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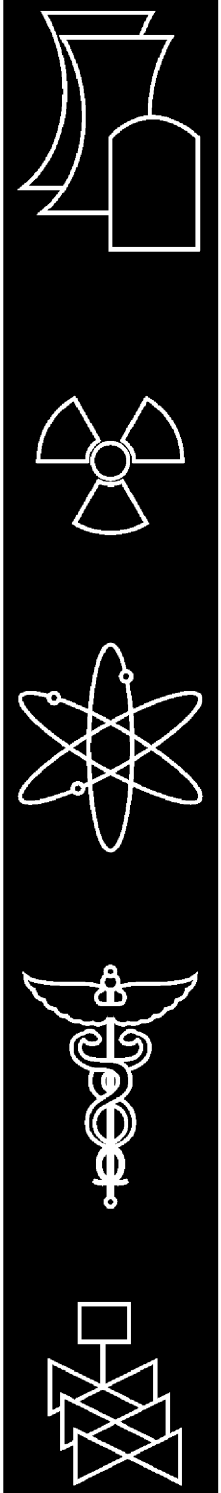

United States Nuclear Regulatory Commission Regulations Handbook

U.S. Nuclear Regulatory Commission
Office of Administration
Washington, DC 20555-0001

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The NRC Technical Library
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212–642–4900

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Abstract

This document is designed to assist NRC staff in drafting, preparing, and reviewing rulemaking documents for publication in the Federal Register. It is intended to serve as a guidance tool, and provides information relevant to each step in the rulemaking process. This revision reflects changes resulting from the consolidation of rulemaking policy matters into Management Directive 6.3, "The Rulemaking Process," and the placement of sample documents and some procedures on the NRC Rulemaker web site. This revision reflects various other changes that have occurred in the rulemaking process and in NRC procedures since the last complete revision of this document in 2001.

Contents

Chapter 1 Rulemaking at the NRC

Background

Rulemaking is the process that ensures that the intent and effect of a rule are fully understood before it is enacted. Rulemakers at the NRC strive to develop high-quality rules that promote sound public policy and satisfy all applicable laws and regulations. Proper rulemaking enhances the mission of the agency by providing order, balance, equity, and openness to the regulatory process.

The Handbook

This *NRC Regulations Handbook* offers guidance to NRC staff members who prepare, review, and coordinate rulemaking actions. It includes procedures, requirements, and background information essential to the successful development and review of rulemaking actions.

This publication is organized into five chapters. Chapter One contains an overview of the NRC's rulemaking process. Chapter Two concerns the formal documents that must be published in the *Federal Register*. Chapter Three contains detailed formatting instructions for preparing your *Federal Register* document. Chapter Four covers the legal and procedural reviews required to support your rulemaking. Chapter Five is devoted to an alternative rulemaking process, the Direct Final Rule.

This handbook has been developed as a basic desk reference and is intended to be used in close consultation with two essential rulemaking tools: Management Directive (MD) 6.3, *The Rulemaking Process*, and an internal web site, *The NRC Rulemaker*[1].

MD 6.3 describes the organizational responsibilities for rulemaking, the delegations of authority, and fundamental agency rulemaking policy. The *NRC Rulemaker* site contains guidance and numerous links to templates, sample documents, checklists, and procedures. The site is continuously updated and highlights breaking news of value to rulemakers. It is wise to regularly consult the *NRC Rulemaker* for current desk procedures and up-to-date document templates as NRC internal procedures for processing rules and petitions are subject to change.

Please note that this handbook was written as a guide to the craft of rulemaking at the NRC. It is intended to be handy – not encyclopedic – and does not attempt to address every technical issue or legislative action that could affect rulemaking.

[1] http://www.internal.nrc.gov/ADM/DAS/cag/RM01/

Legal Framework

The basic legal framework for rulemaking was established by the Administrative Procedure Act (APA) of 1946 (5 U.S.C. 551, et. seq.), as amended. The APA established two general categories of rulemaking: "formal" and "informal." Formal rulemaking proceedings involve public hearings and are required only where a statute other than the APA itself requires a rule to be made "on the record." NRC undertakes very few formal rulemakings.

The "informal" rulemaking process of the APA is found in 5 U.S.C. 553. This process, known as "notice and comment" rulemaking, is used for most NRC rulemakings and is the subject of this handbook. Exceptions to the notice and comment requirement or "APA-exempt" rules are possible, but rare, and are discussed under Alternative Processes later in this Chapter.

Compliance with 5 U.S.C. 553 of the APA requires that the NRC give the public an opportunity to comment on a rule proposed by the agency before the rule can be put into effect. This section also requires that the effective date of a regulation be not less than thirty days from the date of publication unless there is good cause for implementation at an earlier date.

To provide notice to the public, the NRC publishes documents in the *Federal Register*. These documents announce all proposed regulations being promulgated or amended. The *Federal Register* is published each Federal workday by the Office of the Federal Register (OFR), National Archives and Records Administration. The *Federal Register* provides a uniform system for publishing presidential documents, final rules, proposed rules, advance notices of proposed rulemaking, petitions for rulemaking, general notices, policy statements, semiannual regulatory agendas, meeting announcements, and other agency documents concerning the conduct of public business.

