemakings (ANPR)

1. An ANPR is a formal method of soliciting early public involvement in the rulemaking process. Commission approval of a rulemaking plan is required before drafting an ANPR. The technical lead office (after getting appropriate approval from the Commission, the EDO, or CFO) publishes a notice in the *Federal Register* that—
 - (a) Describes the regulatory problem or situation, and
 - (b) Requests public comment or lists questions and issues for public comment to direct public response.
2. The ANPR may—
 - (a) Outline regulatory responses to the problems that are under consideration,
 - (b) Include preliminary rule language, or
 - (c) Propose alternative (including non-rulemaking) solutions.
3. RASB will post the ANPR in the rulemaking docket on <https://www.regulations.gov> under the assigned NRC Docket ID, along with any supporting documents forwarded by the technical lead office. All documents must be made publicly available in ADAMS before posting on <https://www.regulations.gov>. The technical lead office must provide RASB with the ADAMS Accession Numbers for all documents to be posted.

C. Public Participation During the Regulatory Basis Phase

1. The NRC may seek public involvement during the development of the regulatory basis for regulatory action. Early public involvement allows the staff to gather stakeholder input and gauge interest before a final decision is made to pursue rulemaking. Activities may include—

- (a) Conducting public meetings, workshops, or Webinars; or
 - (b) Making documents (that address scoping concerns or lay out various options for handling emergent technical, legal, economic, or policy issues or problems) available for public comment on the public NRC Web site and at <https://www.regulations.gov>.
2. When seeking public involvement in the development of the regulatory basis, the NRC technical lead office, which is responsible for the regulatory basis, should prepare for publication an FRN that explains the regulatory issue under agency consideration.
 3. RASB will post the published notice in the rulemaking docket on <https://www.regulations.gov> along with any related documents forwarded by the office (e.g., an issues paper, interim policy or guidance, questions for directed comment, or an information packet). All documents must be made publicly available in ADAMS before they can be posted on <https://www.regulations.gov>. The technical lead office must provide RASB with the ADAMS Accession Numbers for all documents to be posted.

D. Public Comments for Notice and Comment Rulemaking

1. Some avenues of public participation are specific to rulemaking and required by statute. The APA established the “notice and comment” process found in 5 U.S.C. 553, “Rule Making,” and sets out the requirement to provide the public an opportunity to participate in Federal rulemaking.
2. Notice of a proposed rulemaking must be published in the *Federal Register*, with limited exceptions, as required by 10 CFR 2.807, “Effective Date.”
 - (a) The APA does not specify a minimum length of time for the public comment period, but the time allotted should reflect the complexity of the rule.
 - (b) Executive Order 12889, “Implementation of the North American Free Trade Agreement,” mandated a 75-day comment period for technical regulations issued under 5 U.S.C. 553. The NRC has adopted the 75-day comment period length for all standards-related rulemakings.
 - (c) An interested person may submit comments in the manner described in the proposed rule (e.g., through <https://www.regulations.gov>).
3. All Federal agencies consider public comments received when drafting and justifying final regulations. The statement of considerations for a final rule must include the agency’s response to each significant public comment or set of related, significant public comments that is within the scope of the rulemaking. The NRC’s practice is to provide an explanation as to why a comment is not considered significant or within the scope of the rulemaking.

4. The APA requires that agencies give adequate notice to affected parties when promulgating new rules. The minimum time between the publication of a rule and its effective date is 30 days, with limited exceptions, as required by 10 CFR 2.807.

E. Publication of Guidance with the Proposed Rule

1. Unless otherwise directed by the EDO, NRC staff will not provide the proposed rule package to the Commission or the EDO, as applicable, until draft guidance is complete. This process is part of the enhancements to the NRC's rulemaking process to enable explicit consideration of CER. The draft guidance must then be published at the same time as the proposed rule is published.
2. Publishing the proposed rule along with associated guidance ensures the following:
 - (a) External stakeholders can gain a better understanding of the proposed, new, or amended requirements;
 - (b) Stakeholders will have a better understanding of the implementation actions that the NRC recommends for compliance with the proposed requirements, including engineering, procurement, installation, testing, and analysis to support feedback on estimated cost and impacts associated with the proposed requirements; and
 - (c) Licensees can provide feedback on the CER at the proposed rule stage regarding other ongoing regulatory actions that might adversely impact their ability to implement the proposed requirements.

F. Access to Information on NRC Rulemaking Activities

1. Rulemaking Tracking and Reporting System

The NRC provides current information on its public Web site (<https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html>) on the status of NRC rules and PRMs through the Rulemaking Tracking and Reporting System. The Rulemaking Tracking and Reporting System includes the priority and estimated schedule for each planned rulemaking activity.

2. Agencywide Documents Access and Management System (ADAMS)

The Commission has directed that all rulemaking documents intended to be released to the public be made publicly available in ADAMS (<https://www.nrc.gov/reading-rm/adams.html>) in accordance with MD 3.4, "Release of Information to the Public." Rulemaking documents include all supporting documents, guidance, and analyses referenced in an FRN.

