

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

MD 6.3	THE RULEMAKING PROCESS	DT-13-14
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EXECUTIVE SUMMARY

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. Management Directive and Handbook 6.3 provide guidance to ensure that—

- The NRC gives the public and stakeholders the opportunity for meaningful participation in rulemaking proceedings,
- The NRC gives Agreement States the opportunity to comment on applicable preliminary rulemaking actions,
- Offices establish and meet schedules for rulemaking actions, and
- Offices coordinate with each other so that staff resources are used efficiently during the development of rulemaking actions.

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I. POLICY

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to develop 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 stakeholders the opportunity for meaningful participation in rulemaking proceedings.
- The NRC gives Agreement States the opportunity to comment on applicable preliminary rulemaking actions.
- 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 actions.

III. ORGANIZATIONAL RESPONSIBILITIES AND DELEGATIONS OF AUTHORITY

A. Commission

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.

1. The Commission is responsible for the following:
 - (a) Directing the initiation and prioritization of rulemaking activities;
 - (b) Approving or denying each rulemaking plan, or major modification to a plan, except those that fall within the authority delegated to the Executive Director for Operations (EDO) or the Chief Financial Officer (CFO);
 - (c) Approving or denying each advance notice of proposed rulemaking, proposed rule, direct final rule, final rule, and petition for rulemaking, except those that fall within the authority delegated to the EDO or the CFO;
 - (d) Approving or denying each issuance and revision to Commission policy statements, including the enforcement policy; and
 - (e) Ensuring that the NRC's regulations comply with the Regulatory Flexibility Act and the Congressional Review Act (CRA).
2. The Commission has exclusive authority to issue rules concerning the following:
 - (a) A significant question of policy;
 - (b) Parts 7, 8, and 9 (Subpart C) of Title 10 of the *Code of Federal Regulations* (10 CFR) concerning matters of policy; and
 - (c) Issuance and revision of policy statements.

3. 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) Results in a major commitment of resources by a class of licensee.

In determining whether a rule involves a significant question of policy, the lead office for the rulemaking action should consider the following: the impact of the action on licensees and the public; the degree of controversy that could be associated with the action; the existence of significant public health, safety, environmental, common defense and security, or safeguards issues; the applicability of existing precedent; and resources that will be required for implementation.

4. Delegations of Authority to the EDO

The Commission has delegated to the EDO the authority to ensure that the NRC's rules comply with the Regulatory Flexibility Act and the CRA. The EDO may redelegate this authority, as appropriate.

The Commission has also delegated to the EDO the authority to issue a rule, or grant or deny a petition for rulemaking, if a rulemaking action does not raise a significant policy issue or is corrective in nature. Below is additional information on the type of rule that does not raise a significant policy issue or is corrective in nature (see delegations of authority in 47 FR 11816 and 50 FR 42145).

- (a) A rule involving a minor change in policy.

This type of rule involves a situation in which existing policy is essentially followed with minor modifications to fit a particular situation.

- (b) A rule involving a minor new issue.

This type of rule involves a situation in which the following circumstances apply:

- (i) The issue was previously considered by the Commission in a similar context;
 - (ii) The rule has limited impact;
 - (iii) The rule does not present important or significant public health, safety, environmental, common defense and security, or safeguards issues; and
 - (iv) The rule requires limited resources to implement.
- (c) A rule of a minor, corrective, or nonpolicy nature that does not substantially modify existing precedent.

- (d) A final rule, if the Commission has considered all significant questions of policy in connection with the proposed rule, and one of the following applies:
 - (i) The NRC has not received any significant adverse questions or comments from stakeholders on the proposed rule, or
 - (ii) The proposed rule does not require substantial text changes.

5. Delegations of Authority to the CFO

The Commission delegates to the CFO the authority to develop and issue a rule that is necessary to carry out the CFO's responsibilities, including any revision of the annual fee regulations in 10 CFR Parts 170 and 171.

- (a) The CFO's rulemaking authority does not extend to the promulgation of a proposed or final rule that involves a significant question of policy. (See Section III.A.3 of this directive for a description of what constitutes significant questions of policy.)
- (b) For any rule that is issued by the CFO, the CFO is required to obtain the EDO's concurrence and a determination from the Office of the General Counsel (OGC) that it has no legal objection to the action.
- (c) 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 CRA.

B. Executive Director for Operations (EDO)

The EDO has the following authority:

1. In accordance with Management Directive (MD) 9.17, "O/F, Office of the Executive Director for Operations," the EDO shall ensure that all rulemaking is conducted in accordance with general policy guidance from the Commission.
2. As stated in Section III.A.5 of this directive, the Commission has delegated to the EDO the authority to issue the following types of rulemaking actions:
 - (a) A rule involving a minor change in policy;
 - (b) A rule involving a minor new issue;
 - (c) A rule of a minor, corrective, or nonpolicy nature that does not substantially modify existing precedent; and
 - (d) A final rule that meets the conditions stated in Section III.A.5.
3. Before promulgating a proposed or final rule modifying 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," the EDO shall

- obtain the concurrence of the Office of the General Counsel, 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. Approves or denies the following:
 - (a) Rulemaking plan or any modifications to the plan, for rulemakings that will be issued under the authority delegated to the EDO.
 - (b) Each proposed rule, final rule, direct final rule, and advance notice of proposed rulemaking that will be issued under the authority delegated to the EDO.
 - (c) Each petition for rulemaking that falls within the scope of the authority delegated to the EDO.
 5. Waives the development and submission of a rulemaking plan and regulatory analysis for specific rulemakings, as appropriate. The EDO has redelegated this authority to the following:
 - (a) The Director of the Office of Federal and State Materials and Environmental Management Programs (FSME),
 - (b) The Director of the Office of New Reactors (NRO), and
 - (c) The Director of the Office of Nuclear Reactor Regulation (NRR).
 6. Directs the initiation of rulemakings that are within the scope of the authority delegated to the EDO.
 7. Monitors the progress of rulemakings that are within the scope of the EDO's signature and concurrence authority. If necessary, the EDO resolves issues preventing office concurrence on a rulemaking.
 8. Approves the NRC regulatory guides listing NRC-approved American Society of Mechanical Engineers (ASME) Code cases. The EDO may redelegate this authority, as appropriate.
 9. Releases draft proposed rule text, statements of considerations, and the regulatory basis for public review or comment.
 - (a) The EDO may redelegate this authority as appropriate and has redelegated it to—
 - (i) The Director of FSME,
 - (ii) The Director of NRO, and
 - (iii) The Director of NRR.

- (b) The Directors of FSME, NRO, and NRR may redelegate this authority down to the appropriate staff level. 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.
10. Holds public interactions to obtain external stakeholder input.
- (a) These interactions may include the following:
- (i) Releasing preliminary regulatory basis, preliminary and draft rule text, and preliminary statements of consideration for public review and comment; and
 - (ii) Holding public meetings, workshops, and Webinars in order to obtain public stakeholder input.
- Note: 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.
- (b) The EDO may redelegate this authority as appropriate and has redelegated it to—
- (i) The Director of FSME,
 - (ii) The Director of NRO, and
 - (iii) The Director of NRR.
- (c) The Directors of FSME, NRR, and NRO may redelegate this authority down to the appropriate staff level.
11. Delegates to the Director of NRR the authority to approve the following:
- (a) All final Commission memoranda containing amendments to 10 CFR 50.55a, "Codes and Standards," pertaining to the incorporation by reference of the ASME Boiler and Pressure Vessel Code (BPV Code) and Operations and Maintenance Code (OM Code).
- (i) 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 OM Code, and the related regulatory guides.
 - (ii) 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.
 - (iii) The delegation of authority applies only to rulemakings that are routine in nature and 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 of all applicable NRC offices.
- (iv) The Director of NRR may not redelegate this authority.
 - (v) For additional details, see the February 5, 2010 memorandum from the EDO to the Director of NRR (ADAMS Accession No. ML091730349).
- (b) The NRC's regulatory guides listing NRC-approved ASME Code cases. See SECY-10-0016.
12. Designates NRO as lead office for design certification and other rulemaking activities related to new and advanced reactors. See COMSECY-09-0003 and SRM-COMSECY-009-0003.
13. As delegated by the Commission, ensures that the NRC's regulations comply with the Regulatory Flexibility Act and the CRA.
- (a) The EDO may redelegate this authority as appropriate and has redelegated it to—
 - (i) The Director of ADM,
 - (ii) The Director of FSME,
 - (iii) The General Counsel,
 - (iv) The Director of NRO,
 - (v) The Director of the Office of International Programs, and
 - (vi) The Director of NRR.
 - (b) The Directors of ADM, FSME, NRO, OIP and NRR as well as the General Counsel may redelegate this authority down to the appropriate staff level.
14. Upon concurrence of a rulemaking action—
- (a) Transmits the rule for Commission action.
 - (b) If necessary, returns the rule to the NRC staff for modification or resolution of questions within a specified schedule.
 - (c) Notifies the Commission of the intent to issue the rule under the authority of the EDO.
 - (d) Concurs on rules developed by the Office of International Programs (OIP). The EDO may also issue rules developed by OIP.
 - (e) Concurs on rules developed by the OGC, if appropriate.