The Code of Federal Regulations (CFR) is the codification of regulations promulgated by Federal agencies. The CFR is edited annually to present the regulations effective as of its date of revision. The CFR, used in conjunction with the daily *Federal Register*, provides the definitive version of the NRC's regulations. The Government Printing Office (GPO) nightly updates its Beta (test) site, the "e-CFR," but as yet the GPO has not endorsed this version as an official legal edition of Federal regulations.

The CFR is divided into fifty titles according to subject matter. These titles are divided into chapters, chapters are divided into parts, and parts into sections (and occasionally, subparts.)

NRC regulations are contained in CFR Title 10, "Energy," Chapter I, "Nuclear Regulatory Commission," Parts 0-199. Each part has a heading that reflects its content. Each part sets out the regulations that pertain to a regulatory activity or program of the NRC. Some parts set out procedural requirements and information pertaining to internal agency organization and procedures that describe how the agency conducts its activities. The NRC has not used all of the parts between 0 and 199. The unused parts are reserved for future NRC use. Regulations specific to NRC rulemaking are addressed in 10 CFR Part 2, Subpart H, "Rulemaking." Subpart H governs the issuance, amendment, and repeal of regulations.

The Process

NRC rulemaking involves the completion of four principal tasks:

1. Identify the need for a rulemaking.
2. Develop a rulemaking plan.
3. Prepare a proposed rule package and publish the proposed rule.
4. Prepare a final rule package and publish the final rule.

There are variations on the rulemaking process, such as the procedures employed when preparing direct final rules and APA-exempt rules, but the basic requirements are always the same.

Identify the Need

The NRC initiates a rulemaking in response to a congressional mandate, an internal recommendation, a petition from outside the NRC, or an identified need for a conforming, corrective, or other type of administrative action.

Most rulemakings are staff-initiated. Initiation procedures vary from office to office within the agency; for example, the Office of Nuclear Material Safety and Safeguards (NMSS) requires the submission of a "user-need" memo, and the Office of Nuclear Reactor Regulation (NRR) requires completion of the technical basis before rulemaking can begin. The Commission can direct the staff to proceed with the development of a rule. This is usually accomplished through the issuance of a Staff Requirements Memorandum (SRM). The SRM would indicate whether to prepare a rulemaking plan or proceed directly to a proposed rule.

During this preliminary stage of the rulemaking process, NRC staff may elect to solicit stakeholder input so as to gauge interest before going forward with rulemaking. The NRC could at this point publish an Advance Notice of Proposed Rulemaking (ANPRM) or other document seeking early public input, such as a notice of availability and request for comment on an issues paper or draft rule language.

Develop a Rulemaking Plan

The office responsible for developing a rule assembles a working group to develop a rulemaking plan. The working group is composed of members from the respective offices and divisions within NRC that will be involved in the development of the rule. The working group includes a member from the Office of General Counsel (OGC), and for rulemaking actions involving Agreement States, the working group may include an Agreement State representative and/or a member from the Office of State and Tribal Programs (STP) See MD 5.3 "NRC/Agreement State Working Groups" for more information.

The working group's responsibilities and the required components of a rulemaking plan are outlined in MD 6.3. The APA does not require a rulemaking plan. This is a step that NRC policy imposes. The rulemaking plan is intended to:

- Provide a preliminary outline of the scope and impact of the contemplated action sufficient to determine whether a rulemaking is necessary or desirable.
- Present a preliminary analysis of the cost-efficiency of the action.
- Obtain Commission approval for a rulemaking before significant resources are expended on the project.
- Provide a schedule for the rulemaking that will facilitate efficient and timely completion of a proposed rule.
- Serve as a mechanism for obtaining early substantive input from the Agreement States.

Rulemakings that involve matters of urgency or complex and controversial issues will often have a steering committee overseeing the actions of the working group. The use of a steering committee helps to ensure that senior management is fully involved and policy objectives are effectively represented from the earliest stages of a rulemaking to its completion.

Prepare Proposed Rule Package

After Commission approval of the plan, the rulemaking officially begins. At this point the "clock" starts to keep track of the time spent in completing the rule. This is also a point where an Advance Notice of Proposed Rulemaking (ANPRM) or other document providing opportunity for public participation (such as workshops or meetings with Agreement State representatives) is prepared and published for public comment.

The working group prepares the proposed rule package, including supporting documents. A proposed rule package typically contains:

- The proposed rule document to be published in the *Federal Register*. (This document contains the preamble, also called "Statement of Considerations," and the proposed rule language.)
- An environmental assessment or draft environmental impact statement.
- A draft regulatory analysis.
- A Commission Paper or transmittal memo to the EDO.
- Congressional letters.
- A press release.
- Draft backfitting and Paperwork Reduction Act statements.
- Any additional draft guidance documents.