3. Regulations.gov

- (a) The FRNs for proposed and final rules, policy statements, and other rulemaking-related products may be found on <https://www.regulations.gov>.
- (b) Public comments, preliminary proposed rule language, meeting notices, and significant supporting documents and analyses are also posted to <https://www.regulations.gov> once they have been made publicly available in ADAMS.

4. To support electronic access by the public to rulemaking information, the RM PM must notify RASB of the ADAMS Accession Numbers for any rulemaking documents that should be posted to the docket on <https://www.regulations.gov>—

- (a) All documents included in the FRN publication package; and
- (b) All rulemaking supporting documents not published in the *Federal Register* but referenced in the FRN (e.g., preliminary rule language, technical specifications, environmental analyses, public meeting materials, guidance, and regulatory analyses).

Note: All documents must be made publicly available in ADAMS. If the documents are not NRC-originated and cannot be placed in ADAMS (e.g., for copyright reasons), the technical lead office must provide an alternative means of accessing the document, such as a hyperlink.

5. Public Document Room (PDR)

- (a) Members of the public without access to Internet service can visit the NRC's PDR and use public computers that provide access to ADAMS and to the NRC's public Web site.
- (b) The PDR does not maintain paper copies of post-1999 NRC documents available in ADAMS, but photocopies of publicly available documents can be obtained for a small fee.
- (c) Certain publicly available NRC documents that predate ADAMS are available to visitors at the PDR as part of the PDR's standing collection; other documents can be located and made available upon advance request. More information on the Public Document Room is available on the NRC public Web site at <https://www.nrc.gov/reading-rm/pdr.html>.

6. Posting of Preliminary Language on the Web or in an FRN

- (a) To obtain public feedback early in the rulemaking process, the RM PM may post preliminary rulemaking language on <https://www.regulations.gov>. The staff must notify the Commission beforehand of plans to publicly release preliminary proposed rule language for a proposed rule that has not been submitted to the

Commission. Preliminary rulemaking language is typically posted during the proposed rule phase of the rulemaking process.

- (b) The staff must obtain OGC's analysis of legal sufficiency demonstrating no known basis for legal objection before making preliminary rulemaking language publicly available.
- (c) The preliminary proposed rule language can be included in or appended to the FRN announcing the availability of preliminary language, but typically the FRN simply announces the availability of the preliminary proposed rule language in public ADAMS. The RM PM, in coordination with the technical lead office, may prepare a notice of availability of preliminary proposed rule language for publication in the *Federal Register* and forward a document containing the preliminary proposed rule language to RASB for posting on <https://www.regulations.gov> under the assigned NRC Docket ID. The notice can include the following:
 - (i) A summary of the regulatory approach(es) under consideration,
 - (ii) A request for public comment, and
 - (iii) A schedule of contemplated actions and public meetings.

7. Public Meetings

- (a) When preparing a rule, staff may elect to conduct one or more public meetings to obtain public input. Public meetings on rulemakings must be conducted in accordance with MD 3.5, "Attendance at NRC Staff-Sponsored Meetings," and are generally open to participation by a wide variety of stakeholders. Additional policy and guidance on public meetings can be found in MD 3.11, "Conferences," and the internal Web page on "Communications" (<https://drupal.nrc.gov/comm>).
- (i) Meeting topics may include a specific regulatory issue, a portion of the regulations that the NRC proposes to amend, or specific preliminary proposed rule language under consideration at the proposed or final rule stage.
- (ii) The Commission has delegated the authority to issue preliminary proposed rule language to the following office directors (see Section III.B.2 and Section III.B.6 of this directive for the delegations and Section XIII.F.6 of this handbook for restrictions on issuance):
 - Director, NMSS;
 - Director, Office of New Reactors (NRO); and
 - Director, NRR.

- (b) If the rulemaking is not exempt from CER treatment, then the working group will hold a public meeting on the implementation of the rule during the final rulemaking stage in order to understand better and clarify CER concerns, and to structure the rule implementation and compliance dates appropriately. A public meeting is not held when comments (or lack thereof) on proposed rules show general agreement on the proposed implementation and compliance dates.

XIV. COORDINATION

A. Agreement States and Federally Recognized Tribes

1. Background

Agreement States and Federally recognized Tribes are given the opportunity to comment on rulemakings that impact them. The technical lead office must coordinate this effort with NMSS and OGC. All rulemaking plans must briefly describe any Agreement State considerations and how these considerations will be addressed.