C. Deputy Executive Director for Corporate Management (DEDCM)

1. Provides central coordination for the NRC rulemaking program by overseeing the rulemaking process for the EDO.
2. Ensures consistency in methods used to develop and issue rules through the Rulemaking Coordinating Committee (RCC).
3. Oversees the development of the annual Rulemaking Activity Plan.
4. Submits semiannual status reports on petitions for rulemaking to the EDO.

D. Chairs, Advisory Committees

As appropriate, review and provide comments to the lead office or the Commission on the rulemaking documents.

E. General Counsel (GC)

1. Conducts rulemakings and submits them to the Commission or the EDO for review and approval.
2. Performs the following duties as delegated by the EDO:
 - (a) Waives the development and submission of a rulemaking plan and regulatory analysis for specific rulemakings, as appropriate. The office director may redelegate this authority to a division director, as appropriate.
 - (b) Releases preliminary proposed rule text, statements of consideration, and the regulatory basis for public review and comment; and
 - (c) Holds public workshops, public meetings, or Webinars in order to obtain public stakeholder input.
 - (d) Ensures that rules are compliant with the Regulatory Flexibility 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 rulemaking actions to ensure compliance and consistency with the following:
 - (a) The 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, and risk standards.

6. Forwards review comments on rulemaking documents to the lead office or the Commission.
7. Consults with the Office of Administration (ADM) on the processing of petitions for rulemaking, including determining whether the petition includes the information required in 10 CFR 2.802.
8. Determines whether agency documents under review should be considered final “rules” that are subject to the process dictated in the CRA.

F. Inspector General (IG)

1. Reviews rules and regulations in conducting audits, investigations, and regulatory review.
2. Reviews rulemaking actions before they are submitted to the Commission and provides comments, as appropriate, concerning their impact on the economy and efficiency of programs and operations administered or financed by the NRC or the prevention and detection of fraud and abuse in the administration of these programs and operations.

G. Chief Financial Officer (CFO)

1. The Commission has delegated to the CFO the authority to develop and issue any rule that is necessary to carry out the CFO’s responsibilities, including the revisions of the annual fee regulations in 10 CFR Parts 170 and 171.
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. (See Section III.A.3 of this directive for a description of what constitutes significant questions of policy.)
3. For each rule that is issued by the CFO, the CFO is required to obtain the EDO’s concurrence and a determination from OGC that it has no legal objection to the action.
4. Forwards review comments on final rules to the lead office.
5. Approves or denies each petition for rulemaking that falls within the scope of the authority delegated to the CFO.
6. If a rulemaking will be issued under the authority delegated to the CFO, then the CFO directs the preparation of the rulemaking package and all required supporting documents.
7. If a rulemaking will be issued under the authority delegated to the CFO, then the CFO ensures that the rule complies with the Regulatory Flexibility Act and the CRA.

8. When a rulemaking has a rulemaking plan—
 - (a) The CFO reviews and concurs on the rulemaking plan and any subsequent changes to the plan that have significant resource implications. This ensures that resources have been properly addressed and potential fee implications have been coordinated.
 - (b) The CFO will not review subsequent proposed rule or final rule documents. (See memorandum from the Office of the Chief Financial Officer (OCFO) entitled, “OCFO Concurrence on Rule Packages,” ADAMS Accession No. ML071210374.)
9. When a rulemaking does not have a rulemaking plan, the CFO will review and concur on the final rulemaking documents as part of the normal concurrence process. (See ADAMS Accession No. ML071210374.)

H. Director, Office of Congressional Affairs (OCA)

1. Keeps Congress fully and currently informed of NRC rulemaking actions.
2. Ensures that the NRC staff is aware of the specific Congressional committees that should receive notification of NRC rulemaking actions via a Congressional letter.
3. Signs and transmits Congressional letters and CRA forms to Congress in order to notify Congress of NRC rulemaking actions.

I. Office of International Programs (OIP)

Conducts rulemakings and submits them to the Commission or the EDO for review and approval.

J. Director, Office of Public Affairs (OPA)

1. Determines whether a press release is needed for a rulemaking action.
2. If a press release is needed, designates an OPA representative to prepare a preliminary press release for comment and review by the lead office.
3. Publishes the press release concurrent with—
 - (a) The publication of the proposed or final rule, or
 - (b) The issuance of a Staff Requirements Memorandum (SRM) for a proposed or final rule.

K. Office of the Secretary (SECY)

1. Dockets public comments on proposed rules, petitions for rulemaking, and advance notices of proposed rulemaking. Forwards the comments to the lead office.
2. Transmits the Commission's SRM 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) A proposed rule,
 - (b) A final rule,
 - (c) Revised enforcement policy,
 - (d) An advance notice of proposed rulemaking,
 - (e) A direct final rule (DFR),
 - (f) Petition documents (letter and FRN), and
 - (g) Policy statements.
4. Approves staff requests for extension of ticketed items.

L. Director, Office of Administration (ADM)

1. Chairs meetings of the RCC.
2. Assigns the regulation identifier number and the NRC Docket ID.
3. Maintains NRC rulemaking Web sites.
4. Ensures that the rulemaking actions are consistent with current regulations and other authorization statements of agency policy, including consistency in the use of wording, terminology, and definitions.
5. Reviews rulemaking actions to ensure compliance with the following:
 - (a) CRA;
 - (b) The Federal Register Act;
 - (c) Title 1 of the CFR Chapters I and II;
 - (d) The Plain Language Act of 2010; and
 - (e) Regulatory Flexibility Act.

6. Forwards the monthly CRA report to the Office of Management and Budget (OMB).
7. Forwards review comments on rulemaking actions to the lead office.
8. In consultation with OGC, receives and processes petitions for rulemaking, including determining whether the petition includes the information required in 10 CFR 2.802, docketing the petition, and preparing a notice of receipt to be published in the *Federal Register*.
9. Forwards public comments on petition for rulemaking actions to the lead office and to the petitioner.
10. Posts rulemaking documents on the Federal Government's rulemaking Web site, www.Regulations.gov.
11. Maintains agency historical documents related to rulemaking and issues rulemaking reports.
12. Assigns ADM staff to participate in working groups for rulemaking actions.
13. Prepares the following reports:
 - (a) The Unified Agenda of Federal Regulatory and Deregulatory Actions;
 - (b) The annual Regulatory Plan submitted to OMB as required by Executive Order 12866;
 - (c) The semiannual report to the EDO on the status of all petitions for rulemaking;
 - (d) The Rulemaking Activity Plan that is submitted to the Commission for information and provides a status report on all ongoing rulemakings;
 - (e) The monthly CRA Report; and
 - (f) The Plan for Retrospective Analysis of Existing Rules, which the NRC will periodically update on a voluntary basis, in response to Executive Order 13579.
14. Reviews the electronic compilation of 10 CFR Chapter I that appears on the NRC's public Web site.
15. The Director, ADM, has delegated all of the items in Section III.N of this directive to the Chief, Rules, Announcements, and Directives Branch (RADB).

M. Director, Office of Federal and State Materials and Environmental Management Programs (FSME)

1. Designates an office representative to participate in an NRC staff working group, as appropriate.
2. Coordinates interaction with Agreement States for applicable rulemakings.
3. Coordinates Agreement State review of preliminary rulemaking actions, as appropriate.
4. Performs the following duties as delegated by the EDO:
 - (a) Waives the development and submission of a rulemaking plan and regulatory analysis for specific rulemakings, as appropriate. The office director may redelegate this authority to a division director, as appropriate.
 - (b) Releases preliminary proposed rule text, statements of consideration, and the regulatory basis for public review and comment.
 - (c) Holds public workshops, public meetings, or Webinars in order to obtain public stakeholder input.
 - (d) Ensures that rules are compliant with the Regulatory Flexibility Act and the CRA.

