

U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

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To: NRC Management Directives Custodians

Subject: Transmittal of Management Directive 6.3, "The Rulemaking Process"

Purpose: Management Directive 6.3 is being revised to incorporate recommendations from the Rulemaking Improvement Task Force Working Group Report, November 2002; the Rulemaking Process Improvement Implementation Plan, last updated in November 2004; and additional enhancements identified by NRC staff since MD 6.3 was last revised in 2001.

No change bars have been used on Handbook 6.3 because it is new. Handbook 6.3 describes activities involved in the processing of a rulemaking and provides guidelines for the NRC offices for coordinating, concurring, and reporting on rulemakings. NUREG/BR-0053 that previously served as Handbook 6.3 provides information on the legal and format requirements applicable to the preparation of rulemaking documents.

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The Rulemaking Process

Directive 6.3

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U. S. Nuclear Regulatory Commission

Volume: 6 Internal Management

ADM

The Rulemaking Process

Directive 6.3

Policy (6.3-01)

It is the policy of the U.S. Nuclear Regulatory Commission 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.

Objectives (6.3-02)

- To ensure that schedules for rulemaking actions are established and met. (021)
- To ensure coordination among offices and the efficient use of staff resources during the development of rulemaking actions. (022)
- To ensure that Agreement States are provided an opportunity to comment on applicable draft rulemaking plans and rulemaking actions. (023)
- To provide maximum opportunity for full and robust participation by the public and stakeholders in rulemaking proceedings. (024)

Organizational Responsibilities and
Delegations of Authority
(6.3-03)

Commission
(031)

- Directs the initiation of rulemaking activities. (a)
- Approves or denies each rulemaking plan, or major modification to a plan, not under the authority delegated to the Executive Director for Operations (EDO) or the Chief Financial Officer (CFO). (b)
- Approves or denies each proposed and final rule and petition for rulemaking not under the authority delegated to the EDO or the CFO. (c)

Executive Director for Operations (EDO)
(032)

- Approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that will be issued under the authority delegated to the EDO. (a)
- Approves or denies each petition for rulemaking within the scope of the authority delegated to the EDO. (b)
- Directs the initiation of rulemakings within the scope of the authority delegated to the EDO, as appropriate. (c)
- Monitors the progress of rulemakings within the scope of the EDO's authority and, if necessary, resolves issues preventing office concurrence on a rulemaking. (d)
- Within 20 calendar days of receipt of a proposed rule or a final rule— (e)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Executive Director for Operations (EDO)
(032) (continued)

- Transmits the rule for Commission action. (i)
- If necessary, returns the rule to the NRC staff for modification or resolution of questions within a specified schedule. (ii)
- If appropriate, notifies the Commission of the intent to issue the rule under the authority of the EDO. (iii)

Deputy Executive Director for Information
Services and Administration and Chief
Information Officer (DEDIA)
(033)

- Oversees the rulemaking process for the EDO to provide central coordination for the NRC rulemaking program. (a)
- Ensures consistency in methods used to develop and issue rules through the Rulemaking Coordinating Committee. (b)
- Oversees the development of the annual Rulemaking Activity Plan. (c)
- Submits semiannual status reports on petitions for rulemaking to the EDO. (d)

Chief Financial Officer (CFO)
(034)

- Reviews rulemaking plans and all proposed and final rule documents to ensure that— (a)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Chief Financial Officer (CFO)
(034) (continued)

- Resources required to complete and implement the rulemaking have been fully and properly addressed. (i)
- Rulemakings that have a potential to affect the agency's license fee and annual fee schedules have been coordinated. (ii)

- Forwards review comments on rulemaking plans and proposed and final rules to the lead office. (b)
- Approves the rulemaking plan, or any modifications to the plan, for each rulemaking that will be issued under the authority delegated to the CFO. (c)
- Approves or denies each petition for rulemaking within the scope of the authority delegated to the CFO. (d)
- If a rulemaking will be issued under the authority delegated to the CFO, directs the preparation of the rulemaking plan, the *Federal Register* notices, and all required supporting documents. (e)

Inspector General (IG)
(035)

- Reviews rulemaking actions and makes recommendations concerning the effect of rulemaking actions on the economy and the efficiency of programs and operations administered or financed by NRC or the prevention of fraud and abuse in these programs. (a)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Inspector General (IG)
(035) (continued)

- Forwards review comments to the lead office or the Chairman, as appropriate. (b)

General Counsel (GC)
(036)

- Analyzes each request for a rulemaking action for legal sufficiency. (a)
- Reviews rulemaking actions in accordance with the Office of the General Counsel's (OGC's) Operating Manual. (b)
- Reviews rulemaking actions to ensure that they are consistent with current rules and other authoritative statements of NRC policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards. (c)
- Forwards review comments on rulemaking plans, including OGC's analysis of legal sufficiency that demonstrates that no known basis exists for a legal objection, to the lead office. (d)
- Forwards review comments on rulemaking documents to the lead office or the Commission, as appropriate. (e)
- Designates a staff attorney to provide legal advice and support for each rulemaking action. (f)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Office of the Secretary (SECY)
(037)

Dockets public comments on rulemakings and petitions for rulemaking; forwards comments on rulemakings to the lead office.

Director, Office of Information
Services (OIS)
(038)

- Reviews rulemaking plans and all proposed and final rule documents to ensure that 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)
- Forwards review comments on rulemaking plans and proposed and final rules to the lead office. (b)

Director, Office of Congressional
Affairs (OCA)
(039)

- Keeps Congress fully and currently informed of NRC rulemaking actions. (a)
- Signs and transmits the letters and forms to Congress concerning NRC rulemaking actions. (b)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Director, Office of Public Affairs (OPA)
(0310)

- Determines whether a press release is needed for a rulemaking action. (a)
- If a press release is needed, designates an OPA representative to prepare a draft press release for comment and review by the lead office. (b)

Director, Office of Enforcement (OE)
(0311)

- Determines whether changes to the NRC Enforcement Policy are needed because of the rulemaking action. (a)
- Determines whether the criminal penalties section for each part affected by the rulemaking action must be amended to reflect the action. (b)
- Ensures that *Federal Register* rulemaking documents include an appropriate criminal penalty statement. (c)

Director, Office of Administration (ADM)
(0312)

- Informs the EDO of a rulemaking initiated by offices not reporting to the EDO if the rulemaking will require resource planning by the EDO. (a)
- Chairs meetings of the Rulemaking Coordinating Committee (RCC). (b)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Director, Office of Administration (ADM)
(0312) (continued)