2. Notification of Agreement States and Federally Recognized Tribes

- (a) If they make a request, the Agreement States or Federally recognized Tribes may be briefed on the purpose and scope of the preliminary rulemaking plan.
- (b) In accordance with MD 5.1, "Intergovernmental Consultation," and MD 5.3, "Agreement State Participation in Working Groups," the Director of NMSS will notify the Agreement States by letter, as appropriate, of the opportunity for early comment on preliminary rulemaking documents. See the NRC's Tribal Policy Statement ([ML17011A243](#)) for information on interfaces with Federally recognized Tribes. The NMSS rulemaking project manager (RM PM) will coordinate with the Federal, State, and Tribal Liaison Branch, Division of Materials Safety, Security, State, and Tribal Programs, NMSS.
- (c) The NRC sends preliminary rulemaking documents to the Agreement States concurrent with the office concurrence process, after obtaining OGC's analysis of legal sufficiency demonstrating no known basis for legal objection.
- (c) The RM PM submits an EDO Daily Note when any rule document is sent to the Agreement States or Tribes for comment.
- (d) For further guidance on the process for soliciting early comment from Agreement States, see Agreement State (AS) Procedure SA-800, "Providing NRC Preliminary Documents to Agreement States and Appropriate Working Groups of the Conference of Radiation Control Program Directors, Inc." ([ML011370784](#)), and NMSS Policy and Procedures 6-10, "NMSS Procedures for Preparation and Review of Rulemaking Packages" ([ML18227A110](#)).

3. Commission Notification of Agreement State and Tribal Comments

The Commission paper transmitting the rule documents to the Commission will contain a section on Agreement State and Tribal interactions. This section provides information on Agreement State and Tribal interaction opportunities and a brief discussion of the NRC staff's disposition of the Agreement State or Tribal comments.

B. The Committee to Review Generic Requirements (CRGR)

1. The technical lead office, which is responsible for a rulemaking will determine whether to request CRGR review of the rule. According to SECY-16-0064, "CRGR Response to Staff Requirements—SECY-15-0129 Commission Involvement in Early Stages of Rulemaking" ([ML16075A365](#)), the technical lead office will request a CRGR review of the rulemaking package when any one of the following conditions is met:
 - (a) In the rulemaking plan, NRC staff indicated that the rulemaking would not constitute backfitting. However, in developing the proposed rule, the staff identifies that a backfit is possible.
 - (b) The regulatory analysis identifies significant costs incurred as a result of the proposed rulemaking, and qualitative factors were used to justify the rulemaking.
 - (c) There is substantial uncertainty (in the statistical sense) in the quantitative benefit determinations in the backfit analysis.
 - (d) The staff relied upon the compliance exception or the adequate protection exceptions to justify backfitting or violating issue finality, where the Commission had not previously been advised of the use of these exceptions in the rulemaking plan.
 - (e) The EDO directs the CRGR to review the rulemaking package, or external stakeholders or the NRC staff have raised substantive concerns regarding the backfit or regulatory analysis.
2. The RM PM should coordinate with CRGR early in the rulemaking development to determine whether CRGR review is needed, including—
 - (a) Provide information to CRGR on rules that the staff has determined do not meet the criteria for CRGR review.
 - (b) Upon a request by the CRGR, meet with the committee during preparation of the regulatory basis process to discuss the rationale for the proceeding.
3. When CRGR reviews the rulemaking package, the technical lead office, working with the sponsoring office and DRM, NMSS, must—
 - (a) Review the comments issued by the CRGR. (The CRGR will issue a single document with its comments.)

- (b) Formally document and respond, by memorandum or e-mail, to any consensus comments or recommendations from the committee concerning the rulemaking action.
 - (c) Summarize the results of the CRGR review in the FRN section for backfitting, with references to appropriate staff and CRGR documents.
4. See the CRGR charter and content requirements for packages on the public Web site “The Committee To Review Generic Requirements (CRGR)” at <https://www.nrc.gov/about-nrc/regulatory/crgr.html>.

C. Advisory Committee on Reactor Safeguards (ACRS)

1. The Advisory Committee on Reactor Safeguards (ACRS) reviews rulemakings under three circumstances:
 - (a) ACRS review is required by law (e.g., reactor design certification rules),
 - (b) The Commission directs the review, or
 - (c) The ACRS uses its own discretion to request the review.
2. DRM, NMSS, will coordinate with the ACRS to determine whether a given rule falls within the identified circumstances, as well as the stage(s) at which the ACRS will review the rule.
3. The technical lead office must provide a copy of the rulemaking documents to the ACRS for information before publication. When the ACRS reviews the rulemaking documents (including guidance), the technical lead office also must accomplish the following:
 - (a) Upon a request by the ACRS, meet with the committee to discuss the rationale for the rulemaking action.
 - (b) Review the ACRS comments. (The ACRS will issue a letter report with its comments.)
 - (c) Formally document and respond, by memorandum or e-mail, to any consensus comments or recommendations from the ACRS concerning the rulemaking action.
4. The Commission determined in SRM-M031002, dated October 31, 2003 ([ML033040278](#)), that issues associated with threat assessment, physical security, or force-on-force assessments are outside the area of expertise of the ACRS and involve intelligence information not available to the ACRS; therefore, the ACRS will not review these types of rulemakings.

D. Advisory Committee on the Medical Use of Isotopes (ACMUI)

Interactions with the Advisory Committee on the Medical Use of Isotopes (ACMUI) are described in NMSS Policy and Procedure 2-5, "FSME Procedure for Interacting with the Advisory Committee on the Medical Use of Isotopes During Development of Major Medical Issues" ([ML15260A747](#)).