N. Director, Office of New Reactors (NRO)

1. Designates an office representative to participate in an NRC staff working group, as appropriate.
2. Coordinates interaction with Agreement States through FSME for applicable rulemakings.
3. Performs the following duties as delegated by the EDO:
 - (a) Waives the development and submission of a rulemaking plan and regulatory analysis for specific rulemakings, as appropriate. The office director may redelegate this authority to a division director, as appropriate.
 - (b) Releases preliminary proposed rule text, statements of consideration, and the regulatory basis for public review and comment; and
 - (c) Holds public workshops, public meetings, or Webinars in order to obtain public stakeholder input.
 - (d) Ensures that rules are compliant with the Regulatory Flexibility Act and the CRA.

O. Director, Office of Nuclear Reactor Regulation (NRR)

1. Designates an office representative to participate in an NRC staff working group, as appropriate.
2. Coordinates interaction with Agreement States through FSME for applicable rulemakings.
3. Performs the following duties as delegated by the EDO:
 - (a) Waives the development and submission of a rulemaking plan and regulatory analysis for specific rulemakings, as appropriate. The office director may redelegate this authority to a division director, as appropriate.
 - (b) Releases preliminary proposed rule text, statements of consideration, and the regulatory basis for public review and comment; and
 - (c) Holds public workshops, public meetings, or Webinars in order to obtain public stakeholder input.
 - (d) Ensures that rules are compliant with the Regulatory Flexibility Act and the CRA.
4. Approves amendments to 10 CFR Part 50.55a, "Codes and Standards," pertaining to the incorporation by reference of the ASME BPV Code and ASME OM Code.
5. Approves the NRC's regulatory guide listing NRC-approved ASME Code cases.

P. 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.
2. Determines, in consultation with OGC, whether the criminal penalties section for each part affected by the rulemaking action must be amended to reflect the action.

Q. Director, Office of Information Services (OIS)

1. Reviews the following to ensure that the information technology effects of the rulemaking have been adequately evaluated and addressed and to ensure 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) DFRs, and
 - (d) Final rules.

The Director of OIS has delegated the authority described in Section III.L of this directive to the NRC Clearance Officer.

2. Forwards review comments to the lead office on the following:
 - (a) Rulemaking plans,
 - (b) Proposed rules,
 - (c) DFRs, and
 - (d) Final rules.

R. Director, Lead Office for the Rulemaking Activity

The director of the lead office for the rulemaking activity has overall responsibility for creating all rulemaking documents and recommending their publication in the *Federal Register*. The office performs the following:

1. Initiates and develops each element of a rulemaking action in subject areas for which the office is responsible.
2. Participates in the development of the regulatory basis and the applicable guidance.
3. Approves a regulatory basis before initiating rulemaking activity.
4. Determines if a rulemaking plan is necessary.
5. Designates an office representative to coordinate each rulemaking action.
6. Recommends to the EDO whether the proposed rulemaking should be initiated.
7. Ensures that important new rules involving significant public interest are presented to the Commission. (See Section III.A.3 of this directive for a description of what constitutes significant questions of policy.)
 - (a) This is especially critical if comments received from the public or during office concurrence suggest that the Commission may reconsider certain provisions of the proposed rule.
 - (b) The lead office should ensure that these rules are brought to the Commission's attention, even when the lead office does not plan on making any changes to regulatory text in the final rule.
8. Prioritizes assigned rulemaking actions and coordinates with other program offices to create an integrated prioritization list for NRC rulemakings.
9. Ensures the timely completion of rulemaking actions.

10. Establishes a working group, as appropriate, to assist in the preparation of the rulemaking actions and in obtaining necessary concurrences.
11. Determines the offices from which office concurrence will be requested on the rulemaking actions.
12. Coordinates rulemaking actions with other Federal Government agencies (e.g., the Environmental Protection Agency, the Department of Energy, or the Department of Transportation) when appropriate or when this coordination is required by statute or regulation.
13. Solicits early Agreement State participation from a technical standpoint in the office's area of responsibility in applicable rulemakings through FSME. Sends preliminary rulemaking (FRN only) to Agreement States, as appropriate. Agreement States' participation in working groups will be handled in accordance with MD 5.3, "Agreement State Participation in Working Groups."
14. Informs the Commission when a preliminary rulemaking is provided to the Agreement States.
15. Coordinates with OPA to determine whether a press release is appropriate and, if so, provides OPA with information sufficient to develop the press release.
16. Ensures that rulemaking documents are properly managed and archived in ADAMS.

Note: The director of the lead program office has overall responsibility for developing the regulatory basis and implementing guidance. The authorities and responsibilities of the lead program office are described below in Section III.S of this directive.

S. Directors, Lead Program Offices

The director of the lead program office has overall responsibility for developing the regulatory basis and implementing guidance. The office performs the following:

1. Designates an office representative to lead the development of the regulatory basis and also designates other key staff, as necessary, to assist in development of the regulatory basis.
2. Coordinates the development of the regulatory basis with the lead office that will conduct the rulemaking.
3. Solicits stakeholder participation in development of the regulatory basis.
4. Designates an office representative to lead the development of any supporting guidance and also designates other key staff, as necessary, to assist in development of the guidance.

5. In accordance with MD 6.6, "Regulatory Guides," coordinates the development of the guidance with the lead office that is conducting the rulemaking.
6. Solicits stakeholder participation in development of the guidance.

Note: The director of the lead office for the rulemaking activity has overall responsibility for creating all rulemaking documents and recommending their publication in the *Federal Register*. The authorities and responsibilities of the lead office for the rulemaking activity are described above in Section III.R.

T. Rulemaking Coordinating Committee (RCC)

1. The RCC is a standing interoffice group with representatives from the following lead rulemaking offices: FSME, NRO, NRR, OGC, OIS, and ADM (chair).
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.

U. 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 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 plans and rulemaking packages to the lead office.
5. Serve as concurring official for the rulemaking action or delegate concurring authority to the designated working group member or other appropriate official.

V. Office Representative (or Alternate)

1. The office representative for the lead office for the rulemaking activity has the following responsibilities:
 - (a) Leads the activities of the working group.
 - (b) Prepares or coordinates the preparation of the packages for the rulemaking actions.

- (c) Keeps office management informed of the status of the rulemaking or any policy issues that arise.
 - (d) Obtains necessary concurrences or coordinates the concurrence process.
 - (e) Coordinates interactions with the public (posting preliminary proposed rule language, public meetings, etc.).
 - (f) Prepares a regulatory history for the rulemaking in ADAMS, compiles an index of documents that comprise the history, and forwards the index to RADB, Division of Administrative Services, ADM.
2. The office representative for concurring offices (including concurring lead offices) and OGC have the following responsibilities:
- (a) Prepare or provide input for the rulemaking plan, the packages for the rulemaking actions, and required supporting documents.
 - (b) Keep office management informed of any policy issues that could affect office interests or could constitute a basis for legal objection or for withholding office concurrence.
 - (c) Coordinate rulemaking activities with staff in the representative's office, as necessary, to represent integrated office positions.
 - (d) Oversee office reviews regarding factual matters in the concurrence document.
 - (e) Oversee office development of rulemaking documents as assigned by the lead of the working group.

W. NRC Clearance Officer

1. In accordance with MD 3.54, "NRC Collections of Information and Reports Management," the NRC Clearance Officer reviews the following:
- (a) Rulemaking plans,
 - (b) Proposed rules,
 - (c) DFRs, and
 - (d) Final rules.
2. The NRC Clearance Officer ensures that the information technology impacts of the rulemaking have been adequately evaluated and addressed and to ensure compliance with—
- (a) The information collection requirements of the Paperwork Reduction Act, and
 - (b) The NRC's policies and procedures governing information management.

3. The NRC Clearance Officer certifies that information collections contained in NRC rulemakings adhere to the Paperwork Reduction Act.
4. The NRC Clearance Office submits NRC's rules to the OMB for review and approval.
5. The Director, OIS has delegated all of the items in Section III.W of this directive to the NRC Clearance Officer.

X. Rules, Announcements, and Directives Branch (RADB), ADM

1. Concurs on rulemakings, on behalf of ADM, as appropriate.
2. Performs functions described in Section III.N of this directive.

IV. APPLICABILITY

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

V. DIRECTIVE HANDBOOK

Directive Handbook 6.3 describes activities 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 <http://www.internal.nrc.gov/ADM/DAS/cag/RM01/>.