- Assigns the regulation identifier number (RIN) (see Definitions, Section (6.3-06)). (c)
- Maintains NRC Rulemaking Web sites. (d)
- Reviews rulemaking actions to ensure compliance with the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act of 1996, the Federal Register Act, 1 CFR Chapters I and II, and the Presidential memorandum of June 1, 1998, on plain language and to ensure that the rulemaking actions are consistent with current regulations and other authorization statements of agency policy, including, for example, consistency in the use of wording, terminology, and definitions. (e)
- Forwards review comments on rulemaking plans and proposed and final rules to the lead office. (f)
- In consultation with OGC, receives and processes petitions for rulemaking, including determining whether the petition includes the information required in 10 CFR 2.802(c), docketing, and preparing a notice of receipt to be published in the *Federal Register*. (g)
- Forwards public comments on petition actions to the lead office and to the petitioner. (h)
- Maintains agency historical documents related to rulemaking and issues rulemaking reports. (i)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Director, Lead Office
(0313)

- Initiates and develops each element of a rulemaking action in subject areas for which the office is responsible. (a)
- Designates an office representative to coordinate each rulemaking action. (b)
- Ensures the timely completion of rulemaking actions. (c)
- Establishes a working group, as appropriate, to assist in the preparation of the rulemaking plan and the proposed and final rule packages and in obtaining necessary concurrences. (d)
- In consultation with OGC and other offices that will participate in the rulemaking, prepares a rulemaking plan for each contemplated rulemaking. The rulemaking plan must include a basis for and an indication of whether the rulemaking action will be a "major rule" as defined in the Small Business Regulatory Enforcement Fairness Act, or other law. (e)
- Determines the offices from which office concurrence will be requested on the rulemaking plan and the *Federal Register* notices. (f)
- Ensures that draft rulemaking plans and *Federal Register* notices that have a significant impact on NRC policy or program structure are submitted to the Office of the Inspector General at the interoffice coordination stage. (g)
- Coordinates rulemaking actions with other Government agencies (e.g., the Environmental Protection Agency, the Department of Energy) when appropriate or when such action is required by statute or regulation. (h)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Director, Lead Office
(0313) (continued)

- Recommends to the EDO whether to initiate the proposed rulemaking. (i)
- Informs the Commission of the draft rulemaking plan and makes it available to the advisory committees, the NRC staff, and Agreement States, if applicable. (j)
- Prioritizes assigned rulemaking actions and coordinates with other program offices to create an integrated prioritization list for NRC rulemakings. (k)
- For assigned rulemakings, prepares the *Federal Register* notice and the required supporting documents. (l)
- Solicits early Agreement State participation from a technical standpoint in the office's area of responsibility in applicable rulemakings through the Office of State and Tribal Programs. (m)
- Coordinates with OPA to determine whether a press release is appropriate and, if so, provides OPA with information sufficient to develop the press release and includes the draft OPA press release in the rulemaking package. (n)
- Ensures that rulemaking documents are properly managed and archived in the Agencywide Documents Access and Management System (ADAMS). (o)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Director, Office of State and Tribal
Programs (STP)
(0314)

- Designates an office representative to participate in a working group, as appropriate, and to coordinate Agreement State participation. (a)
- Coordinates interaction with Agreement States for applicable rulemakings. (b)
- Designates an office representative to participate in an NRC Agreement State working group, as appropriate, and coordinates Agreement State participation in the working group in accordance with Management Directive (MD) 5.3, "NRC/Agreement State Working Groups," Handbook, Part III. (c)

Chairs, Advisory Committees
(0315)

As appropriate, review and provide comment to the lead office or the Commission on the rulemaking plan and the proposed and final rule packages.

Directors, Concurring Offices
(0316)

- Designate an office representative and an alternate to coordinate each rulemaking action, including development of the rulemaking plan, and indicate whether the representative is authorized to provide office concurrence while participating as a member of the working group, and also designate other key staff, as necessary, to assist in developing documents necessary for the rulemaking. (a)

Organizational Responsibilities and
Delegations of Authority
(6.3-03) (continued)

Directors, Concurring Offices
(0316) (continued)

- Respond to the lead office within 20 calendar days of the date of the transmittal memorandum with any questions or concerns regarding any technical analysis of information or data that may invalidate or raise doubts about the proposal. (b)
- Review rulemaking actions to ensure that they are consistent with current rules and other authoritative statements of agency policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards. (c)
- Forward comments on rulemaking plans and rulemaking documents to the lead office. (d)
- Serve as concurring official for the rulemaking action or delegate concurring authority to the designated working group member or other appropriate official. (e)

Office Representative (or Alternate)
(0317)

- The office representative for the lead office has the following responsibilities: (a)
 - Leads the activities of the working group. (i)
 - Prepares or coordinates the preparation of the rulemaking plan, the *Federal Register* notices, and required supporting documents. (ii)
 - Keeps office management informed of the status of the rulemaking or any policy issues that may arise. (iii)

Organizational Responsibilities and Delegations of Authority (6.3-03) (continued)

Office Representative (or Alternate) (0317) (continued)

- Obtains necessary concurrences or coordinates the concurrence process. (iv)
- Creates a Regulatory History for the rulemaking in ADAMS, compiles an index of documents that comprise the history, and, within 60 days of publication in the *Federal Register*, forwards the index to the Rules and Directives Branch (RDB), Division of Administrative Services (DAS), ADM. (v)
- The office representative for concurring offices and OGC has the following responsibilities: (b)
 - Keeps office management informed of any policy issues that could affect office interests or that constitute a basis for legal objection. (i)
 - Oversees office reviews regarding factual matters in the concurrence document. (ii)
 - Interacts in the concurrence process either in the traditional role or as a member of a working group. (iii)
 - Oversees office development of rulemaking documents as assigned. (iv)

Applicability (6.3-04)

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

Handbook
(6.3-05)

Handbook 6.3 describes activities involved in the processing of a rulemaking and provides guidelines for the 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 NUREG/BR-0053, "NRC Regulations Handbook," or 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/>.

Definitions
(6.3-06)

Advisory committees. Advisory committees include the Advisory Committee on Reactor Safeguards, the Advisory Committee on the Medical Uses of Isotopes, and the Advisory Committee on Nuclear Waste.

Lead office. The lead office for a rulemaking action is the office assigned the responsibility for a rulemaking action, including preparation of the rulemaking plan, the proposed and final rule packages, and any required supporting documents.

Regulation Identifier Number (RIN). A unique sequential number assigned to a rulemaking after a rulemaking plan is approved by the Commission or when a draft of an approved rulemaking action is submitted to the Rules and Directives Branch, Division of Administrative Services, ADM, for review. The RIN is used for interagency and internal tracking of rulemakings.

Rulemaking Coordinating Committee (RCC). A standing interoffice group with representatives from the primary rulemaking offices: the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Reactor Regulation, the Office of the General Counsel, and the Office of Administration (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.