If the EDO is signing the rule, the package also contains the authority statement for the EDO's signature and an entry for the weekly report to the Commission. The OMB clearance package for the rule is provided to the Office of Information Services (OIS) and is not usually part of the package sent to the EDO or Commission.

The length of time from the approval of the rulemaking plan to the publication of the proposed rule notice in the *Federal Register* is generally one year. The standard public comment period is seventy-five days. For rulemakings with enhanced public participation, public meetings may be held either during the rule development or comment period.

Under certain very narrow conditions, the Commission may waive publishing a proposed rule for public comment. When this occurs, either a direct final rule (including a companion proposed rule) or an immediately effective final rule is prepared and published. Non-controversial actions that do not involve significant technical or policy issues may be published as direct final rules. Strictly administrative rules are exempt from APA notice and comment provisions and are commonly published as immediately effective final rules.

Prepare Final Rule Package

A final rule addresses all comments received on the proposed rule. Most schedules call for the final rule to be published one year after the proposed rule, or approximately two years after approval of the rulemaking plan. This schedule can vary depending upon the complexity of, or the degree of public interest in the rule.

At the end of the public comment period, the public comments are summarized and the working group prepares responses to the comments. The working group assembles the final rule package, including the supporting documents. A final rule package typically contains:

- The final rule document to be published in the *Federal Register* that contains the preamble (Statement of Considerations) including a resolution of public comments, and the rule language.
- An environmental assessment or final environmental impact statement.
- A final regulatory analysis.
- A Commission Paper or transmittal memo to the EDO.
- Congressional letters.
- Congressional Review Act (CRA) form (formerly SBREFA form)
- A press release.
- Final backfitting and Paperwork Reduction Act statements.
- Any additional draft or final guidance documents.

If the EDO is signing the rule, the package would also contain the authority statement for the EDO's signature and the notice to the Commission (formerly called the daily staff note). The OMB package is provided to the Office of Information Services (OIS) and is not usually part of the package going to the EDO or Commission. Strictly administrative rules do not require an environmental assessment, regulatory analysis, backfit analysis, or in most cases, an OMB clearance package.

Oversight Responsibilities

Responsibility for overseeing the development of a rule is held by the lead program office. That office typically forms the working group which:

- Prepares rulemaking documents.
- Prepares necessary supporting documents.
- Keeps management informed about the progress of the rulemaking.
- Facilitates final management review and approval of the complete rulemaking package.

NRC rulemaking packages undergo review and approval at several levels. A typical concurrence chain would include:

- The originator of the package.
- Administration (ADM), Office of General Counsel (OGC), Office of Information Services (OIS), the Office of the Chief Financial Officer (OCFO), and the Office of Enforcement (OE).
- The rule writer's chain of management up to the Office Director level.
- The Office of the Executive Director for Operations (EDO).

The EDO transmits the package to the Commission for final consideration and approval. For certain rules, further reviews may be needed. Depending upon the nature of the rulemaking, it may be reviewed by:

- Agreement State participants
- The Office of State and Tribal Programs (STP).
- NRC's Committee to Review Generic Requirements (CRGR).
- Any of NRC's three Advisory Committees: Reactor Safeguards, Nuclear Waste, Medical Use of Isotopes.
- Other Federal agencies with cooperating agency status.

Most rules are approved by the Commission and signed by the Secretary to the Commission prior to publication. For certain types of rules, the Commission has delegated approval and signature authority to the Executive Director for Operations (EDO) or the Chief Financial Officer (CFO).

The authority delegated to the EDO and CFO extends only to rules which:

- Do not have significant policy implications.
- Do not substantially alter established agency practices.
- Are within the purview of the EDO or the CFO.

External Review

Congressional Oversight

Under the Atomic Energy Act of 1954, NRC is required to keep the Congress informed of its activities. NRC notifies Congress whenever the agency submits an advance notice of proposed rulemaking, a proposed rule, or a final rule to the Office of the Federal Register for publication; strictly administrative rules do not require Congressional notification. The lead office drafts a letter, for signature by the Director of OCA, describing the action that the agency is undertaking. Identical letters are prepared for the Chair and the ranking minority member of each of the House and Senate Committees charged with overseeing NRC. On occasion, as the substance of a rulemaking warrants, letters will be sent to additional Congressional oversight committees.

Under the Congressional Review Act (CRA), Congress is provided an opportunity to review agency rules. For each final rule the agency is required to submit a report to each House of Congress and the Comptroller General before the rule takes effect.

Office of Management and Budget (OMB) Approval

NRC obtains OMB approval when a proposed rule under development imposes new information collection requirements, or alters or deletes existing information collection requirements. The OMB clearance package that the staff develops provides the information needed by OMB to evaluate compliance with the Paperwork Reduction Act. A final rule containing an information collection requirement may not be published until OMB clearance is granted. The process for obtaining OMB approval is described in MD 3.54, "Collections of Information and Reports Management."