VI. REFERENCES

Code of Federal Regulations

- 1 CFR, Chapter I, "Administrative Committee of the Federal Register."
- 1 CFR, Chapter III, "Administrative Conference of the United States."
- 1 CFR, Part 51, "Incorporation by Reference."
- 10 CFR, Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders."
- 10 CFR, Part 7, "Advisory Committees."
- 10 CFR, Part 9, "Public Records."
- 10 CFR, Part 50.55a, "Codes and Standards."
- 10 CFR, Part 50.109, "Backfitting."
- 10 CFR, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

10 CFR, Part 70.76, "Certification of Gaseous Diffusion Plants."

10 CFR, Part 72.62, "Backfitting."

10 CFR Part 76.76, "Backfitting."

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."

10 CFR, Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, Quality Assurance Program Approvals and Government Agencies Licensed by the NRC."

Executive Orders

Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (September 30, 1993) (<http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>).

Executive Order 12889, "Implementation of the North American Free Trade Agreement," 58 FR 69681 (December 27, 1993) (<http://www.archives.gov/federal-register/executive-orders/pdf/12889.pdf>).

Executive Order 13258, "Amending Executive Order 12866 on Regulatory Planning and Review," 67 FR 9385 (February 26, 2002) (<http://www.gpo.gov/fdsys/pkg/FR-2002-02-28/pdf/02-5069.pdf>).

Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," 72 FR 2763 (January 18, 2007) (<http://www.gpo.gov/fdsys/pkg/FR-2007-01-23/pdf/07-293.pdf>).

Executive Order 13579, "Regulation and Independent Regulatory Agencies," 76 FR 41587 (July 14, 2011) (<http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17953.pdf>).

Executive Order 13563, "Improving Regulation and Regulatory Review," 76 FR 3821 (January 18, 2011) (<http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>).

Office of the Federal Register

"Document Drafting Handbook," October 1998 Revision; Chapters 5 and 6, 2011 Revision, (<http://www.archives.gov/federal-register/write/handbook/>).

Office of Management and Budget

Memorandum from Rob Portman, "Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices," April 25, 2007

<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-13.pdf>).

Memorandum from Peter R. Orsag, “Open Government Directive,” December 8, 2009 (<http://www.whitehouse.gov/open/documents/open-government-directive>).

Memorandum (M-11-19) from Cass Sunstein, OIRA, “Retrospective Review of Significant Regulations,” April 25, 2011 (<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-19.pdf>).

Memorandum (M-11-28) from Cass Sunstein, “Executive Order 13579, Regulation and Independent Regulatory Agencies,” July 22, 2011.

Memorandum from Cass Sunstein, OIRA, “Cumulative Effects of Regulation,” March 20, 2012 (<http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/cumulative-effects-guidance.pdf>).

Memorandum from Cass Sunstein, OIRA, “Reducing Reporting and Paperwork Burdens,” June 22, 2012.

Presidential Memorandum

Presidential Memorandum for the Heads of Executive Departments and Agencies, “Transparency and Open Government,” January 21, 2009.

U.S. Nuclear Regulatory Commission

Delegations and Redelegations of Authority—

“Statement of Organization and General Information; Delegation of Rulemaking Authority to Executive Director for Operations,” March 19, 1982, 47 FR 11816.

“Statement of Organization and General Information,” October 18, 1985, 50 FR 42145.

Office of Administration, Memorandum to Chief, Rules Review and Directives Branch, “Office of Administration’s Concurrence in Rulemakings,” December 1, 1993 (ADAMS Accession No. ML12201B514).

SRM on SECY-97-167, “Staff Requirements – SECY-97-167 – DSI 22 Implementation (Role of the Office of Research),” September 16, 1997 (ADAMS Accession No. ML003752935).

Office of the Chief Financial Officer, Memorandum to PMDA Directors in the Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Federal and State Materials and Environmental Management, the Office of Nuclear Security and Incident Response, and the Branch of the Rulemaking,

Directives, and Editing Branch in the Office of Administration, "OCFO Concurrence on Rule Packages," May 1, 2007 (ADAMS Accession No. ML071210374).

COMSECY-009-0003, "Designation of the Office of New Reactors as Lead Office for New and Advanced Reactor-Related Rulemakings," February 4, 2009 (ADAMS Accession No. ML082750224) and SRM-COMSECY-009-0003, "Designation of the Office of New Reactors as Lead Office for New and Advanced Reactor-Related Rulemakings," February 27, 2009 (ADAMS Accession No. ML090580508).

SECY-10-0016, "Redelegation of Authority by the Executive Director for Operations to the Director, Office of Nuclear Reactor Regulation, to Approve Title 10 of the Code of Federal Regulations 50.55a Rulemakings," January 28, 2010 (ADAMS Accession No. ML092730529).

Office of Nuclear Reactor Regulation, Memorandum to Director, NRR, from the EDO, "Delegation of Authority to the Director, Office of Nuclear Reactor Regulation, to Approve 10 CFR 50.55a Rulemakings," February 5, 2010 (ADAMS Accession No. ML091730349).

Management Directives—

- 3.5, "Attendance at NRC Staff-Sponsored Meetings."
- 3.54, "NRC Collections of Information and Reports Management."
- 5.3, "Agreement State Participation in Working Groups."
- 6.6, "Regulatory Guides."
- 8.4, "Management of Facility-specific Backfitting and Information Collection."
- 9.17, "O/F, Office of the Executive Director for Operations."
- 10.158, "NRC Non-Concurrence Process (Interim Guidance)."
- 10.159, "The NRC Differing Professional Opinions Program."

Memorandum

NRC Policy Statement on Enhancing Public Participation in NRC Meetings, May 28, 2002 (67 FR 36920) (ADAMS Accession No. ML021350492).

NUREGs

NUREG/BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook" (ADAMS Accession No. ML052720461).

NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the United States Nuclear Regulatory Commission," September 2004 (ADAMS Accession No. ML042820192).

NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook – Final Report," January 1997 (ADAMS Accession No. ML050190193).

NUREG-1409, "Backfitting Guidelines," July 1990 (ADAMS Accession No. ML032230247).

Office Instructions

FSME Policy and Procedure 6-10, Rev. 1, "FSME Procedures for Preparation and Review of Rulemaking Packages," May 2009 (ADAMS Accession No. ML091060034).

FSME Policy and Procedure 2-5, Rev. 0, "FSME Procedure for Interacting with the Advisory Committee on the Medical Use of Isotopes During Development of Major Medical Issues," January 12, 2011 (ADAMS Accession No. ML100640325).

NRO Office Instruction No. REG-114, Rev 0, "Rulemaking Procedures," October 30, 2009 (ADAMS Accession No. ML091540815).

NRR Office Instruction No.: LIC-300, Revision 3, "Rulemaking Procedures," May 25, 2011 (ADAMS Accession No. ML102860268).

Office of State and Tribal Programs, SA-800, "Providing NRC Predecisional Documents to Agreement States and Appropriate Working Groups of the Conference of Radiation Control Program Directors, Inc.," May 4, 2001 (ADAMS Accession No. ML011370784).

SECY Papers

SECY-94-141, "Improvement of the Rulemaking Process," May 23, 1994 (ADAMS Accession No. ML003757908).

SECY-07-0134, "Evaluation of the Overall Effectiveness of the Rulemaking Process Improvement Implementation Plan," August 10, 2007 (ADAMS Accession No. ML071780644).

SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," March 2, 2011 (ADAMS Accession No. ML110190027).

Staff Requirement Memoranda (SRMs)

Staff Requirements Memorandum (SRM) from John C. Hoyle to William C. Parler and James M. Taylor, SECY-94-141, "Improvement of the Rulemaking Process," June 28, 1994 (ADAMS Accession No. ML003757908).

SRM from John C. Hoyle to James M. Taylor, COMSECY-96-035 - SECY-96-034, "Interaction with Agreement States in Rulemaking Planning," June 11, 1996 (ADAMS Accession No. ML003755583).

SRM on COMNJD-06-0004/COMEXM-06-0006, "Streamlining the NRR Rulemaking Process," May 31, 2006 (ADAMS Accession No. ML061510316).

SRM from Karen Cyr to Annette Vietti-Cook, COMSECY-07-0134, "Final Statement of Policy on Conduct of New Reactor Licensing Proceedings and Response to Comments," March 14, 2008 (ADAMS Accession No. ML080740404).

SRM on SECY-09-0190, "Major Revision to NRC Enforcement Policy," August 27, 2010 (ADAMS Accession No. ML102390327).

SRM on SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," October 11, 2011 (ADAMS Accession No. ML112840466).

Task Force Report

"Rulemaking Process Improvement Task Force Final Report to the Rulemaking Coordinating Committee, November 6, 2002" (ADAMS Accession No. ML023180108).