References (6.3-07)

Code of Federal Regulations

Title 1, "General Provisions."

Title 10, "Energy."

Executive Orders

Executive Order 12866, "Regulatory Planning and Review,"
September 30, 1993 (ML040070197).

Presidential Memorandum

Presidential Memorandum for the Heads of Executive
Departments and Agencies, "Plain Language in Government
Writing," June 1, 1998.

U.S. Nuclear Regulatory Commission

Management Directives

3.5, "Attendance at NRC Staff Sponsored Meetings."

5.3, "NRC/Agreement State Working Groups."

5.9, "Adequacy and Compatibility of Agreement State
Programs."

9.17, "Organization and Functions, Office of the Executive
Director for Operations."

12.6, "NRC Sensitive Unclassified Information Security
Program."

NMSS Policy and Procedures Letter 1-63, Revision 1, "NMSS
Policy and Procedures for Preparation and Review of
Rulemaking Packages," August 2001 (ML011560791).

References

(6.3-07) (continued)

NRC Policy Statement on Adequacy and Compatibility of Agreement State Programs, approved by the Commission, June 30, 1997 (62 FR 46517; September 3, 1997) (ML040070213) (<http://www.internal.nrc.gov/ocm/policy-stmts/62fr46517.pdf>).

NRC Policy Statement on Enhancing Public Participation in NRC Meetings, approved by the Commission, May 21, 2002 (67 FR 36920) (ML021350492).

- SECY-94-141, “Improvement of the Rulemaking Process,” May 23, 1994.
- Staff Requirements Memorandum, from John C. Hoyle to James M. Taylor, COMSECY-96-0357 - SECY-96-034, “Interactions With the Agreement States in Rulemaking Planning,” June 11, 1996 (ML003755583).
- Staff Requirements Memorandum, from John C. Hoyle to William C. Parler and James M. Taylor, SECY-94-141, “Improvement of the Rulemaking Process,” June 28, 1994 (ML003757908).

NRC URLs

“The NRC Rulemaker,” <http://www.internal.nrc.gov/ADM/DAS/cag/RM01/>.

“RuleForum,” <http://ruleforum.llnl.gov/>.

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 (ML003701921).

NRR Office Instruction No.: LIC-300, Revision 1, “Rulemaking Procedures,” December 9, 2003 (ML032740005).

References

(6.3-07) (continued)

“Rulemaking Process Improvement Task Force Final Report to the Rulemaking Coordinating Committee, November 6, 2002” (ML023180108).

NUREGs

NUREG/BR-0053, Revision 5, Supplement 1, “NRC Regulations Handbook” (ML011010183, ML011010201, ML021990398).

NUREG/BR-0058, “Regulatory Analysis Guidelines of the USNRC,” Rev. 4, September 2004 (ML042820192).

NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” January 1997.

Office of the General Counsel Operating Manual.

Office of State and Tribal Programs Internal Procedure SA-200, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements” (ML042820600).

—SA-800, “Providing NRC Predecisional Documents to Agreement States and Appropriate Working Groups of the Conference of Radiation Control Directors, Inc.” (ML011370784).

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.).

References

(6.3-07) (continued)

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

Federal Register Act (5 U.S.C. Chapter 15).

Information Quality Act (Pub. L. 106-554, Section 515).

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

National Environmental Policy Act (42 U.S.C. 4321 et seq.).

National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113).

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

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

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

Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121).

The Rulemaking Process

Handbook

6.3

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Part I

Scope of Authority

Commission Rulemaking Authority (A)

Rulemaking authority for NRC is vested in the Commission by the Atomic Energy Act, as amended by the Energy Reorganization Act (42 U.S.C. 2201). As part of its oversight, the Commission conducts rulemaking to protect public health and safety and to regulate the civilian uses of nuclear power. The Commission has exclusive authority to issue regulations concerning the following: (1)

- A significant question of policy; (a)
- 10 CFR Parts 7, 8, and 9 (Subpart C) concerning matters of policy; and (b)
- 10 CFR Part 2 if one of the following offices fails to concur on or provide no legal objection to the rulemaking: the Office of the General Counsel (OGC), the Office of Commission Appellate Adjudication, or the Atomic Safety and Licensing Board Panel. (c)

A rule involves a significant question of policy and must be submitted to the Commission for approval and issuance if it— (2)

- Represents a major change in existing Commission policy, (a)
- Addresses a major new issue, or (b)
- Results in a major commitment of resources by a class of licensee. (c)

In determining whether a rule is considered to involve a significant question of policy, the lead office should consider the following: (3)

- Impact of the action on licensees and the public; (a)

Commission Rulemaking Authority (A) (continued)

- Degree of controversy that may be associated with the action; (b)
- Existence of significant public health, safety, environmental, or common defense and security questions; (c)
- Applicability of existing precedent; and (d)
- Resources that will be required for implementation. (e)

Rulemaking Authority of the Executive Director for Operations (EDO) (B)

Subject to general policy guidance from the Commission, the EDO is delegated authority to issue the following types of proposed or final rules, which should be submitted to the EDO for signature unless they fall within one of the excepted parts of 10 CFR Chapter 1: (1)

- 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. (a)
- A rule involving a minor new issue. This type of rule involves a situation in which the following circumstances apply: (b)
 - The issue was previously considered by the Commission in a similar context; (i)
 - The rule has limited impact; (ii)
 - The rule does not present important health, safety, environmental, or safeguards or security questions; or (iii)
 - The rule requires limited resources to implement. (iv)

Rulemaking Authority of the Executive Director for Operations (EDO) (B) (continued)

- A rule of a minor, corrective, or nonpolicy nature that does not substantially modify existing precedent. (c)

A final rule may be submitted for the EDO's signature if the Commission has considered all significant questions of policy in connection with the proposed rule and no significant adverse questions or comments have been received on the proposed rule or no substantial changes in regulatory text are necessary. (2)

The lead office should ensure that important new rules involving significant public interest are brought before the Commission if comments received suggest that the Commission might wish to reconsider certain provisions of the proposed rule even when the lead office determines that no changes to regulatory text are necessary. (3)

Rulemaking Authority of the Chief Financial Officer (CFO) (C)

The Chairman has delegated the CFO the authority to develop and issue rules needed to carry out his or her responsibilities, including the revisions of the annual fee regulations in 10 CFR Parts 170 and 171. (1)

The CFO's rulemaking authority does not extend to the promulgation of proposed or final rules that involve significant questions of policy. (2)

For rules that are issued by the CFO, the CFO is required to obtain the EDO's concurrence, as appropriate, and a determination from OGC that it has no legal objection to the action. (3)