E. Office of Public Affairs (OPA)

1. The RM PM must contact OPA during the office concurrence process to determine if a press release needs to be prepared for the rulemaking action. The technical lead office must—
 - (a) Review the preliminary press release if OPA determines one is necessary or desirable and provide comments to OPA.
 - (b) Include a statement in the Commission paper indicating that a press release has been prepared and will be issued concurrent with the publication of the proposed or final rule. If OPA determines that a press release is not necessary or desirable, a note to that effect is included in the Commission paper or the memorandum signed by the EDO or the CFO.
 - (c) Include a copy of the preliminary press release as background in the completed concurrence package forwarded with the Commission paper or attached to the memorandum requesting the signature of the EDO or the CFO. See the [Internal Commission Procedures](#) for more information.
 - (d) Inform OPA of any change in the proposed or final rule resulting from EDO or CFO review or Commission action that would require a change in the press release or the preparation of a press release if one was originally determined to be unnecessary.
2. For rules approved by the Commission, when the SRM is prepared, SECY will inform OPA of any changes to the press release directed by the Commission in its action on the paper. After making these changes, OPA will review the press release with the technical lead office to ensure that the changes are technically accurate, that no other changes are needed to reflect the SRM, and that no other actions need to be taken before the press release is issued. The RM PM must coordinate with OPA until the proposed or final rule is submitted to SECY for publication or the press release is issued.
3. For rules signed by the CFO or EDO, the technical lead office should notify OPA shortly before the EDO or the CFO has signed the proposed or final rule. This action allows OPA to issue the press release at the earliest appropriate time.

F. Congressional Letters

1. To notify Congress of NRC rulemakings, RASB drafts the appropriate letters to congressional committees.
2. Include a copy of the draft congressional letters as background in the completed concurrence package forwarded with the Commission paper or attached to the memorandum requesting the signature of the EDO or the CFO. See the [Internal Commission Procedures](#) for more information.
3. As the signing office for the congressional letters, OCA—
 - (a) Dates the original hard copy letters, and
 - (b) Distributes copies of the letters appropriately.

XV. CONCURRENCE AND NON-CONCURRENCE**A. Office Concurrence**

1. Office concurrence means that the concurring office—
 - (a) Agrees with the overall approach, objective, technical content, and resource impacts of the rulemaking action;
 - (b) Believes that the rulemaking action will not adversely affect or conflict with other NRC regulations, guidance, programs, and policies in its area of responsibility; and
 - (c) Agrees that the material for which the office has a programmatic basis for judgment is factual and accurate.
2. Office concurrence (or a determination of no legal objection) on the rulemaking plan is requested from the following:
 - (a) OCFO;
 - (b) OCIO;
 - (c) OGC;
 - (d) The Director of DRM, NMSS; and
 - (e) Other NRC organizations to be affected by the rulemaking action from a technical standpoint, based on their designated areas of responsibility (e.g., OE or the regions). If formal concurrence is not necessary from certain affected offices or regions based on the significance of the activity, they should be included on distribution.

3. Office concurrence (or a determination of no legal objection) on the regulatory basis and the proposed and final rulemaking packages is requested from the following:
 - (a) OCIO;
 - (b) OGC;
 - (c) The Director of DRM, NMSS; and
 - (d) Other NRC organizations to be affected by the rulemaking action from a technical standpoint, based on their designated areas of responsibility (e.g., OE or the regions). If formal concurrence is not necessary from certain affected offices or regions based on the significance of the activity, they should be included on distribution.
4. Office review and comment, but not concurrence, is requested on the CA Note associated with a draft regulatory basis or regulatory basis from the following:
 - (a) OGC;
 - (b) The Director of DRM, NMSS; and
 - (c) Other NRC organizations to be affected by the rulemaking action from a technical standpoint, based on their designated areas of responsibility (e.g., OE or the regions). If formal concurrence is not necessary from certain affected offices or regions based on the significance of the activity, they should be included on distribution.

B. Office of General Counsel Concurrence

OGC concurrence means that—

1. The recommended action is legally sufficient,
2. The recommended action is consistent with existing (or sound future) Commission policy, and
3. OGC supports the recommended action.

C. OGC's Statement of No Legal Objection

No legal objection means that—

1. The recommended action is legally sufficient, and
2. OGC is not taking a position with respect to the policy aspects of the recommendation.

D. Legal Objection

1. Where the attorney finds that the recommended action is legally deficient or is objectionable from a legal policy standpoint, the attorney should work with the technical lead office in arriving at a legally acceptable action.
2. Where no legally acceptable accommodation is reached, OGC should formally communicate the basis for its objection to the technical lead office.