Alternative Processes

Abbreviated Rulemaking Procedures

The APA provides for "Good Cause" exceptions to the usual requirements for prior notice and an opportunity to comment where an agency for good cause finds (and includes the finding in the rule) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. Courts have warned that these exceptions will be narrowly construed and only reluctantly countenanced. The Attorney General has interpreted the meaning of these exceptions. Notice-and-comment rulemaking is "impracticable" where it would impede the agency from performing its statutory functions, such as taking measures necessary to correct an ongoing safety problem; it is "unnecessary" where there is no public interest, such as changing the addresses of agency officials; it is "contrary to the public interest" where advance notice would defeat the public interest, such as the issuance of price controls, where issuance of advance notice would defeat their purpose. Case-specific findings are needed to establish that there is good cause for dispensing with notice-and-comment procedures. These APA exceptions are primarily applied to two different types of rulemakings:

emergency rules and very minor rules in which there is no public interest. To use an exception for an emergency rule, the agency should be able to demonstrate the existence of a safety or health problem which must be addressed immediately. Although the APA does not require a post-promulgation comment period when a good cause exception is used, NRC's rules require that the Agency provide a 30-day post-promulgation comment period when good cause is based on prior notice being impracticable or contrary to the public interest. 10 CFR 2.804(e).

Note that the APA also generically excepts from the notice and comment requirements interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice, without the need for a finding of good cause. In addition, APA rulemaking requirements do not apply to matters involving a military or foreign affairs function of the United States, or relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

NRC Processes

The staff has developed special procedures for some types of rulemakings. NMSS has developed a streamlined process using a direct final rule for issuance of rulemakings related to Certificates of Compliance for spent fuel storage. Concurrence authority for these rulemakings has been delegated to managers and staff at the branch level, thus significantly reducing the amount of time needed for processing of the rule.

The direct final rule procedure is not discussed in the Administrative Procedure Act, but has been used by NRC and other agencies when issuing a proposed rule that involves fairly routine issues.

If the lead office expects that the rulemaking will be without controversy and does not expect any adverse comments on the proposed rule, NRC publishes a direct final rule concurrent with a companion proposed rule stating that the rule will go into effect on a certain date, usually 75 days after publication, unless NRC receives significant adverse comment within a certain time period, usually 30 days. The direct final rule and its companion proposed rule are published in the same issue of the *Federal Register*. After the time period for any public comment has passed, the NRC publishes a notice confirming the effective date.

If NRC receives adverse comment on the proposed rule, it withdraws the direct final rule before it goes into effect and prepares a final rule instead, following the usual APA rulemaking process.

ADM uses a simplified process to notice corrections to a published rule and for publication of administrative or technical amendments.

The NRC may issue a rule in final form without first publishing a proposed rule if the action qualifies as an exception under the APA (5 U.S.C. 553(b)) and the Office of the General Counsel (OGC) approves this course of action. Strictly administrative rules are typically issued in this manner, as are certain actions mandated by Congress.

Occasionally, the staff may issue an advance notice of proposed rulemaking (ANPRM) or an issues paper to solicit stakeholder views before making a recommendation to go forward with a particular rulemaking action. The working group

develops the ANPRM. The concurrence and review process is the same for an ANPRM or issues paper as it is for a proposed rule. The ANPRM or issues paper is published for comment, in the *Federal Register*, usually for a 75-day comment period. The staff may conduct a public workshop during this period to solicit and discuss comments. The staff, through the working group, analyzes and resolves the public comments in the preamble to the proposed rule or in the rulemaking plan. Based on the comments, NRC may decide to change course or to terminate the rulemaking action.

Chapter 2 The Federal Register Document

Background

Format requirements for every document the NRC sends for publication in the Federal Register are specified in 1 CFR Chapter I. The Office of the Federal Register (OFR) classifies documents for publication in one of the following four sections of the Federal Register: Presidential Documents, Rules and Regulations, Proposed Rules, and Notices.

Proposed Rules

Once the Commission has approved a rulemaking plan, the working group prepares and assembles the proposed rule package. The central document is the proposed rule, to be published in the Federal Register, and contains a preamble (Statement of Considerations) and the proposed rule language. This will be published in the Proposed Rules section of the Federal Register.

In the Proposed Rules section, agencies announce contemplated amendments to their regulations or anticipated agency rulemaking actions and provide the public with an opportunity to comment on the proposed changes as required by the Administrative Procedure Act (APA) (5 U.S.C. 553). As a result, documents published in the Proposed Rules section are subject to greater public scrutiny and are included in the numerical finding aids compiled by the OFR. In addition to proposed rules, the OFR classifies the following types of NRC documents for publication in the Proposed Rules section of the Federal Register:

Documents that Relate to Previously Proposed Rules

The OFR classifies each document that relates to a previously published proposed rule as a proposed rule for purposes of publication in the *Federal Register*. This type of document may:

- Extend a comment period;
- Announce a public hearing or meeting on a proposed regulation;
- Publish or announce the availability of information supplemental to a rulemaking;
- Withdraw a proposed rule;
- Terminate a proposed rule proceeding;
- Correct a previously published proposed rule.

Documents that Begin a Rulemaking Proceeding

The OFR classifies any document that serves as the first public notice that a rulemaking proceeding is anticipated as a proposed rule for publication in the Federal Register.