Procedures for Commission Consideration of a Rulemaking Action (D)

The lead office shall forward a rulemaking action for the Commission's consideration by way of a Commission paper submitted through the EDO, OGC, or the CFO. The Office of the Secretary (SECY) schedules meetings on controversial rulemaking actions for the Commission's consideration at the request of the Commission. Usually, Commission meetings on these matters are open to the public under the Government in the Sunshine Act. In some cases, such as those involving classified, sensitive, or safeguards matters, the meeting may be closed to the public. (1)

Copies of the Commission paper are sent to every Commission-level office that may have an interest in the regulation. The Commission may approve the rulemaking action as submitted by the EDO or the CFO, approve the rulemaking action subject to specified changes, disapprove the rulemaking action entirely, or direct that the rulemaking action be revised and issued or revised and resubmitted to the Commission for reconsideration. (2)

The Commission's decision on a rulemaking action is affirmed by each Commissioner in a public meeting. The decision is then reflected in a staff requirements memorandum (SRM) issued by SECY. If the Commission orders changes to be made in the rulemaking action, the SRM describes these changes and establishes the deadline for resubmission for Commission consideration or submission for signature and publication. (3)

Procedures for Rulemaking Under the Authority of the EDO (E)

If a rulemaking action falls within the scope of the EDO's rulemaking authority, the director of the lead office shall forward the action to the EDO by memorandum. The memorandum must explain the basis and purpose of the rule. In addition, the lead

Procedures for Rulemaking Under the Authority of the EDO (E) (continued)

office shall include a certification statement (the approved-for-publication page), prepared for the EDO's signature, which appears after the office director's signature. This statement must identify the rule and explain how it falls within the scope of the EDO's rulemaking authority. If appropriate, the statement should reference earlier Commission policy decisions that relate to the subject of the rule. (1)

Before the rulemaking is submitted to the EDO for signature, the lead office shall obtain concurrence from the CFO indicating that the CFO has no resource-related objection to the rulemaking. (2)

Notifying the Commission of the Exercise of the Rulemaking Authority (F)

The EDO and the CFO shall inform the Commission each time they exercise their rulemaking authority as follows:

- The EDO and the CFO shall notify the Commission of each proposed rule they issue for publication in the *Federal Register* through a Weekly Information Report entry for the proposed rule. The lead office shall prepare the Weekly Information Report entry and include it with the memorandum forwarding the proposed rule for signature by the EDO or the CFO. After the proposed rule has been signed, the lead office shall forward the completed rulemaking package for final action to the Rules and Directives Branch (RDB), Division of Administrative Services (DAS), Office of Administration (ADM). (1)
- The EDO and the CFO shall notify the Commission before forwarding a final rule for publication in the *Federal Register* through a Notice of Final Rule Signed by the EDO or the CFO. The lead office shall prepare this Notice of Signature and include it with the memorandum forwarding the final rule for the signature of the EDO or the CFO. (2)

Notifying the Commission of the
Exercise of the Rulemaking Authority (F)
(continued)

- The EDO or the CFO will forward a copy of the Notice of Signature and the final rule for circulation in the Commission's reading file and return the signed rule to the lead office. A rule signed by the EDO or the CFO may not be forwarded to the Office of the Federal Register for publication for 5 working days after the date it was signed. This practice provides the Commission with an opportunity to review the action before it is issued as an official agency action. When the 5-working-day period has elapsed, the lead office shall forward the completed rulemaking package to RDB for final action. (3)

Part II

Rulemaking Plan

Initiation of Rulemaking (A)

A program office that wishes to initiate a rulemaking action should, after developing a technical assessment of the rulemaking issue, prepare a rulemaking plan. The plan should discuss various options for resolving the technical issues and demonstrate that a sound technical basis exists before moving forward with rulemaking. Because procedures differ between program offices, the lead office may need to obtain preliminary approval of the technical basis from an office review board before proceeding with the rulemaking plan. When a rulemaking is initiated by the Commission, a rulemaking plan is not required unless the Commission so directs, but the lead office may decide to develop a rulemaking plan for the action to serve as a guide for the working group.

Components of the Rulemaking Plan (B)

The rulemaking plan is a brief document that outlines the scope and impact of the contemplated action with only as much detail as necessary for the Commission to determine whether the rule is needed or desirable. The rulemaking plan includes the following:

- A definition of the regulatory problem or issue to be resolved.
(1)
- Preliminary concept of actions needed to resolve the problem, including a discussion of the existing regulatory framework that provides — (2)
 - An explanation of why NRC or the licensees cannot take actions to resolve the problem effectively within the existing regulatory framework. (a)

Components of the Rulemaking Plan (B) (continued)

- An explanation of why the necessary actions under the existing framework are burdensome. (b)
- An initial determination of whether the rulemaking will be developed using risk-informed, performance-based criteria. (c)
- Identification of rulemaking and non-rulemaking options, and justification for the selection of the option recommended in the rulemaking plan. (d)
- An analysis of legal sufficiency prepared by OGC that includes the following: (3)
 - A demonstration that no known bases exist for a legal objection. (a)
 - A discussion of any potential legal complications. (b)
- A rationale determining that the rulemaking will be — (4)
 - Cost-effective (a)
 - Compliant with backfit rule criteria, where applicable (b)
 - A major rule or not, as defined by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (c)
- A discussion of any known Agreement State issues, including compatibility classifications for the rulemaking action. (5)
- A list of supporting documents that will need to be prepared during the course of the rulemaking, including, as applicable, the following: (6)
 - A generic environmental impact statement (GEIS). (a)

Components of the Rulemaking Plan (B)

(continued)

- The clearance package necessary to obtain Office of Management and Budget (OMB) approval of new or amended information collection requirements. (b)
- Regulatory impact analyses, including information sufficient either to constitute a regulatory flexibility analysis or to support a certification that the proposed regulation will not have a significant economic impact on a substantial number of small entities as required by the Regulatory Flexibility Act. (c)
- Other related documents, such as regulatory guides, NUREGs, inspection plans, or enforcement guidance. (d)
- Resources required to complete and implement the rulemaking, including those required to develop any supporting documents. The discussion on resources must — (7)
 - Indicate whether these resources are included in the projected budget for the next 2 years. (a)
 - Identify the office(s) that will be responsible for each activity. (b)
- An indication of whether a technical standard developed by a voluntary consensus standards body is appropriate for use instead of a Government-unique standard, as required by the National Technology Transfer and Advancement Act of 1995, or whether there are no applicable standards. (8)
- A recommendation by the lead office regarding the issuance of the rulemaking by either the Commission or, under delegated rulemaking authority, by the EDO or the CFO. (9)
- A contact list for the lead office and the staff of participating offices, including office representatives and alternates. (10)