E. Concurrence Procedures

1. The RM PM, who is responsible for the development of the rule, must obtain simultaneous concurrences for each significant action taken during the development of the rulemaking. At a minimum, appropriate concurrences must be obtained for the following:
 - (a) Each rulemaking plan before it is submitted to the EDO and the Commission for approval.
 - (b) Each proposed rule package before the proposed rule is submitted to the Commission for consideration or to the EDO or the CFO for signature and publication.
 - (c) Each final rule package before the final rule is submitted to the Commission for consideration or to the EDO or the CFO for signature and publication.
 - (d) Preliminary proposed rule language before it is posted on <https://www.regulations.gov>.
 - (e) Each CA Note before it is submitted to the Commission offices for consideration.
2. During the concurrence process, a concurring office may withhold concurrence if it provides valid questions or concerns regarding any technical analysis or information that may invalidate or raise doubts about a rulemaking. Concurrence or a determination of no legal objection may not be withheld based on the following:
 - (a) Questions concerning material that is presented as factual, unless the office has a programmatic basis for judging the accuracy of the material;
 - (b) Editorial style or manner of presentation that does not affect the policy recommendations of the rulemaking action; or
 - (c) Policy disagreements that do not have a legal or regulatory basis.
3. Each concurring office will respond to the RM PM, by memorandum, NRC interoffice mail, e-mail, or telephone. For most rulemaking actions, the RM PM requests that responses be made within the requested response period, normally 20 working days. The responding office must do one of the following:

- (a) Concur;
 - (b) In the case of OGC, provide a determination of no legal objection;
 - (c) Withhold concurrence pending the resolution of specific technical, policy, or legal issue(s) raised by the concurring office; or
 - (d) Withhold concurrence pending review of required Paperwork Reduction Act supporting documents, in accordance with MD 3.54, "NRC Information Collections Program."
4. If a responding office withholds concurrence (also known as "non-concurrence"), then the responding office must do at least one of the following:
- (a) Work with the technical lead office to resolve any reasons for withholding concurrence, or
 - (b) State the reasons for being unable to respond on schedule and send a copy of this memorandum to OEDO.
5. Additional information on the NRC's non-concurrence policy can be found in MD 10.158, "NRC Non-Concurrence Policy."
6. After receiving the concurrence memoranda or e-mails and updating the rulemaking package appropriately, the RM PM must forward a copy of the entire rulemaking package to OGC. OGC requires a minimum of 10 working days to review the rulemaking package. OGC will do one of the following:
- (a) Provide a determination of no legal objection without comment in the rulemaking document;
 - (b) Provide a determination of no legal objection with the condition that specific technical, policy, or legal recommendations be accommodated; or
 - (c) Withhold a determination of no legal objection pending resolution of specific technical, policy, or legal recommendations.
 - (d) If the reviewing attorney disagrees with the recommended rulemaking action on policy grounds, then OGC may formally communicate the basis for the policy disagreement and the supporting reasons, in writing, to the technical lead office, branch chief or above, or to the proposed signer of the document, and to OGC management, as appropriate.
7. After receiving the determination of no legal objection from OGC, the RM PM will—
- (a) Provide a revised rulemaking package, including the rulemaking plan, the proposed rule, or the final rule, to the technical lead office for final concurrence and transmittal to OEDO; or

- (b) Hold a meeting with the designated representatives of participating offices (or their alternates) and with the appropriate Deputy Executive Director for Operations to resolve any impasse that is preventing presentation of the rulemaking to the EDO for review.
8. After reviewing a proposed rule, a final rule, a direct final rule, an advance notice of proposed rulemaking, or a PRM closure, the EDO must do one of the following:
- (a) Transmit the package to SECY for Commission consideration, or
 - (b) If the action falls under the rulemaking authority delegated to the EDO:
 - (i) Notify the Commission of the intent to issue the rule under the rulemaking authority delegated to the EDO;
 - (ii) Return the package to the RM PM and the technical lead office responsible for the rulemaking action, to modify or resolve any questions; or
 - (iii) For staff-delegated rules, instruct the technical lead office not to proceed with the rulemaking and initiate discontinuation of the rulemaking, as outlined in Section XVI of this handbook.

F. Non-Concurrence Process

NRC staff may choose not to concur on any part of a document in which he or she does not agree. For more information, see MD 10.158, "NRC Non-Concurrence Process."

G. Differing Professional Opinion Program

The Differing Professional Opinions (DPO) Program is a formal process that allows all employees and contractors to have their differing views on established, mission-related issues considered by the highest level managers in their organizations (i.e., office directors and regional administrators). For more information, see MD 10.159, "NRC Differing Professional Opinion Program."

XVI. DISCONTINUING A RULEMAKING ACTIVITY

A. Staff Identifies a Rulemaking Activity to be Discontinued

1. A rulemaking activity may be discontinued at any stage in the rulemaking process.
2. When NRC staff identifies a rulemaking activity to be discontinued that has been previously approved by the Commission for initiation, the staff will request, through a Commission paper, approval from the Commission to discontinue the rulemaking.

3. The NRC staff may follow simplified procedures to discontinue a rulemaking activity that either has not yet been approved by the Commission or whose initiation and issuance is delegated to the staff. See Appendix L of NMSS Policy and Procedures 6-10 ([ML18227A110](#)).

B. Notification of the Public when a Rulemaking Activity will be Discontinued

1. The NRC will inform the public of the agency's decision to discontinue rulemaking.
2. After the agency's decision to discontinue rulemaking, in the next edition of the Unified Agenda, the NRC will update the entry for that rulemaking activity to indicate that it is no longer being pursued. The rulemaking activity will appear in the completed section of that edition of the Unified Agenda but will not appear in future editions.
3. If a rulemaking action has taken place on the discontinued rule, the NRC also will issue an FRN to notify the public that the rule is no longer being pursued.