Web Sites—

Information on the NRC's public meetings and involvement at <http://www.nrc.gov/public-involve.html>.

Information on public involvement in NRC rulemaking at <http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html>.

"The NRC Rulemaker" at <http://www.internal.nrc.gov/ADM/DAS/cag/RM01/>.

The NRC's rulemaking dockets at <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/rulemaking-dockets/index.html>.

The NRC's Unified Agenda at <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

The NRC's Office Web Liaisons at <http://www.internal.nrc.gov/web-standards/authority/web-liaisons.html>.

Regulations.gov at <http://www.regulations.gov>.

Yellow Announcement

NRC Yellow Announcement YA-00-0039, "Revised Policy Goal on Timing the Release of Documents to the Public in the ADAMS Environment," May 22, 2000 (ADAMS Accession No. ML003701921).

United States Code

Administrative Procedure Act (5 U.S.C. 551 et seq.).

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Congressional Review Act of 1996 (Pub. L. 104-121, Sec. 251).

Energy Reorganization Act of 1974, as amended (42 U.S.C. 5801 et seq.).

Inspector General Act (5 U.S.C. App. 3).

Negotiated Rulemaking Act (5 U.S.C. 561 et seq.).

Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Plain Language Act of 2010 (Pub. L. 111-274).

Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

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

DH 6.3	THE RULEMAKING PROCESS	DT-13-14
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EXECUTIVE SUMMARY

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. Management Directive and Handbook 6.3 provide guidance to ensure that—

- The NRC gives the public and stakeholders the opportunity for meaningful participation in rulemaking proceedings,
- The NRC gives Agreement States the opportunity to comment on applicable preliminary rulemaking actions,
- Offices establish and meet schedules for rulemaking actions, and
- Offices coordinate with each other so that staff resources are used efficiently during the development of rulemaking actions.

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

1. Memorandum from Rob Portman, “Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices,” April 25, 2007
(<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-13.pdf>).
2. Memorandum from Peter R. Orsag, “Open Government Directive,” December 8, 2009
(<http://www.whitehouse.gov/open/documents/open-government-directive>).
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”
(<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-15.pdf>).
4. Memorandum (M-11-19) from Cass Sunstein, Office of Information and Regulatory Affairs (OIRA), “Retrospective Review of Significant Regulations,” April 25, 2011
(<http://www.whitehouse.gov/sites/default/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 (<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-28.pdf>.)
6. Memorandum from Cass Sunstein, OIRA, "Cumulative Effects of Regulation;" March 20, 2012 (<http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg/cumulative-effects-guidance.pdf>).
7. Memorandum from Cass Sunstein, OIRA, "Reducing Reporting and Paperwork Burdens," June 22, 2012 (<http://www.whitehouse.gov/sites/default/files/omb/inforeg/memos/reducing-reporting-and-paperwork-burdens.pdf>).

B. The NRC also voluntarily complies with the following Presidential Memoranda and Executive Orders:

1. Presidential Memorandum for the Heads of Executive Departments and Agencies, "Transparency and Open Government," January 21, 2009 (<http://www.whitehouse.gov/the-press-office/transparency-and-open-government>).
2. Executive Order 13579, "Regulation and Independent Regulatory Agencies," 76 FR 41587 (July 14, 2011) (<http://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 States, face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a number of complex regulatory positions, programs, or requirements within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security.
- 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 as to how to mitigate CER.

For additional information on CER, see the Office of the Secretary (SECY) paper SECY-11-0032 (ADAMS Accession No. ML110190027) and the Staff Requirements Memorandum (SRM) on SECY-11-0032 (ADAMS Accession No. ML1129404666). Both documents are entitled "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process."

III. COMMISSION CONSIDERATION OF A RULEMAKING ACTION

- A.** The lead rulemaking office must forward a rulemaking action for the Commission's consideration by way of a Commission decision-making paper (known as a SECY paper) submitted through the Executive Director for Operations (EDO), the General Counsel (OGC), the Chief Financial Officer (CFO), or the Office of International Programs (OIP).
 - 1. SECY schedules meetings on significant or controversial rulemaking actions, or items of interest to the Commission, at the request of the Commission.
 - 2. Commission meetings on these matters are open to the public under 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.
- B.** SECY distributes information copies of the SECY paper to the EDO and Commission-level offices that may have an interest in the regulation.
- C.** The Commission may take one of the following actions:
 - 1. Approve the rulemaking action as submitted,
 - 2. Approve the rulemaking action subject to specified changes,
 - 3. Disapprove the rulemaking action entirely, or
 - 4. Direct that the rulemaking action be revised and issued or revised and resubmitted to the Commission for reconsideration.
- D.** The Commission's decision on a direct final rule or final rule is affirmed by each Commissioner in a public meeting.
- E.** The Commission's decision is then reflected in a SRM issued by SECY. If the Commission directs changes to be made in the rulemaking action, the SRM describes these changes, and may establish the deadline for resubmission for Commission consideration or submission for signature and publication.

IV. RULEMAKINGS UNDER THE AUTHORITY OF THE EDO OR THE CFO

A. Lead Office Forwards Action to the EDO Via Memorandum

If a rulemaking action falls within the scope of the EDO's rulemaking authority, then the director of the lead rulemaking office must forward the action to the EDO by memorandum.

1. The memorandum must explain the basis and purpose of the rule.
2. In addition, the lead office must include as an enclosure to the memorandum a certification statement (the approved-for-publication page) prepared for the EDO's signature. This statement must identify the rule and explain how it falls within the scope of the EDO's rulemaking authority.
3. Before submitting a rulemaking plan to the EDO for signature, the lead office must obtain concurrence from the CFO indicating that the CFO has no resource-related objection to the rulemaking.
4. If a final rulemaking did not have a rulemaking plan, then the lead office must obtain concurrence from the CFO indicating that the CFO has no resource-related objection to the rulemaking.

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

1. Before the EDO and the CFO exercise their rulemaking authority, they must inform the Commission.

(a) Proposed Rules Issued by the EDO or the CFO

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, the lead rulemaking office prepares a Weekly Information Report entry. The Weekly Information Report entry is an enclosure to the memorandum forwarding the proposed rule for signature by the EDO or the CFO.
- (ii) After the proposed rule has been signed, the lead office forwards the completed rulemaking package for publication in the *Federal Register* to the Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services (DAS), Office of Administration (ADM).

(b) 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.

- (i) The lead rulemaking office prepares the following:
 - A Notice of Final Rule and
 - A Daily Note.
 - (ii) The lead rulemaking office includes the Notice of Final Rule and the Daily Note with the memorandum forwarding the final rule for the signature of the EDO or the CFO.
 - (iii) The EDO or the CFO must then—
 - Forward a copy of the Notice of Final Rule, the Daily Note, and the final rule to SECY for circulation in the Commission's reading file; and
 - Return the signed rule to the lead office.
2. 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 5 working days after the rule's signature date. This practice provides the Commission with an opportunity to review the action before it is transmitted to OFR for publication. Once the 5-working-day period has elapsed, the lead office must forward the completed rulemaking package to RADB for publication in the *Federal Register*.

V. REGULATORY BASIS

A. Purpose of Regulatory Basis

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 will not work;
3. Different approaches to resolve the issue;
4. Supporting scientific, policy, legal, 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.

B. Responsibilities of the Program Office

The program office must do the following:

1. Engage internal and external stakeholders during the regulatory basis development.

2. Inform the Commission of significant stakeholder interactions through a Commissioners' Assistant Note.

C. Regulation Identifier Number (RIN)

1. The Regulation Identifier Number (RIN) provides the unique number assigned to the rulemaking action. This number is used to identify the rulemaking action in the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda") at <http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.
2. During the development of the regulatory basis, the lead rulemaking office should contact RADB in ADM to obtain a RIN. The lead rulemaking office will then submit to RADB an entry for the Unified Agenda.

D. Docket ID

1. During the development of the regulatory basis, the lead program office will contact RADB to request a Docket ID. RADB will then assign a Docket ID.
2. The Docket ID allows the public to search related documents on www.Regulations.gov.

VI. RULEMAKING PLAN

A. Purpose of the Rulemaking Plan

1. The rulemaking plan provides a preliminary outline of the scope and impact of the contemplated action sufficient for the approving official to determine that the contemplated rule is needed and desirable and to approve the continuation of the action before the agency expends resources on the project.
2. The rulemaking plan also provides a framework for completing the contemplated action and a mechanism for obtaining early substantive input from the Agreement States.