Components of the Rulemaking Plan (B) (continued)

- A list of senior managers designated by each office director to concur for that office and to report to the office director on key policy issues related to the rulemaking action. (11)
- An indication as to whether a steering group or a working group format will be used to develop the contemplated rulemaking action and identifying, if appropriate, members of a working group. (12)
- A Communication Plan that details use of enhanced public participation, if applicable. (13)
- A schedule for preparing supporting documents and completing the proposed rule, the comment evaluation process, and the final rule. The schedule must be based on the following: (14)
 - The priority or importance given to the action. (a)
 - The complexity of the issues to be resolved. (b)
 - The number and complexity of supporting documents, or the need for development of technical tools, such as computer codes. (c)
 - The degree of interaction with interested parties needed to complete the rulemaking. (d)

Omission of a Rulemaking Plan (C)

A rulemaking plan is not needed if—

- Congress mandates that a rulemaking be conducted. (1)
- The Commission specifically directs the initiation of a rulemaking action. The lead office may elect to develop a

Omission of a Rulemaking Plan (C)

(continued)

modified rulemaking plan to guide the process. The lead office is responsible for notifying the Office of State and Tribal Programs (STP), which, in turn, informs the Agreement States, when applicable. (2)

- The issue to be resolved is of sufficient urgency that the lead office director, OGC, and the EDO or the CFO will directly oversee the writing of the rule. In these circumstances, the EDO or the CFO will do the following: (3)
 - formally notify the Commission of this activity via a Commissioner's Assistant note; (a)
 - provide a rationale for proceeding without a rulemaking plan; (b)
 - obtain approval from the Commission; and (c)
 - submit the proposed rule to the Commission for approval. (d)
- The lead office shall notify STP, which, in turn, informs the Agreement States, when applicable. The authorities specifically delegated to office directors, OGC, and the EDO and the CFO regarding matters that are a significant threat to public health and safety are not diminished by the need to obtain Commission approval to omit preparation of a rulemaking plan. (4)
- The issue is addressed through the issuance of a direct final rule. (5)
- The rulemaking action is to issue or amend a certificate of compliance for a spent fuel storage cask. (6)
- The rulemaking action is purely administrative or corrective in nature. (7)

Approval of Rulemaking Plan (D)

For rulemaking plans requiring Agreement State comment before Commission decision, the lead office submits the draft of the rulemaking plan to the Commission via a Commissioner's Assistant note; this note is submitted during the concurrence process but after OGC's analysis of legal sufficiency that demonstrates that no known basis exists for a legal objection. (1)

Final rulemaking plans are submitted to the Commission via a Commission paper. When a rulemaking plan is approved by the EDO, the final plan is submitted to the Commission via an information paper. See Part V, "Coordination," of this handbook for approval procedures for plans that concern Agreement State issues. (2)

Post-Approval Actions (E)

The following actions are taken after the Commission, the EDO, or the CFO has approved a rulemaking plan:

- The lead office shall prepare an entry for inclusion in the Rulemaking Activity Plan. (1)
- ADM shall assign the plan a Regulation Identifier Number (RIN) and include a new entry in the next edition of the NRC Regulatory Agenda. If the intended action will be a major rule, ADM shall include an entry for it in the NRC Regulatory Plan that is submitted to OMB as required by Executive Order 12866. (2)
- The lead office shall enter all publicly available documents related to the rulemaking plan in the Agencywide Documents Access and Management System (ADAMS) and make them available to the public via the agency's Publicly Available Records System (PARS) Library. (3)

Post-Approval Actions (E) (continued)

- The lead office shall notify ADM to make the approved rulemaking plan available to the NRC staff and the public through RuleForum, the NRC's rulemaking Web site (<http://ruleforum.llnl.gov>). (4)
- Each participating office shall implement the plan as approved by the Commission, the EDO, or the CFO. The office representative for each office will oversee the activities of his or her office so that the schedule is maintained. (5)
- A rulemaking plan shall be revised when it becomes apparent that there is a significant change in one of the fundamental premises underlying the contemplated rulemaking sufficient to alter the projected scope, outcome, resource expenditures, and time frame of the action. A revision to a rulemaking plan must be approved at the same level that the original rulemaking plan was approved. (6)

Part III

Working Group

Members (A)

A working group will be formed if it is appropriate for a specific rulemaking action. A working group should have— (1)

- A task leader from the lead office. (a)
- Members within the lead office who have program responsibilities related to the rulemaking. (b)
- A member from the Office of the General Counsel (OGC) to provide legal advice and support. (c)
- A member from the Rules and Directives Branch, Division of Administrative Services, ADM, to provide input on the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), plain language, and formatting requirements of the Office of the Federal Register (OFR). (d)
- A member from the Records and FOIA/Privacy Services Branch, Information and Records Services Division, Office of Information Services, to provide advice on information collection requirements. (e)
- An Agreement State representative, as appropriate. (f)
- Staff from other offices, as appropriate. (g)

Responsibilities (B)

The working group is responsible for the following:

Responsibilities (B) (continued)

- Assessing the scope of the rulemaking action, identifying the tasks necessary to complete the rulemaking action, identifying members responsible for completing these tasks, and developing schedules and resource estimates for completing each stage of the action. (1)
- Assisting the lead office in the preparation of rulemaking plans and proposed and final rule packages and supporting documents by providing necessary technical input. (2)
- Addressing comments, estimating the information collection burden, and preparing briefing materials. (3)
- Reviewing contractor reports or monitoring contractor effort if contract support is necessary. (4)
- Preparing associated guidance, including licensing, inspection, and enforcement guidance, as appropriate, and coordinating the completion of the guidance documents so that the final guidance is available when the final rule becomes effective. (5)
- Facilitating the concurrence process. (6)
- Apprising management of policy developments throughout the course of the rulemaking action. (7)
- Supporting the lead office in management briefings and public meetings. (8)

Steering Group (C)

A steering group may be established for certain significant rulemaking actions. The steering group is composed of senior managers from the affected offices and OGC, and an Agreement State representative, as appropriate. The steering group resolves significant questions of policy and facilitates concurrence of the rulemaking plan.