C. Public Comments Received on Rulemaking Activity that will be Discontinued

If a rulemaking activity has received public comments, the NRC will consider those comments before discontinuing the rulemaking activity; however, the NRC will not provide individual comment responses.

XVII. INCORPORATION BY REFERENCE

- A.** Incorporation by reference (IBR) allows Federal agencies to comply with the requirement to publish rules in the *Federal Register* by referring to materials already published elsewhere. The legal effect of incorporation by reference is that the material is treated as if it were published in the *Federal Register*. This material has the force and effect of law, just like regulations published in the CFR.
- B.** The NRC follows the OFR's requirements governing approval for IBR at 1 CFR Part 51, "Incorporation by Reference," and the IBR procedures described in the OFR's handbook on IBR (<https://www.archives.gov/files/federal-register/write/handbook/ibr.pdf>).
- C.** Consensus standards should be considered for use instead of Government-unique standards except where inconsistent with law or otherwise impractical, in accordance with the National Technology Transfer and Advancement Act (15 U.S.C. 3701 et seq.). See MD 6.5, "NRC Participation in the Development and Use of Consensus Standards." The use of consensus standards should be consistent with the guidance in OMB Circular A-119, "[Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities](#)," January 27, 2016.

- D. Consistent with [OMB Circular A-119](#), agencies should, on a regular basis, review and, if necessary, update references to standards that have been incorporated by reference. Therefore, when considering the practicality of using a consensus standard, the repetitive maintenance costs for the rule and related guidance associated with the selected standard's revision process should be considered and these considerations documented in the regulatory analysis. The documentation is intended to capture revision costs associated with the maintenance of the rule and endorsing guidance, and the documentation also supports reporting requirements contained in [OMB Circular A-119](#). The costs are usually associated with the life-of-the-rule or guidance exceptions or clarifications as compared to a stand-alone rule (e.g., repetitive 10 CFR 50.55a rulemaking and regulatory guide update costs over 60 years).

XVIII. REGULATORY ANALYSIS AND RULEMAKING SUPPORT BRANCH (RASB)

RASB plays the following role in the NRC's rulemaking process ([ML17040A503](#)):

- A. Develops, recommends, and administers policies and procedures for regulatory analysis (see Section XI of this handbook) and the review and publication of all NRC regulations.
- B. Ensures, with the advice of OGC, as necessary and appropriate, that the NRC's exercise of the rulemaking process complies with the following:
1. The Administrative Procedure Act,
 2. The Congressional Review Act,
 3. The Federal Register Act,
 4. Title 1 of the CFR Chapters I and II,
 5. The Plain Language Act of 2010,
 6. Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act.
- C. Provides rulemaking support for development of rulemakings that revise CFR requirements (1) under the purview of offices reporting to the Commission and (2) are administered by NRC's corporate offices.
- D. Prepares administrative rules, presenting no policy issues, which may be issued without review and approval of the Commission or the EDO in accordance with MD 6.3.
- E. Manages the NRC program for PRMs, including drafting notices of docketing and reviewing notices to consider, partially consider, or deny PRMs.

- F. Maintains the agency's collection of regulatory histories. The technical lead office, which is responsible for the rulemaking activity, prepares a regulatory history for each proposed and final action and submits it to RASB upon completion of the activity.
- G. Prepares rulemaking reports for submission to the EDO.

XIX. GLOSSARY

See also the NRC Rulemaking Dataset Dictionary ([ML17160A116](#)).

Advisory Committees

Include the Advisory Committee on Reactor Safeguards (ACRS), the Committee to Review Generic Requirements (CRGR), and the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

Backfitting and Issue Finality

Backfitting of a nuclear power reactor is defined in 10 CFR 50.109, "Backfitting," as the modification of or addition to systems, structures, components, or design of a plant or a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a plant or a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after certain date(s). Related issue finality provisions for nuclear power reactors are found in 10 CFR Part 52. Additional related backfitting provisions exist for certain materials licensees. For more information on backfitting and issue finality, see Section XII, "Backfitting and Issue Finality," of this handbook.

Centralized Rulemaking Services Provided by the Division of Rulemaking

Responsible for the planning, development, documentation, tracking, reporting, and implementation of policies and procedures for the NRC's rulemaking functions in the reactor and materials business lines ([ML17040A503](#)).

Congressional Review Act (CRA)

The Regulatory Analysis and Rulemaking Support Branch (RASB) is responsible for coordinating the Office of Management and Budget (OMB) review of NRC final rule actions as required by the Congressional Review Act (CRA). These final actions were formerly requested under the Small Business Regulatory Enforcement Fairness Act (SBREFA). A final action is defined as "major" under CRA if the action will result in or is likely to result in—

1. An annual effect on the economy of \$100 million or more;
2. A major increase in costs or prices for consumers, individual industries, or geographical regions; or

3. Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises, in domestic and export markets.