Advance Notices of Proposed Rulemaking (ANPRM)

These documents generally describe a problem or situation and may outline NRC's anticipated regulatory response. In an ANPRM, the NRC may request public comment on whether a regulation is necessary and, if so, on the merits of NRC's anticipated regulatory response. The NRC may propose several alternative solutions in an ANPRM and solicit public comment on each alternative.

Petitions for Rulemaking

The NRC publishes a notice of receipt of a petition for rulemaking filed with the Commission under its rulemaking procedures (10 CFR 2.802). Because a petition proposes changes to existing regulations in 10 CFR Chapter I, documents concerning a petition are classified as proposed rules for purposes of publication in the Federal Register.

Meetings or Hearings

If a meeting or hearing is the first step in a rulemaking proceeding, the OFR classifies the document announcing the meeting or hearing as a proposed rule for purposes of publication in the Federal Register.

Regulatory Agendas

The NRC publishes an agenda of regulations under agency development in the Federal Register twice a year. The agenda, which is included in the Unified Agenda of Federal Regulatory and Deregulatory Actions, consists of regulatory actions that have been approved by the Commission, the Executive Director for Operations (EDO), or the Chief Financial Officer. This agenda is intended to comply with the requirements of the Regulatory Flexibility Act (Pub. L. 96-354; 5 U.S.C. 601 et seq.) and to implement the program for improving regulatory planning and review contained in Executive Order 12866. Because these documents often provide the public with advance notice of anticipated NRC rulemaking activities, the OFR classifies them as proposed rules for publication in the Federal Register.

Twice a year the NRC independently updates its agenda of regulations approved by the EDO for development (NUREG-0936). This document, the NRC Agenda, also includes a summary of petitions for rulemaking pending before the Commission (10 CFR 2.802(g)). The NRC places an electronic copy of the NRC Regulatory Agenda into the Agency-wide Documents Access and Management System (ADAMS) and on the NRC public web site.

Rules and Regulations

Documents published in the Rules and Regulations section usually have "general applicability and legal effect," as defined in 1 CFR 1.1. They inform the public of the regulations applicable to them. As a result, these documents are subject to increased public scrutiny and are included in the numerical finding aids compiled by the OFR.

Final Rules

Final rule documents amend NRC regulations in 10 CFR Chapter I by adding new text or revising or removing existing text. In a final rule document, NRC publishes each change to 10 CFR Chapter I in full and states an effective date for each change made. A final rule document and its supporting documents are based upon the proposed rule document and the draft supporting documents that preceded it. The final rule document mirrors the text of the proposed rule document except for changes resulting from the evaluation of public comments and changes necessary to reflect the change in status from proposed to final form. In addition to final rules, the OFR classifies the following types of documents for publication in the Rules and Regulations section of the Federal Register:

Direct Final Rules

A direct final rule is a regulatory document that is used for non-controversial regulatory amendments. A direct final rule becomes effective in a certain number of days, usually seventy-five days after publication, unless the NRC receives significant adverse comments within a prescribed comment period, usually thirty days after publication. The NRC publishes with each direct final rule a companion proposed rule (in the proposed rule section of the same issue.) The direct final rule states that any significant adverse comments received will be considered as comments on the companion proposed rule and that the NRC will not initiate a separate comment period for the action.

Interim or Temporary Rules

An interim or temporary rule is a regulatory document that is effective for a defined period of time. An interim or temporary rule has the same effect on 10 CFR Chapter I as a final rule in that it amends text in the Code of Federal Regulations (CFR) and provides an effective date for each amendment. When issuing an interim or temporary rule, the NRC must request public comment (unless an APPA exception to the requirement for an opportunity to comment applies) and consider adjustments to the regulation before adopting it in final form. An interim or temporary rule must meet the format requirements outlined for final rules in this part.

Documents Related to Previously Published Final Rules

The OFR classifies each document that relates to a previously published final rule as a final rule for purposes of publication in the Federal Register.

This type of document may:

- Correct a previously published final rule;
- Announce a meeting or hearing on a previously published final rule;
- Change, suspend, or establish the effective date of a previously published final rule;
- Withdraw an interim rule, final rule, or direct final rule before it goes into effect;
- Change the comment period of an interim or temporary rule; or
- Publish or announce the availability of additional information concerning a previously published final rule.

Policy Statements

The Administrative Procedure Act (APA) (5 U.S.C. 552(a)(1)(D)) requires that each agency publish "statements of general policy or interpretations of general applicability formulated and adopted by the agency" in the Federal Register. Therefore, each draft and final policy statement should comply with the heading format requirements for rules. RDB reviews policy statements to verify that all procedural and format requirements for publication have been met.

Chapter 3 Document Formatting

Background

Crafting a rulemaking document requires the rulewriter to take the unique text of the rule, fit it into the rigid formatting scheme required by the Office of the Federal Register, and combine it with carefully written standard ("boilerplate") paragraphs. The end result should be a logical, readable, and legally enforceable rule. This chapter steps you through the process; additional sample documents are available on the *NRC Rulemaker*[2] web site. Note that examples of document language are frequently single-spaced in this handbook. You should double-space the entire rule documents you prepare for publication, including the "boilerplate" paragraphs presented in this Handbook and on *The NRC Rulemaker* website.