Part IV

Public Participation

Rulemaking Information on the Web: ADAMS and RuleForum (A)

ADAMS (the Agencywide Documents Access and Management System) and RuleForum are the NRC's principal means of communicating public information about agency rulemaking activities. 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>). These documents include all supporting documents and analyses referenced in a *Federal Register* notice (FRN). Certain documents are also posted to RuleForum (<http://ruleforum.llnl.gov/>), which facilitates public involvement in the rulemaking process by allowing stakeholders to easily access and comment on key rulemaking documents. (1)

FRNs for proposed and final rules, policy statements, and other rulemaking-related actions are posted to RuleForum by ADM's Rules and Directives Branch (RDB) in the appropriate category under *Related Documents*. Public comments, draft rule language, meeting notices, and significant supporting documents and analyses are also posted to RuleForum once they have been made available in ADAMS. (2)

In order to make rulemaking information available to the public online, the lead office must— (3)

- Enter all publicly available documents cited in the FRN into ADAMS and make those documents available to the public through the agency's Publicly Available Records System (PARS) Library. RDB cannot post rulemaking documents to RuleForum unless they are already available in PARS. See the NRC Rulemaker Web site (under *Procedures*) for detailed instructions on making NRC documents publicly available in PARS. (a)

Rulemaking Information on the
Web: ADAMS and RuleForum (A)
(continued)

- Prepare an FRN announcing the public availability of the material and/or soliciting public comment, as appropriate. (b)
- Notify RDB of the ADAMS accession numbers for (1) all documents included in the FRN publication package and (2) all rulemaking supporting documents not published in the *Federal Register* but referenced in the FRN (e.g., draft rulemaking text, technical specifications, NUREGs, environmental analyses). (c)
- Periodically review RuleForum postings and provide RDB with current schedule information. The lead office should also notify RDB if there is a change in contact information for the project manager for the rulemaking. (d)

Pre-2000 documents referenced in an FRN, especially documents relied upon in the statement of considerations supporting a proposed or final rule, should be placed in ADAMS if possible. Contact the Office of Information Services Publishing Services Branch about entering NUREGs into ADAMS. If making an older document available in ADAMS is technically impossible or simply impracticable, the text of the FRN must detail how the document can be accessed by the public. Inspection copies of older documents may be made available to the public by arrangement with the Public Document Room (PDR). Individual copies may be provided to members of the public through Reproduction and Distribution Services or in response to requests submitted to an NRC contact person designated in the FRN. (4)

The Public Document Room (B)

Members of the public without 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. The PDR does not maintain

The Public Document Room (B) (continued)

paper copies of post-1999 NRC documents available in ADAMS, but photocopies of publicly available documents can be obtained for a small fee. Certain publicly available NRC documents that predate ADAMS are available to walk-in visitors as part of the PDR's standing collection; other documents can be located and made available upon advance request. The PDR Reference Staff is available to assist researchers at PDR@nrc.gov or 301-415-4737.

Public Participation During the Technical Basis Phase (C)

When addressing complex or controversial regulatory issues, NRC may seek public involvement during the development of the technical 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 going to the Commission or the EDO for approval to pursue rulemaking. Pre-rulemaking public engagement may include conducting public meetings or workshops, or posting to RuleForum for public comment documents that address scoping concerns or lay out various options for handling emergent technical issues or problems. (1)

When seeking public involvement in technical basis development, the lead NRC office should prepare for publication in the *Federal Register* a notice that— (2)

- Explains the regulatory issue under agency consideration, (a)
- Requests public comment on regulatory alternatives or supporting documents, and/or (b)
- Seeks participation in the process of establishing the technical basis for resolving the regulatory issue. (c)

Public Participation During the Technical Basis Phase (C) (continued)

RDB will post the notice under the category of *Other Rulemaking-Related Comment Requests*, along with any related documents forwarded by the office, for example, an issues paper, interim policy or guidance, questions for directed comment, or an information packet. All documents must be made available in PARS before posting to the Web. (3)

Rulemaking Plan (D)

A rulemaking plan prepared for Commission approval should lay out the lead office's plans for encouraging public participation in the rulemaking process. Rulemaking staff may choose from a wide range of public participation techniques; the individual circumstances attendant upon a given rulemaking will determine which methods of soliciting public input are most appropriate.

Communications Plan (E)

Complex rulemakings or rulemakings that affect a large number or a disparate group of stakeholders may warrant the formulation of a formal communications plan. Guidance on drafting communication plans and a listing of current agency plans are contained in "Communications and Public Meetings," found on the internal Web site at <http://www.internal.nrc.gov/communications>.

Advance Notice of Proposed Rulemaking (ANPRM) (F)

An ANPRM is a formal method of soliciting early public involvement in the rulemaking process. The lead office publishes a notice in the Federal Register that— (1)

- Describes the regulatory problem or situation. (a)

Advance Notice of Proposed Rulemaking (ANPRM) (F) (continued)

- Outlines the anticipated regulatory response to the problem or includes draft regulatory text. (b)
- Proposes alternative (including non-rulemaking) solutions. (c)
- Requests public comment or lists questions and issues for comment to direct public response. (d)

RDB will post the ANPRM on RuleForum under the category of *Advance Notices of Proposed Rulemaking*, along with any supporting documents forwarded by the lead office. All documents must be made available in PARS before posting on the Web. The lead office must provide RDB with the ADAMS accession numbers for all posted documents and for any other documents cited in the FRN. (2)

Notice and Comment Process (G)

Some avenues of public participation are specific to rulemaking and required by statute. The Administrative Procedure Act (APA) of 1946 (U.S.C. 551, et. seq.), as amended, 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. (1)

Notice of a proposed rulemaking must generally be published in the *Federal Register*. The APA does not specify a minimum length for the public comment period, but the time allotted should reflect the complexity of the rule. 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; NRC has adopted this comment period length for all standards-related rulemakings. Interested persons may submit comments to NRC by mail, fax, e-mail, hand delivery, or through Web portals such as Regulations.gov, the

Notice and Comment Process (G)

(continued)

Governmentwide site for Federal rulemaking at <http://www.regulations.gov/> and RuleForum, the NRC's rulemaking Web site at <http://ruleforum.llnl.gov>. (2)

In addition to soliciting comment on proposed rules, agencies must consider all public comments received when drafting and justifying final regulations. This is why the statement of considerations for a final rule must include a thorough analysis that details the agency's response to each substantive comment. Finally, the APA requires that agencies give adequate notice to affected parties when promulgating new rules. The standard lag time between publication of a rule and its effective date is 30 days. (3)

Meetings or Workshops (H)

During the course of a rulemaking, staff may elect to conduct one or more public meetings or workshops to obtain public input. Meeting topics may range from a specific regulatory issue or a portion of the regulations that is a candidate for amendment, to specific draft rule language under consideration at either the proposed or final rule stage. For guidance on planning and conducting a public meeting, staff should consult "Communications and Public Meetings" found on the internal Web site at <http://www.internal.nrc.gov/communications>. For guidance on scheduling and announcing a public meeting, staff should refer to Management Directive 3.5, "Attendance at NRC Staff Sponsored Meetings."