B. Omission of a Rulemaking Plan

A rulemaking plan is not needed if any of the following conditions apply:

1. Congress or the Commission specifically directs the initiation of a rulemaking action;
2. The rule is purely administrative;
3. The rule is sufficiently urgent to proceed to preparation of a rule package;
4. The rulemaking will be performed under the direct final rule process; or

5. The rule was included in the NRC's Common Rulemaking Prioritization listing provided to the Commission, and a regulatory basis document resolving all technical, policy, and legal issues has been prepared and approved.

C. Accessing More Information on Rulemaking Plans

For additional information about rulemaking plans, see Chapter 1 of the NRC's *Regulations Handbook* (Agencywide Documents Access and Management System (ADAMS) Accession No. ML052720461).

VII. REGULATORY ANALYSIS PROCESS

- A.** The regulatory analysis process, an integral part of NRC decisionmaking, systematically provides complete disclosure of relevant information supporting a regulatory decision. The conclusions and recommendations included in a regulatory basis document are neither final nor binding, but are intended to enhance the soundness of decisionmaking by NRC managers and the Commission.
- B.** A regulatory analysis is a document that 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," Rev. 4, September 2004; and
 2. NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook – Final Report" January 1997.

VIII. WORKING GROUP FOR RULEMAKING

A. Members

A working group will be formed if it is appropriate for a specific rulemaking action. A working group should have the following members:

1. A team leader from the lead rulemaking office.

2. Members within the lead program office who have program responsibilities related to the rulemaking.
3. A member from OGC to provide legal advice and support.
4. A member from RADB to provide input on the Regulatory Flexibility Act, the Congressional Review Act (CRA), plain language, and formatting requirements of the OFR. In addition, RADB provides support for drafting and editing rulemaking documents.
5. A member from the FOIA, Privacy, and Information Collections Branch, Customer Service Division, Office of Information Services (OIS), to provide advice on information collection requirements.
6. An Agreement State representative, as appropriate.
7. Staff from other offices, as appropriate.

B. Responsibilities

The working group will do 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 external stakeholders during the development of the regulatory basis and preliminary guidance in the rulemaking process.
3. Solicit and consider stakeholder feedback on the CER related to the rulemaking, as applicable.
4. 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 better understand and clarify the concerns of the cumulative effects of regulation and structure the rule implementation and compliance dates appropriately.
 - (a) Public meetings will be held in accordance with Management Directive (MD) 3.5, "Attendance at NRC Staff Sponsored Meetings," and the NRC Policy Statement on Enhancing Public Participation in NRC Meetings, May 28, 2002 (67 FR 36920) (ADAMS Accession No. ML021350492).
 - (b) A public meeting is not held when comments on proposed rules (or lack thereof) show general agreement on the proposed implementation and compliance dates.

5. Prepare associated guidance, including licensing, inspection, and enforcement guidance, as appropriate (unless the guidance is prepared by a guidance working group).
 - (a) Ensure that preliminary guidance is contemporaneously available for public comment when the proposed rule is published in the *Federal Register*.
 - (b) Coordinate the completion of the guidance documents so that the final guidance documents are available when the final rule is published in the *Federal Register* (unless this is done by a guidance working group).
 - (c) Ensure that guidance involving regulatory guides is developed in accordance with MD 6.6, "Regulatory Guides."
6. Assist the lead office in the preparation of rulemaking packages and supporting documents by providing necessary technical input.
7. Address comments, estimate the information collection burden, and prepare briefing materials.
8. Review contractor reports or monitor contractor effort if contract support is necessary.
9. Facilitate the concurrence process.
10. Apprise management of policy developments throughout the course of the rulemaking action.
11. Support the 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 resolves significant questions of policy, provides direction on significant technical issues, and facilitates concurrence of the rulemaking action.

B. Members

The steering committee is composed of the following members:

1. Senior managers from the affected offices;
2. A representative from OGC;
3. Agreement State representative(s), if appropriate; and
4. The Chief, RADB, in ADM.

X. PUBLIC PARTICIPATION

A. General Information on Public Participation in the Rulemaking Process

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. Open Government Initiative

In all aspects of its rulemaking, the NRC is committed to making public participation as meaningful as possible.

C. Communication Plan

Rulemakings that represent significant actions, are complex or controversial, or affect a large number or a disparate group of stakeholders may warrant the formulation of a communication plan. Guidance on drafting communication plans and a listing of current agency plans are contained in "Communications and Public Meetings," available on the NRC Web site at <http://www.internal.nrc.gov/communications>.

D. Access to Public Information on NRC Rulemaking Activities

1. ADAMS and Regulations.gov
 - (a) ADAMS and the Federal Docket Management System are the NRC's principal means of communicating information about agency rulemaking activities to the public.
 - (b) The Commission has directed that all rulemaking documents released to the public be made publicly available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>) in accordance with Yellow Announcement 00-39, "Revised Policy Goal on Timing the Release of Documents to the Public in the ADAMS Environment." These documents include all supporting documents, guidance, and analyses referenced in a *Federal Register* notice (FRN).
 - (c) The FRNs for proposed and final rules, policy statements, and other rulemaking-related actions may be found on <http://www.regulations.gov>.

- (d) Public comments, preliminary proposed rule language, meeting notices, and significant supporting documents and analyses are also posted to <http://www.regulations.gov> once they have been made publicly available in ADAMS.
2. To make rulemaking information available to the public electronically, the lead office must—
- (a) Enter all publicly available NRC documents cited in the FRN into ADAMS and make those documents available to the public through the ADAMS Publicly Available Records System (PARS) Library. RADB cannot post rulemaking documents to <http://www.regulations.gov> unless the documents are available in PARS. See the NRC Rulemaker Web site at <http://www.internal.nrc.gov/ADM/DAS/cag/RM01/> for detailed instructions on making NRC documents publicly available in PARS.
- (b) Enter those publicly available, non-NRC documents cited in the FRN which the NRC possesses but may not be readily available to the public into ADAMS. Make those documents available to the public through the ADAMS Publicly Available Records System (PARS) Library, or provide hyperlinks to such documents in the FRN.
- (c) Prepare an FRN announcing the public availability of the material and/or soliciting public comment, as appropriate.
- (d) Notify RADB of the ADAMS accession numbers for—
- (i) All documents included in the FRN publication package; and
- (ii) All rulemaking supporting documents not published in the *Federal Register* but referenced in the FRN (e.g., preliminary rulemaking text, technical specifications, NUREGs, environmental analyses, and regulatory analyses).
- (e) Respond to RADB request for schedule information.
3. 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 walk-in visitors at the PDR as part of the PDR's standing collection; other documents can be located and made available upon advance request.

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

- (a) To obtain public feedback early in the rulemaking process, a lead office may post preliminary rulemaking language on <http://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 preliminary proposed rule language can be included in or appended to the FRN announcing the availability of preliminary language, but typically the notice simply announces the availability of the preliminary proposed rule language. The 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 RADB for posting on <http://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.

5. Single-Topic Rulemaking Web Pages

- (a) Single-topic pages on the NRC's public Web site can be used to announce potential rulemakings (<http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking.html>) or the issuance of a rule to assist the public in understanding the effects of a new regulation.
 - (i) This type of public communication is useful for reaching stakeholders unfamiliar with the rulemaking process.
 - (ii) It also provides higher visibility, a more detailed description, and a more extended Web presence for a proposed or final rule than is provided by posting the final rule to www.regulations.gov.
- (b) When a lead office is about to publish a proposed or final rule that significantly revises a large portion of the regulations or affects a large number of stakeholders, the project manager may elect to contact the respective Office Web Liaison (OWL) to request the design, development, and posting of a single-topic Web page for the public Web site. The OWL will then coordinate with the OIS Web Content Services Group (WebWork.Resource@nrc.gov) to assist with information architecture and technical editing of the new page, as well as appropriate placement and cross-linking within the overall site. Single-topic Web pages should

communicate, in plain language, why the NRC developed the new rule and how it will be implemented and enforced.

- (c) Stakeholders can access single-topic rulemaking Web pages from the NRC home page under “Key Topics or What's New at Our Web Site.”

E. Obtaining Public Comments

1. Notice and Comment Rulemaking

- (a) 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 and sets out the requirement to provide the public an opportunity to participate in Federal rulemaking.
- (b) Notice of a proposed rulemaking must be published in the *Federal Register*, with limited exceptions, as required by 10 CFR 2.807.
 - (i) 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.
 - (ii) Executive Order 12889, which implemented 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.
 - (iii) Interested persons may submit comments to the NRC by mail, hand delivery, or through <http://www.regulations.gov>.
- (c) 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 that is within the scope of the rulemaking. The NRC's practice has been to provide an explanation as to why a comment is not considered significant or within the scope of the rulemaking. Finally, 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.