Headings

The NRC's Federal Register billing code [7590-01P] always appears in the upper right-hand corner on the first page of a Federal Register document. This number simply indicates to the Government Printing Office the agency that is to be charged for printing the document. The number is identical for each NRC document.

Each rule document the NRC submits for publication in the Federal Register begins with a series of centered headings. These headings serve to identify:

- NRC as the agency issuing the document.
- The parts within 10 CFR Chapter I to which the document applies.
- The unique regulation identifier number (RIN) of the rule.
- The subject matter of the document.

Example

Issuing Agency	NUCLEAR REGULATORY COMMISSION
CFR Citation	10 CFR Parts 30 and 35
RIN	RIN 3150-BB22
Subject	Testing Radioisotope Generators

The "Issuing Agency" heading for all NRC rulemakings in the Federal Register is always simply "Nuclear Regulatory Commission."

The "CFR Citation" heading must identify all of the parts of the CFR that are affected by the rulemaking document. If the document affects even one paragraph within a CFR part, that CFR part number must be included in the heading. If a document does not contain new or changed text but is classified as a proposed or

[2] http://www.internal.nrc.gov/ADM/DAS/cag/RM01/drafting/sampledocs.html

final rule for Federal Register publication, this heading must include the number of the CFR part that the subject matter of the document most closely matches. If no specific CFR part is affected, you should use the CFR chapter designation alone (e.g., 10 CFR Chapter I).

The "RIN" heading 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. The Office of Management and Budget (OMB) has requested that this number be included in the headings of each rulemaking document published in the Federal Register. RDB assigns a RIN to each regulatory action when the rulemaking plan is approved; contact RDB to determine if a RIN has been assigned to a rule or to obtain a RIN for a new rulemaking action.

The "Subject" heading is a brief statement that describes the content of the document. The subject heading(s) from the affected part(s) or section(s) of the CFR may be sufficient for this purpose. If the CFR headings do not fully and uniquely describe the content of the document, additional information should be included in the heading.

Occasionally a document that appears in the Proposed Rules or the Rules and Regulations sections of the Federal Register concerns the identical subject matter of a document published previously. This situation usually occurs when follow-up documents are necessary in a rulemaking proceeding. To emphasize the relationship between the two documents, the Office of the Federal Register (OFR) requires that the later document use the same headings as the earlier document. In this situation, a word or phrase identifying the action, or the type of the second document, is added to the subject heading.

Example

NUCLEAR REGULATORY COMMISSION
10 CFR Parts 30 and 35
RIN 3150-BB22
Testing Radioisotope Generators; Extension of Comment Period

Preamble

Each rule the NRC prepares for publication in the Federal Register must begin with a preamble. At the NRC, the preamble is also known as the "Statement of Considerations." Although the preamble contains no regulatory text, it contains the information necessary for the user to understand the basis and purpose of the regulation. Each preamble must comply with the format requirements of 1 CFR 18.12. These requirements arrange basic information concerning the regulation in a predictable format that allows users to quickly scan documents for essential information.

The rulemaking preamble must include the following parts:

- AGENCY
- ACTION

- SUMMARY
- DATES/EFFECTIVE DATE
- ADDRESSES
- FOR FURTHER INFORMATION CONTACT
- SUPPLEMENTARY INFORMATION

AGENCY

This caption identifies NRC as the agency issuing the document. The initials "U.S." are not included as part of the agency entry, but are used in the official mailing address of the Commission. Punctuate this and all other required preamble entries with a period.

Example

AGENCY: Nuclear Regulatory Commission.

ACTION

This caption identifies the type of action effected by the document being published. This caption may not be used to summarize the content or amendatory action of the document. Permissible entries under this caption for a rule document include the following.

For Proposed Rules:

ACTION: Proposed rule.

ACTION: Proposed rule: Extension of comment period.

ACTION: Proposed rule: Correction.

ACTION: Proposed rule: Notice of hearing (or meeting).

ACTION: Proposed rule: Withdrawal (or termination).

ACTION: Advance notice of proposed rulemaking.

ACTION: Petition for rulemaking.

ACTION: Petition for rulemaking: Denial.

ACTION: Proposed policy statement.

ACTION: Proposed rule: Availability of supplemental information.

For Final Rules:

ACTION: Final rule.

ACTION: Final rule: Change of effective date.

ACTION: Final rule: Suspension of effective date.

ACTION: Final rule: Confirmation of effective date.

ACTION: Final rule: Correction.

ACTION: Correcting amendments.

ACTION: Final rule: Interpretation.

ACTION: Direct final rule.

ACTION: Interim rule.

ACTION: Interim rule with request for comment.

ACTION: Policy statement.