Posting Draft Rule Language (I)

To obtain public feedback early in the rulemaking process, a lead office may, by Commission direction or after the approval of a rulemaking plan, post draft rulemaking language on the RuleForum Web site if the responsible division director identifies

Posting Draft Rule Language (I) (continued)

a rulemaking as meeting one or more of the following criteria for enhanced public participation: (1)

- Controversial or complex subject matter. (a)
- Significant variety of stakeholders or anticipated high number of public comments. (b)
- Stakeholder requests for early input. (c)
- Schedule and resource considerations. (d)

The lead office prepares a Notice of Availability of Draft Rule Wording for publication in the *Federal Register* and forwards a document containing the draft regulatory text to RDB for posting on RuleForum under the category of *Draft Rule Text for Comment*. The notice can include— (2)

- A summary of the regulatory approach(es) under consideration. (a)
- A request for public comment. (b)
- A schedule of contemplated actions and public hearings. (c)

The contemplated regulatory text in draft form can be included in or appended to the notice, but typically the notice simply announces the availability of the draft rule language on RuleForum. To assist stakeholder understanding, this draft text may be supported by explanatory paragraphs that detail what the contemplated amendment is intended to accomplish. Staff may also wish to post drafts of related supporting documents for comment at this time. (3)

Single-Topic Web Pages for Informing the Public of Rulemaking Actions (J)

Single-topic pages on the NRC's public Web site can be used to announce the promulgation of a final rule and assist the public in understanding the effects of a new regulation. When a lead office is about to publish a 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 Office of Information Services' Web team (WEBWORKS@nrc.gov) to request design of a single-topic Web page for posting to the NRC Web site. This page is posted once the rule has gone into effect and should communicate, in plain language, why the new rule was developed, and how it will be implemented and enforced. Stakeholders can access single-topic rulemaking Web pages from the NRC home page under *Key Topics or What's New at Our Web Site*. This type of public communication is useful for reaching stakeholders unfamiliar with the rulemaking process. It provides higher visibility, more detailed exposition, and a more extended Web presence for a final rule than is provided by postings to the RuleForum site.

Negotiated Rulemaking (K)

Negotiated rulemaking is a very formal process seldom used by NRC. This technique was most recently used by NRC in the late 1980s to establish the Licensing Support Network (LSN) as a means to resolve issues involving public access to high-level waste repository related information. (1)

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 NRC might use this process, staff should adhere to the procedures set out by the Negotiated Rulemaking Act (5 U.S.C. 561 et seq.). (2)

Part V

Coordination

Agreement States (A)

Preparing Documents for Agreement State Review (1)

For rulemakings that may affect Agreement States, the lead office, in consultation with the appropriate NRC offices and the Office of the General Counsel (OGC)— (a)

- Develops a draft rulemaking plan that includes suggested Agreement State compatibility classifications for the proposed rule. If the compatibility classification for Agreement State regulations is "C" or involves Health and Safety Elements, the essential objectives of each section of the proposed rule need to be identified. For a full explanation of Agreement State Compatibility, see Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," and the Office of State and Tribal Programs (STP) Internal Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements." (i)
- Marks all draft rulemaking documents for Agreement State review with OFFICIAL USE ONLY header/footers and stamp block. For further guidance on marking sensitive documents, see Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program." (ii)
- Drafts a summary of the rulemaking plan for inclusion in a letter from the Director of STP to all Agreement States. (iii)

Upon receipt of the draft rulemaking plan and plan summary, the Director of STP issues to the Agreement States a letter that— (b)

- Notifies the Agreement States of the opportunity for early comment and the availability of the draft rulemaking plan on

Agreement States (A) (continued)

Preparing Documents for Agreement State Review (1) (continued)

the Technical Conference Forum (<http://techconf.llnl.gov>), accessible via the NRC Home Page (<http://www.nrc.gov>). (i)

- Specifies that comments are to be made directly to the lead project manager by e-mail, fax, or phone. The Technical Conference Forum allows NRC to quickly disseminate information amongst the States and provides a forum for informal discussion of the pros and cons of rulemaking actions; however, it is not a means for States to submit formal comment on rulemaking actions to NRC. (ii)

Agreement State Notification (2)

Most rulemaking plans are sent to the Agreement States during the office concurrence process after obtaining OGC's analysis of legal sufficiency demonstrating no known basis for legal objection. The lead office— (a)

- Submits the draft of the rulemaking plan to the Commission through a Commissioner's Assistant note. (i)
- Provides STP with the draft rulemaking plan and summary for the Director's letter to the Agreement States. (ii)
- Provides, by letter or e-mail, notice of the plan to the Executive Director of the Conference of Radiation Control Program Directors (CRCPD), who will ensure that the CRCPD Suggested State Regulations (SSRs) Council Chair is notified of the plan. (iii)

For rulemaking plans concerning controversial policy issues, the lead office sends the final (not draft) plan to the EDO for transmission to the Commission through a SECY paper and obtains Commission approval before sending the plan to STP. (b)

Agreement States (A) (continued)

Agreement State Notification (2) (continued)

For rulemakings initiated by Commission direction or when a rulemaking plan is not required, the lead office transmits the draft rulemaking document to STP at the time of office concurrence without formal Commission notification. The lead office sends to the EDO a copy of the memorandum transmitting the rulemaking document to STP, and the EDO forwards the rulemaking document to the Commission through a Commissioner's Assistant note. (c)

The Agreement States are provided opportunity for early review and comment of draft rulemaking documents as follows: (d)

- 45 days for predecisional draft rulemaking plans. (i)
- 30 days for draft proposed rules and draft final rules. (ii)

For further guidance on the process for soliciting early comment from Agreement States, see STP Internal Procedure SA-800, "Providing NRC Predecisional Documents to Agreement States and Appropriate Working Groups of the Conference of Radiation Control Program Directors, Inc." (e)

Notification of Commission Action (3)

In concert with the appropriate NRC offices and OGC, the lead office revises the draft rulemaking plan in response to comments received from the Agreement States and the CRCPD. The lead office provides the revised plan to the Commission for approval, including the staff's disposition of Agreement State and CRCPD comments. (a)

After Commission approval of the rulemaking plan, the lead office— (b)

Agreement States (A) (continued)

Notification of Commission Action (3) (continued)

- Notifies the Executive Director of the CRCPD, who will ensure that the CRCPD SSRs Council Chair is notified. This step will permit the development of an SSR, if desired, to parallel the development of the NRC rulemaking. (i)
- Forwards to ADM an entry for inclusion in the next edition of the NRC Regulatory Agenda and the Unified Agenda of Federal Regulatory and Deregulatory Actions. (ii)