4. Advance Notice of Proposed Rulemakings (ANPR)

- (a) An ANPR is a formal method of soliciting early public involvement in the rulemaking process. The lead office (after approval from the Commission, the EDO, or CFO) publishes a notice in the *Federal Register* that—
 - (i) Describes the regulatory problem or situation, and

- (ii) Requests public comment or lists questions and issues for comment to direct public response.
- (b) The ANPR may—
 - (i) Outline regulatory responses to the problems that are under consideration,
 - (ii) Include preliminary regulatory text, or
 - (iii) Propose alternative (including non-rulemaking) solutions.
- (c) RADB will post the ANPR on <http://www.regulations.gov> under the assigned NRC Docket ID, along with any supporting documents forwarded by the lead office. All documents must be made publicly available in PARS before posting on <http://www.regulations.gov>. The lead office must provide RADB with the ADAMS accession numbers for all posted documents and for any other documents cited in the FRN.

5. Negotiated Rulemaking

- (a) Negotiated rulemaking is a very formal process which is seldom used by the NRC. This technique was most recently used by the NRC in the late 1980s to establish the regulations governing the Licensing Support Network as a means to provide access to the discovery materials disclosed in high-level radioactive waste repository licensing proceedings.
- (b) Negotiated rulemaking brings interested parties into the regulatory process, including the drafting of regulatory text, at an early stage and under circumstances that encourage cooperation to solve regulatory problems. On the rare occasion when the NRC may use this process, staff should adhere to the procedures set forth by the Negotiated Rulemaking Act (5 U.S.C. 561 et seq.).

6. Public Meetings

- (a) During the preparation of a rule, staff may elect to conduct one or more public meetings to obtain public input. Absent special circumstances, all public meetings should be “Category 3,” in accordance with MD 3.5, “Attendance at NRC Staff-Sponsored Meetings.”
 - (i) Meeting topics may range from a specific regulatory issue or a portion of the regulations that the NRC proposes to amend, to specific preliminary proposed rule language under consideration at either the proposed or final rule stage.
 - (ii) The Commission has delegated to the following office directors the authority to issue preliminary proposed rule language:
 - Director, Office of Federal and State Materials and Environmental Management Programs (FSME);

- Director, Office of New Reactors (NRO); and
 - Director, Office of Nuclear Reactor Regulation (NRR).
- (b) The NRC may hold a public meeting on the implementation of the rule in order to—
- (i) Better understand and clarify the concerns regarding the cumulative effects of regulation, and
 - (ii) Structure the rule implementation and compliance dates appropriately.
- (c) For guidance on scheduling and announcing a public meeting, staff should refer to MD 3.5, "Attendance at NRC Staff-Sponsored Meetings."
- (d) For guidance on planning and conducting a public meeting, staff should consult "Communications and Public Meetings," which is available on <http://www.internal.nrc.gov/communications/>.

F. Public Participation During the Regulatory Basis Phase

1. The NRC may seek public involvement during the development of the regulatory basis for regulatory action before any decision is made to initiate rulemaking. 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, or policy issues or problems) available for public comment on the public NRC Web site and at <http://www.regulations.gov>.
2. When seeking public involvement in the development of the regulatory basis, the lead NRC office responsible for the regulatory basis should prepare for publication a notice in the *Federal Register* that explains the regulatory issue under agency consideration.
3. RADB will post the published notice on <http://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 PARS before they can be posted on <http://www.regulations.gov>.

G. Publication of Guidance with Proposed Rule

1. Unless otherwise directed by the EDO, the staff will not provide the proposed rule package to the Commission or the EDO, as applicable, until preliminary guidance is complete. This process is part of the enhancements to the NRC's rulemaking

process to enable explicit consideration of CER. The preliminary guidance must then be published contemporaneously with the publication of the proposed rule.

2. The contemporaneous publication of the proposed rule and 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.

XI. COORDINATION

A. Agreement States

1. Agreement States are given the opportunity to comment on rulemakings that impact them. The lead office must coordinate this effort with FSME and OGC. All rulemaking plans shall include suggested Agreement State compatibility classifications for the proposed rule.
2. Agreement State Notification
 - (a) The Director of FSME will notify the Agreement States by letter, as appropriate, of the opportunity for early comment on rulemaking plans, rule FRNs, and regulatory bases.
 - (b) The FRN, the rulemaking plan, and the regulatory basis are sent 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) (fatal flaw review). The lead office submits a daily note when any rule document is sent to the Agreement States for comment.
 - (c) If a preliminary rulemaking plan addresses controversial policy issues, the lead office may send a SECY paper and the preliminary rulemaking plan to the EDO. The EDO will then transmit the SECY paper and the preliminary rulemaking plan to the Commission. If the Commission approves the rulemaking plan, then the EDO may send it to the Agreement States.

- (d) The Agreement States are provided an opportunity for early review of and comment on preliminary rulemaking documents as follows:
 - (i) 45 days for predecisional preliminary rulemaking plans,
 - (ii) 30 days for preliminary proposed rules and preliminary final rules, and
 - (iii) A minimum of 30 days for all other rulemaking documents.
- (e) For further guidance on the process for soliciting early comment from Agreement States, see FSME Procedure Number SA-800, "Providing NRC Predecisional Documents to Agreement States, Organization of Agreement States, Inc., and Appropriate Working Groups of the Conference of Radiation Control Program Directors, Inc."

3. Commission Notification of Agreement State Comments

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

B. Advisory Committees and the Committee to Review Generic Requirements (CRGR)

As appropriate, the lead office for the rulemaking action forwards the rulemaking documentation to the appropriate advisory committee. The lead office must also accomplish the following:

1. Formally document and respond by memorandum or e-mail to any consensus comments or recommendations from the advisory committee concerning the rulemaking action.
2. Include the analysis and response to advisory committee comments with any other public comments in the SUPPLEMENTARY INFORMATION section of the FRN for the rulemaking action.
3. Review the comments issued by the appropriate advisory committee. (The advisory committee will issue a single document with its comments.)
4. Upon a request by the advisory committee, meet with the appropriate committee during preparation of the regulatory basis process to discuss the rationale for the proceeding.
5. Provide a copy of the preliminary final rule to the CRGR for their information.
6. Provide a copy of the proposed rule package to the Office of the Advisory Committee on Reactor Safeguards (ACRS) for information. If the ACRS asks to be briefed on the proposed rule, then the lead office for rulemaking will conduct the briefing.

7. Provide the ACRS with the preliminary final rule package for its review before the package is submitted for Commission review and approval.
8. Interactions with the Advisory Committee on the Medical Use of Isotopes (ACMUI) are covered by FSME's 2011 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" (ADAMS ML100640325).

C. Office of Public Affairs (OPA)

1. The lead office for the rulemaking action must contact OPA during the office concurrence process to determine if a press release is to be prepared for the rulemaking action. The lead office must also accomplish the following:
 - (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 SECY 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 SECY 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 SECY paper or attached to the memorandum requesting the signature of the EDO or the CFO.
 - (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. 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 lead office to make sure 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 lead office must coordinate with OPA until the proposed or final rule is submitted to SECY for publication or the press release is issued.
3. The 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.

D. Congressional Letters

1. To notify Congress of NRC rulemakings, the lead rulemaking office drafts the appropriate letters to Congressional committees.
2. The lead rulemaking office enters the Congressional letters into ADAMS and provides hard copies of the letters in the rulemaking package that is routed for office concurrence.
3. RADB forwards the Congressional letters (hard copies) to OCA.
4. Copies of the draft Congressional letters are included as background in the completed concurrence package which is forwarded with the SECY paper or attached to the memorandum requesting the signature of the EDO or CFO.
5. As the signing office for the Congressional letters, OCA—
 - (a) Dates the original hard copy letters, and
 - (b) Distributes copies of the letters appropriately.

XII. CONCURRENCES AND NON-CONCURRENCES**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.
 - (c) Agrees that the material for which the office has a programmatic basis for judgment is factual and accurate.
2. Office concurrence on the regulatory basis and FRNs is requested from the following:
 - (a) All of the other NRC offices that are affected by the rulemaking action from a technical standpoint based on their designated areas of responsibility;
 - (b) OGC (see Sections XII.B, C, and D of this handbook); and
 - (c) Office of the Chief Financial Officer (final rules only).