SUMMARY

The Summary is a brief description, written in language that a non-expert will understand, that allows the reader to determine the subject and intended effect of the proposed rule or the regulation. Generally, the Summary is a single paragraph of three or four sentences. The Summary is not intended to be a detailed abstract or a complete summation of the document. The Summary must answer these questions:

- What does this document do?
- Why is this action necessary?
- What is the intended effect of this action?
- Who is affected by the proposed rule or the regulation?

The answers to these questions should be no more than three or four brief sentences in length and should provide the general public with enough information to determine whether to continue reading the document. An insufficient or incorrectly prepared summary paragraph is the most frequent cause for delayed publication of documents by the OFR and may result in the OFR returning a document to the NRC for required revisions. The Summary must:

- Avoid legal citations (e.g., 10 CFR 35.15(c)(2) or 42 U.S.C. 2201).
- Refer to an act of Congress by popular name (e.g., Atomic Energy Act of 1954).
- Avoid qualifications, exceptions, extensive background, or specific details.
- Describe what the document does rather than how it affects the CFR (e.g., "revises certification criteria for licensed operators," not "adds new Appendix A to 10 CFR Part 50.").

Example (Summary: proposed rule)

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its power reactor safety regulations by adding a set of licensing requirements applicable only to construction permit and manufacturing license applications. These requirements stem from the Commission's ongoing effort to apply the lessons learned from the incident at Three Mile Island to power plant licensing. Each applicant covered by these regulations would have to meet these requirements, together with existing regulations, to obtain a permit or license.

Example (Summary: final rule)

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its licensing and regulatory policies and procedures for environmental protection. The amended regulation provides that, for purposes of the National Environmental Policy Act, the need for power and alternative energy sources issues are not considered in operating license proceedings for nuclear power plants and need not be addressed by operating license applicants in environmental reports submitted to the NRC at the operating license stage. This action is necessary to avoid the potentially duplicative and unnecessary litigation of issues previously resolved at the construction permit stage.

DATES

This caption identifies the dates within the document that are essential to the rulemaking proceeding. Detailed information concerning compliance schedules, application procedures, public hearing procedures, meeting agendas, content of materials available for public inspection, and other matters should be presented in the Supplementary Information portion of the preamble, not under the DATES caption. In a proposed rule document, the following dates may be included when appropriate:

- Comment closing deadlines.
- Public hearing or meeting dates.
- Dates relevant to public knowledge of the proceeding.

Example

DATES: Submit comments on the rule by October 11, 2005. Submit comments specific to the information collections aspects of this rule by August 29, 2005. Comments received after the above dates will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after these dates.

Each final rule must present the date on which the regulation is effective. Other dates relevant to public knowledge of the proceeding may be included as appropriate.

Example

EFFECTIVE DATE: September 24, 2001.

Occasionally, a final rule may contain several provisions that may become effective on different dates. In these situations, a different effective date may be specified for particular amendments. However, each amendment contained in the document must be covered by one of the specified effective dates.

Examples

EFFECTIVE DATE: October 22, 2001, for §§2.744(e), 2.790(d)(1), 73.11(j) and (m), and 73.21(a), (b), and (c)(1). All remaining sections will be effective on January 20, 2002.

EFFECTIVE DATE: The amendments to §§30.7, 30.21, and 30.30 are effective December 21, 2001. The amendments to §§30.40(a) and (b), 30.41(a)(3), and 30.70 are effective January 20, 2002. The amendments to Part 40 are effective February 17, 2002.

If a final rule contains an incorporation by reference that has been approved by the Director of the Office of the Federal Register, this information must be included under the "Dates" caption.

Example

EFFECTIVE DATE: November 21, 2001. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Federal Register as of November 21, 2001

ADDRESSES

This caption identifies addresses that an interested person needs to participate in the rulemaking proceeding. (This caption is optional in a final rule because comments are not requested and no other address may be necessary.) Information presented includes the addresses for:

- Mailing or hand delivering comments.
- Electronic access to published information
- Submitting comments electronically, by e-mail, and by fax.
- Attending a public hearing or meeting.
- Examining any material available for public inspection.
- Obtaining other documents referred to in the rule.

Detailed information concerning how to submit comments, how to register for a meeting, hearing procedures, meeting agendas, or the content of material available for public inspection should be presented in the Supplementary Information portion of the preamble.

Example

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150-XXXX or PRM-XX-XX) in the subject line of your comments. Comments on <rulemakings or petitions> submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking web site to Carol Gallagher (301) 415-5905; email cag@nrc.gov. Comments can also be submitted via the Federal eRulemaking Portal http://www.regulations.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

You may submit comments on the information collections by the methods indicated in the Paperwork Reduction Act Statement.

Publicly available documents related to this rulemaking or petition may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by email to pdr@nrc.gov.

The public hearing will be held in the NRC auditorium, 11545 Rockville Pike, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT

This caption identifies a person who can answer questions or provide additional information concerning the document. Contact information includes at a minimum the name and telephone number of the designated individual, but typically also includes the person's title, mailing address, and e-mail address. Two or more persons may be listed as contacts concerning different aspects of a document.