If the Commission does not approve the rulemaking plan, the lead office notifies STP and, by letter or e-mail, the Executive Director of the CRCPD. STP notifies the Agreement States of the Commission's approval or disapproval of a rulemaking plan. (c)

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

The lead office for the rulemaking action shall forward it to the appropriate advisory committee and, if appropriate, the CRGR for review during the concurrence process unless a decision has been made to defer review. The lead office shall also accomplish the following:

- Formally document and respond to any consensus comments or recommendations from the advisory committee concerning the rulemaking action. (1)
- Include the analysis and response to advisory committee comments with any other public comments in the Supplementary Information section of the *Federal Register* notice for the rulemaking action. (2)

Advisory Committees and the
Committee To Review Generic
Requirements (CRGR) (B) (continued)

- Maintain any individual committee member comments as part of the rulemaking record. (3)
- Upon a request by the advisory committee, meet with the committee at any time during the rulemaking process to discuss the rationale for the proceeding. (4)

Office of Public Affairs (OPA) (C)

The lead office for the rulemaking action shall contact OPA before initiating the concurrence process to determine if a press release is to be prepared for the rulemaking. The lead office shall also accomplish the following: (1)

- Provide OPA with a draft of the rulemaking action that will be forwarded for office concurrence, as well as draft versions of any supporting documents developed for the action. (a)
- Review the draft press release if OPA determines one is necessary or desirable and provide comments to OPA. (b)
- Include a copy of the draft press release in the completed concurrence package forwarded with the Commission paper or attached to the memorandum requesting the signature of the EDO or the CFO. If OPA determines that a press release is not necessary or desirable, a note to that effect is included in the Commission paper or the memorandum requesting the signature of the EDO or the CFO. (c)
- Inform OPA of any change in the rulemaking action resulting from the concurrence process, 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. (d)

Office of Public Affairs (OPA) (C) (continued)

When the staff requirements memorandum (SRM) is prepared, the Office of the Secretary (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 shall continue to coordinate with OPA until the proposed or final rule is submitted for publication and the press release is issued. (2)

If possible, the lead office shall notify OPA shortly before the SRM is issued for a proposed or final rule or when 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. (3)

Part VI

Concurrences

Office Concurrence (A)

Office concurrence means that the concurring office— (1)

- Agrees with the overall approach, objective, technical content, and resource impacts of the rulemaking action. (a)
- Believes that the rulemaking action will not adversely affect or conflict with other NRC programs and policies in its area of responsibility. (b)
- Agrees that the material for which the office has a programmatic basis for judgment is factual and accurate. (c)

Office concurrence on rulemaking plans and *Federal Register* notices is requested from the following: (2)

- All other NRC offices that are affected by or interested in the rulemaking action from a technical standpoint in their area of responsibility (a)
- OGC (b)
- Rules and Directives Branch (RDB), Division of Administrative Services, ADM (c)
- Records and FOIA/Privacy Services Branch, Information and Records Services Division, Office of Information Services (d)
- OE (e)
- OCFO (f)

OGC Concurrence (B)

OGC concurrence means that from OGC's standpoint, the recommended action is— (1)

- Legally sufficient. (a)
- Consistent with existing Commission policy. (b)
- Supported by OGC in a manner consistent with OGC's Operating Manual (c)

No legal objection means that— (2)

- The recommended action is legally sufficient. (a)
- OGC is not taking a position with respect to the policy aspects of the recommendation. (b)

Concurrence Procedures (C)

The lead office shall 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: (1)

- Each rulemaking plan before it is submitted for approval. (a)
- 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. (b)
- 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. (c)
- Each document relating to the rulemaking before it is submitted for signature and publication. (d)

Concurrence Procedures (C) (continued)

- Each document containing draft rule language before it is posted to RuleForum, the NRC's rulemaking Web site. (e)

During the concurrence process, a concurring office may provide timely questions or concerns regarding any technical analysis or information that may invalidate or raise doubts about a rulemaking. An office may not withhold its concurrence or determination of no legal objection on the basis of the following: (2)

- Questions concerning material that is presented as factual unless the office has a programmatic basis for judging the accuracy of the material. (a)
- Editorial style or manner of presentation that does not affect the policy recommendations of the rulemaking action. (b)
- Policy disagreements that do not have a legal or technical basis. (c)

If the reviewing attorney disagrees with the recommended rulemaking action on policy grounds, OGC shall 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. (3)

Each concurring office shall respond to the lead office by hand-carried memorandum, NRC mail, or e-mail. For most rulemaking actions, the lead office requests that responses be made within 20 calendar days. The responding office shall do one of the following— (4)

- Concur or provide a determination of no legal objection without comment in the rulemaking document; (a)

Concurrence Procedures (C) (continued)

- Concur or provide a determination of no legal objection with the condition that specific technical, policy, or legal recommendations of the concurring office can be accommodated; (b)
- Withhold concurrence or a determination of no legal objection pending resolution of specific technical, policy, or legal issue raised by the concurring office. (c)

If concurrence is withheld, the responding office shall do one or more of the following— (5)

- Work with the lead office to resolve any policy reasons for withholding concurrence; (a)
- State the policy reasons for withholding concurrence or for the legal objections that are not resolved at the staff level, present the suggested solutions that would result in concurrence, and send a copy of this memorandum to OEDO; or (b)
- State the reasons for being unable to respond on schedule and send a copy of this memorandum to OEDO. (c)

After receiving the concurrence memoranda or e-mail, the lead office shall— (6)

- Provide a revised rulemaking package, including the rulemaking plan, the proposed rule, or the final rule, to the EDO, or (a)
- 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. (b)

Concurrence Procedures (C) (continued)

Within 20 calendar days of receipt of a proposed or final rule, the EDO shall do one of the following— (7)

- Transmit the proposed or final rule for Commission consideration; (a)
- Notify the Commission of the intent to issue the rule under the rulemaking authority delegated to the EDO; (b)
- Return the rulemaking package to the lead office for modification or resolution of questions within a specified schedule; or (c)
- Instruct the lead office not to proceed with the rulemaking. (d)

Part VII

Reports

The Rules and Directives Branch (RDB), Division of Administrative Services (DAS), ADM, is responsible for preparing the following:
(1)

- The NRC Regulatory Agenda and the Unified Agenda of Federal Regulatory and Deregulatory Actions (a)
- The annual Regulatory Plan submitted to the Office of Management and Budget required by Executive Order 12866 (b)
- The semiannual report to the EDO on the status of all petitions for rulemaking (c)
- The Rulemaking Activity Plan that is submitted to the Commission for information and provides a status report on all ongoing rulemakings and petitions (d)
- The monthly Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) Report (e)

RDB/ADM also reviews the electronic compilation of 10 CFR Chapter I that appears on the NRC's public Web site. (2)