B. OGC 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 decline to sign off on the paper but should work with the originating office in arriving at a legally acceptable action.
2. Where no legally acceptable accommodation is reached, the attorney should formally communicate the basis for his or her refusal to sign off to the responsible office director. The General Counsel should receive a copy of the communication.

E. Concurrence Procedures

1. The lead office 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 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) Each document containing preliminary rule proposed language before it is posted on <http://www.regulations.gov>.

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 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. If the reviewing attorney disagrees with the recommended rulemaking action on policy grounds, then OGC must formally communicate the basis for the policy disagreement and the supporting reasons, in writing, to the lead office, branch chief or above, or to the proposed signer of the document, and to OGC management, as appropriate.
4. Each concurring office shall respond to the lead office via memorandum, NRC interoffice mail, e-mail, or telephone. For most rulemaking actions, the lead office requests that responses be made within 20 working days. The responding office must do one of the following:
 - (a) Concur;
 - (b) In the case of OGC, provide a no legal objection, or
 - (c) Withhold concurrence pending the resolution of specific technical, policy, or legal issue raised by the concurring office.
5. 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 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 the Office of the Executive Director for Operations.

Additional information on the NRC’s non-concurrence policy can be found in MD 10.158, “NRC Non-Concurrence Policy (Interim Policy).”
6. After receiving the concurrence memoranda or e-mails and updating the rulemaking package appropriately, the lead office 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.
7. After receiving the determination of no legal objection from OGC, the lead rulemaking office will—
- (a) Provide a revised rulemaking package, including the rulemaking plan, the proposed rule, or the final rule, to the EDO; 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 petition for rulemaking closure, the EDO must do one of the following:
- (a) Transmit the proposed or final rule to SECY for Commission consideration,
 - (b) Notify the Commission of the intent to issue the rule under the rulemaking authority delegated to the EDO,
 - (c) Return the rulemaking package to the lead office for modification or resolution of questions, or
 - (d) Instruct the lead office not to proceed with the rulemaking.

F. Non-Concurrence Process

1. Employees may choose not to concur on any part of a document in which he or she does not agree.
2. In addition, employees are permitted to document their concerns and attach them to proposed staff positions or other documents to be forwarded with the position as it moves through the management approval chain by using the Non-Concurrence Process (NCP).
3. For more information, see MD 10.158, “NRC Non-Concurrence Process (Interim Policy).”

G. Differing Professional Opinions Program

1. 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.
2. The process also provides managers with an independent, three-person review of the issue (one person chosen by the employee).
3. After a decision is issued to an employee, he or she may appeal the decision to the EDO (or the Chairman for those offices reporting to the Commission).
4. For more information, see MD 10.159, "The NRC Differing Professional Opinions Program."

XIII. BACKFITTING AND ISSUE FINALITY

- A.** The NRC's regulations governing nuclear power reactors and certain nuclear materials licenses contain provisions which 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).
- 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; 52.171; and Paragraph VI in Part 52, Appendices A through D. Backfitting restrictions applicable to certain licensees possessing specified quantities of special nuclear material are in 10 CFR 70.76. Backfitting restrictions applicable to independent spent fuel storage are set forth in 10 CFR 72.62. Backfitting restrictions applicable to gaseous diffusion plants are set forth in 10 CFR 76.76.
- C.** For additional information on backfitting and issue finality, see the following documents:
 1. 10 CFR Part 50.109, "Backfitting;"
 2. MD 8.4, "Management of Facility-Specific Backfitting and Information Collection;" and
 3. NUREG-1409, "Backfitting Guidelines" (July 1990).

XIV. 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 Office of the Federal Register's requirements governing their approval for IBR at 1 CFR Part 51, and the IBR procedures described in the Office of the Federal Register's Document Drafting Handbook (<http://www.archives.gov/federalregister/write/handbook/>).

XV. RULES, ANNOUNCEMENTS, AND DIRECTIVES BRANCH (RADB)

The Rules, Announcements, and Directives Branch (RADB) plays the following role in the NRC's rulemaking process:

- A.** Develops, recommends, and administers policies and procedures for 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. Congressional Review Act (CRA),
 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.** Assists the technical staff in writing NRC regulations and *Federal Register* documents.
- D.** Prepares "corrective" 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 petitions for rulemaking (PRMs), including drafting notices of receipt and reviewing notices to grant or deny PRMs.
- F.** Prepares the report for the Unified Agenda of Federal Regulatory and Deregulatory Actions.
- G.** Publishes the NRC Regulations Handbook.
- H.** Prepares the Rulemaking Activity Plan.
- I.** Other functional responsibilities noted in Section III.N of this directive.

XVI. GLOSSARY

Advisory Committees

Advisory committees include the Advisory Committee on Reactor Safeguards, the Committee to Review Generic Requirements, and the Advisory Committee on the Medical Uses of Isotopes.

Backfitting and Issue Finality

In 10 CFR 50.109 and 10 CFR Part 52, backfitting for a nuclear power reactor are 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). For certain materials facilities, the backfitting and issue finality definitions are slightly different. For more information on backfitting and issue finality, see Section XIII of this handbook.

Category 3 Public Meeting

This type of meeting would be held with representatives of non-government organizations, private citizens or interested parties, or various businesses or industries (other than those covered under Category 2) to fully engage them in a discussion on regulatory issues. For additional information, see the NRC's 2002 policy statement entitled "Enhancing Public Participation in NRC Meetings."

Congressional Review Act (CRA)

The Rulemaking, Announcements, and Directives Branch (RADB) is responsible for coordinating the Office of Management and Budget (OMB) review of major NRC final 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.

Cumulative Effects of Regulation (CER)

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

Draft Rulemaking Language

Draft rule language means 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

Final rule language means 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 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)

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.

Lead Office for the Rulemaking Activity

The lead office for a rulemaking action is the office that has the overall responsibility for creating all rulemaking documents and recommending their publication in the *Federal Register*.

Lead Program Office

The lead program office has overall responsibility for developing the regulatory basis and implementing guidance.

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 decline to sign off on the paper but should work with the originating office in arriving at a legally acceptable action.
2. Where no legally acceptable accommodation is reached, the attorney should formally communicate the basis for his or her refusal to sign off to the responsible office director. The General Counsel should receive a copy of the communication.

Non-Concurrence

If a responding office withholds concurrence, this is known as “non-concurrence.” For additional information, see Section XII.E of this handbook.

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 assigned in the Federal Document Management System to identify all rulemakings. Example: NRC-2011-0058.

Preliminary Rulemaking Language

Preliminary rule language means rule language which 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 Web site or the NRC public Web site, and
4. Distribution of printed copies at a public meeting.

Proposed Rule Language

Proposed rule language means 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 AEA. This distinguishes 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 proposed rulemaking, as opposed to the statement of considerations (SOC)¹, which are published as part of the *Federal Register* notice of proposed rulemaking.

Regulation Identifier Number (RIN)

A unique sequential number assigned to a rulemaking after a rulemaking plan is approved by the Commission, when the regulatory basis is approved, or when a draft of an approved rulemaking action is submitted to RADB/DAS/ADM, for review. The RIN is used for interagency and internal tracking of rulemakings. Example: RIN 3150-BB22.

Regulatory Analysis Process

The regulatory analysis process, an integral part of NRC decisionmaking, systematically provides complete disclosure of relevant information supporting a regulatory decision. The conclusions and recommendations included in a regulatory basis document are neither final nor binding, but are intended to enhance the soundness of decisionmaking by NRC managers and the Commission. For additional information on regulatory analysis, see NUREG/BR-0058, Rev. 3, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (September 2004) and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," January 1997.

¹ Some Federal agencies use the term "preamble," rather than the term "statement of considerations (SOC)."

Regulatory Basis

The 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, 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.

Rulemaking Coordinating Committee (RCC)

A standing interoffice group with representatives from the lead rulemaking offices: FSME, Office of New Reactors (NRO), Office of Nuclear Reactor Regulation (NRR), OGC, and ADM (Chair). 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 Plan

The rulemaking plan provides a preliminary outline of the scope and impact of the contemplated action sufficient for the approving official to determine that the contemplated rule is needed and desirable and to approve the continuation of the action before the agency expends resources on the project. The rulemaking plan also provides a framework for completing the contemplated action and a mechanism for obtaining

early substantive input from the Agreement States. For additional information, see Chapter I of the NRC's *Regulations Handbook* (NUREG/BR-0053, Rev. 6).

Steering Committee

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 resolves significant questions of policy, provides direction on significant technical issues, and facilitates concurrence of the rulemaking action.