See the NRC CRA SharePoint site, at <https://usnrc.sharepoint.com/teams/NMSS-Congressional-Review-Act>, for each office's CRA contact and the NRC's List of Actions Subject to the Congressional Review Act at <https://usnrc.sharepoint.com/teams/NMSS-Congressional-Review-Act/Shared%20Documents/List%20NRC%20actions%20subject%20to%20CRA.docx>.

Cumulative Effects of Regulation (CER)

Describes the challenges that licensees, or other impacted entities such as Agreement 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 significant number of new and complex regulatory actions stemming from multiple regulatory actions, 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. CER can be aggravated if the new requirements lack clarity.

Direct Final Rule

A regulatory document that is used for non-controversial regulatory amendments. The direct final rule process allows an agency to issue a rule without having to go through the review process twice (i.e., at the proposed and final rule stages), while at the same time offering the public the opportunity to challenge the agency's view that the rule is non-controversial. See the NRC public Web site on Rulemaking, Direct Final Rule, at <https://www.nrc.gov/about-nrc/regulatory/rulemaking/rulemaking-process/direct-final-rule.html>, for direct final rule procedures and criteria for determining a significant adverse comment.

The Administrative Conference of the United States (ACUS) endorsed use of the direct final rule process as a means for expediting rulemaking. See ACUS Recommendation 95-4, "Procedures for Non-controversial and Expedited Rulemaking" (60 FR 43110; August 18, 1995).

Discontinued Rulemaking Activity

A rulemaking is discontinued when the Commission (or senior management, for rulemaking activities not yet approved by the Commission or delegated to the staff) directs the staff to stop working on it. The NRC may discontinue a rulemaking activity at any stage in the rulemaking process.

Draft Rulemaking Language

Rule language that is part of a recommendation to the NRC rulemaking decisionmaker that the NRC issue a proposed or final rule. Thus, there can be both “draft proposed rule language,” as well as “draft final rule language.”

Final Rulemaking Language

Rule language that the NRC rulemaking decisionmaker has approved and that the NRC has transmitted to the Office of the Federal Register for publication in the *Federal Register* as a notice of final rulemaking announcing the agency’s adoption of a final rule. The notice of final rulemaking is required by the Administrative Procedure Act (APA). Final rule language also refers to the actual rule language published as part of the *Federal Register* notice of final rulemaking.

Incorporation by Reference (IBR)

Allows Federal agencies to comply with the requirement to publish rules in the *Federal Register* by referring to materials already published elsewhere. The legal effect of incorporation by reference is that the material is treated as if it were published in the *Federal Register*. This material has the force and effect of law, just like regulations published in the CFR.

Legal Objection

The Office of the General Counsel (OGC) may use this term when it is reviewing a document.

1. OGC has a legal objection where the attorney finds that the recommended action is legally deficient or is objectionable from a legal policy standpoint. The attorney should work with the originating office in arriving at a legally acceptable action.
2. Where no legally acceptable accommodation is reached, OGC should formally communicate the basis for its legal objection(s) to the technical lead office.

No Legal Objection

OGC may use this term when it is reviewing a document. It means that—

1. The recommended action is legally sufficient, and
2. OGC is not taking a position with respect to the policy aspects of the recommendation.

NRC Docket ID

A unique tracking number that the Federal Document Management System uses to identify all rulemakings. Example: NRC-2011-0058.

Preliminary Final Rulemaking Language

See the definitions for “preliminary rulemaking language” and “final rulemaking language.” Exhibit 1 provides additional detail.

Preliminary Proposed Rulemaking Language

See the definitions for “preliminary rulemaking language” and “proposed rulemaking language.” Exhibit 1 provides additional detail.

Preliminary Rulemaking Language

Rule language that is *not* part of an official recommendation to the NRC decisionmaker with rulemaking authority that the NRC issue a proposed or final rule. Thus, there can be both “preliminary proposed rule language,” as well as “preliminary final rule language.” Preliminary rule language is developed by working level staff but does not constitute the NRC’s official rulemaking proposal, even though it may be made available to the public. Preliminary rule language may be made available to the public in several ways, including—

1. An advance notice of proposed rulemaking (ANPR) published in the *Federal Register*,
2. A *Federal Register* notice announcing the public availability of such language,
3. A posting at the [Regulations.gov](http://www.Regulations.gov) Web site or the NRC public Web site, and
4. Distribution of printed copies at a public meeting.

Proposed Rule Language

Rule language that meets the following requirements:

1. The NRC decisionmaker with rulemaking authority has approved it, and
2. The NRC has transmitted it to the Office of the Federal Register for publication in the *Federal Register* as the official NRC rulemaking proposal for public comment.

This notice of proposed rulemaking is required by the APA and the Atomic Energy Act of 1954, as Amended (AEA). These requirements distinguish a notice of proposed rulemaking from an ANPR and the public release of preliminary rule language, both of which are not required by either the APA or the AEA.

Proposed rule language also refers to the actual language published as part of the *Federal Register* notice of a proposed rule.

Regulation Identifier Number (RIN)

A unique sequential number that RASB assigned to a rulemaking after the Commission approves a rulemaking plan. The RIN is used for interagency and internal tracking of rulemakings. Example: RIN 3150-BB22.

Regulatory Analysis

An integral part of NRC decisionmaking, systematically provides complete disclosure of relevant information, including the costs and benefits of the regulatory action, to support a regulatory decision. The conclusions included in a regulatory analysis are neither final nor binding, but are intended to enhance the soundness of decisionmaking by NRC managers and the Commission. For additional information, see the latest version of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook."

Regulatory Basis

Often includes details about the following:

1. Why a current regulation or policy needs to be changed;
2. Why alternatives to rulemaking will not work;
3. Different approaches to resolve the issue;
4. Supporting scientific, policy, legal, economic, or technical information;
5. Stakeholder interactions in developing the technical portion of the regulatory basis and stakeholder views;
6. Any backfit considerations, as appropriate; and
7. Any limitations on the scope and quality of the regulatory basis.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S. C. 601 et seq.) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires that each Federal agency consider the impact of its rulemaking on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. In essence, the Act requires that each agency:

1. Analyze the impact of the proposed rule on different sized entities,
2. Estimate the effectiveness of the regulatory proposal in addressing the source of the problem, and
3. Consider alternatives that would minimize compliance costs.

Rule

Refers to an agency statement of general or particular applicability and future effect. A rule is designed to—

1. Implement, interpret, or prescribe law or policy; or
2. Describe the organization, procedure, or practice requirements of an agency.

Rulemaking

The agency process for formulating, amending, or repealing a rule. It is the process that ensures that the intent and effect of a rule are fully understood before it is enacted. Proper rulemaking enhances the mission of the agency by providing order, balance, equity, and openness to the regulatory process.

Rulemaking Actions

At the NRC, the staff and the Commission engage in “rulemaking actions” once the Commission approves the rulemaking plan. For example, the technical lead office could develop a draft regulatory basis and develop a draft regulatory guide. The technical lead office could perform the following rulemaking actions: engage in public meetings, release preliminary (proposed and final) rule language, publish a proposed rule, publish a final rule, and develop a regulatory history.

Rulemaking Activity

At the NRC, the entire set of rulemaking actions that the staff and the Commission perform to effect a change to the *Code of Federal Regulations*. For example, a rulemaking activity could include a rulemaking plan, a regulatory basis, a proposed rule, and a final rule.

Rulemaking Coordinating Committee (RCC)

A standing interoffice group with representatives from the technical lead offices (Office of New Reactors, Office of Nuclear Reactor Regulation, and Office of Nuclear Material Safety and Safeguards (Chair)), as well as OGC and other relevant offices. The RCC’s focus is to ensure consistency in methods used to develop and promulgate rules and to initiate and implement improvements to the rulemaking process.

Rulemaking Documents

Rulemaking documents include all documents necessary to issue a proposed or final rule. This includes documents in the rulemaking package as well as guidance documents.

Rulemaking Package

Rulemaking package includes all documents for Commission or EDO review.

Rulemaking Plan

Raises potential policy issues for early Commission involvement. Provides the regulatory issue, a preliminary outline of the scope of the proposed rule, and the existing regulatory framework. Also identifies the regulatory options and alternatives to rulemaking and discusses why rulemaking is preferable to these other options and how the proposed rule relates to the safety and security goals found in the NRC's Strategic Plan and describes the impact that the rule will have on regulatory efficiency. See SRM-SECY-15-0129 ([ML16034A441](#)).

Sponsoring Office (formerly Technical and Corporate Offices)

Offices without delegated rulemaking authority may sponsor a rulemaking activity. For example, the Office of Nuclear Security and Incident Response and the Office of Administration sponsor rulemaking activity.

Steering Committee

May be established for certain rulemakings, particularly those that are unusually controversial or complex and those for which the implementation responsibilities cut across several divisions or offices. The steering committee resolves significant questions of policy, provides direction on significant technical issues, and facilitates concurrence of the rulemaking action. The steering committee chair is from the technical lead office, which is responsible for the regulatory action.

Technical Lead Office (formerly Rulemaking Office)

The Commission has delegated rulemaking authority to the Office of Nuclear Material Safety and Safeguards (NMSS), the Office of New Reactors (NRO), and the Office of Nuclear Reactor Regulation (NRR), the Office of International Programs, the Office of the General Counsel, and the Office of the Chief Financial Officer. When one of these offices takes the lead on a rulemaking, it is referred to as "the technical lead office." The consolidation of rulemaking support provides for effective oversight of the rulemaking process involving the materials, new reactor, and operating reactor business lines and supports the agency's goal of accomplishing rulemaking activities in an efficient, effective, and transparent manner. Note: The rulemaking terminology of "technical lead office" is used rather than the budgetary term "business line lead" in this document, though the application is similar given that the technical lead office also budgets for rulemaking in its designated business line (e.g., new reactors for NRO, operating reactors for NRR, and the four materials business lines for NMSS).

EXHIBIT

Exhibit 1 Illustration of the Terms “Preliminary,” “Draft,” and “Final” with Regard to Rulemaking Language