Example (One contact person)

FOR FURTHER INFORMATION CONTACT: <name of contact person>, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-XXXX; xxx@nrc.gov.

Example (Two contact persons)

FOR FURTHER INFORMATION CONTACT: <name of contact person>, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-9876; e-mail xxx@nrc.gov, or <name of contact person>, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-XXXX; e-mail xxx@nrc.gov.

SUPPLEMENTARY INFORMATION

The Supplementary Information section of the preamble serves as the published history of the document.

In a proposed rule the Supplementary Information section presents the background information and specific details necessary to inform interested persons of the issues involved in the rulemaking proceeding.

In a final rule the Supplementary Information section will, in most respects, be exactly the same as the Supplementary Information for the preceding proposed rule, except it also contains:

- A comment analysis.
- A discussion of how the final rule differs from the proposed rule's recommendation.
- Wording changes reflecting the differing status between a proposed rule and a final rule.

For proposed rules the Supplementary Information section of the preamble must, at a minimum, explain the NRC's reasons for developing the proposed regulation in sufficient detail to ensure interested persons of the opportunity to provide meaningful comments on the proposed rule. To provide an adequate "on the record" legal basis for the rulemaking (in the event of a court challenge to the proposed rule) your Supplementary Information section should discuss:

- The purpose of the proposed regulation.
- The need for the proposed regulation.
- The laws or directives that authorize the proposed regulation.
- The relationship of the proposed regulation to existing regulations.
- The history of the rulemaking proceeding to this point.
- The alternatives considered in developing the proposed regulation.
- The estimated economic impact of the alternatives considered on those likely to be affected by the proposed regulation or the need for their cooperation in developing this analysis.
- The issues to be commented on in the proposed regulation.
- Any noncompliance or penalty provisions.

While the treatment of these topics may be organized as appropriate and tailored to the unique circumstances of each rulemaking, the following issues, like the Procedural Requirements discussed in Chapter Four, are addressed in sections that appear (when applicable) in every rulemaking preamble:

- A section-by-section analysis of the substantive requirements of the proposed regulation on a provision-by-provision basis.
- Whether the proposed rule will use a voluntary consensus standard or a Government-unique standard.
- The views, concerns, and comments raised by Agreement States during the development of the proposed rule.
- The response to public comment from an advance notice of proposed rulemaking or any other preliminary document that solicited public participation.

Use descriptive center headings to divide and describe material in the Supplementary Information section. Center headings help break up long stretches of text and help the reader find particular items of interest. You should collect these preamble headings into a table of contents. This table of contents presents the user with a quick overview of the preamble information, and should be provided for all but the briefest rules.

Example

SUPPLEMENTARY INFORMATION:

Section-by-Section Analysis

The Supplementary Information section for both proposed and final rules must contain a section-by-section analysis. In this analysis the drafter reviews each substantive provision of the regulatory text, providing a brief description of the change that is proposed, or in the case of a final rule, is effected by the regulation. For new regulatory requirements you should give a concise description of what the provision does; for amendments this analysis should focus on how the provision changes the current regulatory text.

The purpose of the section-by-section analysis is to assist the user in determining exactly what section(s) are being affected by the rulemaking action, and the nature of the change being proposed or implemented. Generally, this analysis should not explain the reasons (basis) why the NRC is adopting the provision or

change in question; that rationale is covered in the discussion portions of the Supplementary Information for the rulemaking.

The section-by-section analysis for a proposed rule can serve as a basis for the analysis for the final rule, but the final rule analysis should also describe any substantive differences between the proposed rule and the final rule.

The examples demonstrate various types of changes to rulemaking language and how these changes are handled in the section-by-section analysis.

Example

Section-by-Section Analysis of Substantive Changes

Section 2.107--Withdrawal of Application

This section describes how the Commission will process a withdrawal of an application by an applicant. The second sentence was changed to correctly state that if an application is withdrawn before the NRC issues a notice of hearing, the Commission dismisses the proceeding. The last sentence of this section was rewritten to make clear that the presiding officer determines the terms and conditions for withdrawal of an application after the NRC issues a notice of hearing.

Section 2.108--Denial of Application for Failure To Supply Information

Conforming changes were made to this section to reflect the new section numbers in part 2.

Section 2.339--Expedited Decisionmaking Procedure

This section, formerly designated §2.763, has not been substantively changed.

Section 2.340--Initial Decision in Contested Proceedings on Applications for Facility Operating Licenses

This section consolidates provisions on the effectiveness of initial decisions which were formerly in §§2.760a and 2.764. No substantive changes were made to the provisions, but conforming changes were made to reference the applicable provisions of new Subpart C that were formerly in Subpart G.

Section 2.390--Public Inspections, Exemptions, Requests for Withholding

This section, formerly designated §2.790, sets forth provisions of generic applicability concerning the public's access to information which apply irrespectively of whether there is an NRC proceeding. Following the publication of the proposed amendments to Part 2, the Commission adopted a final rule amending §2.790 to revise the procedures regarding the submission and agency handling and disclosure of proprietary, confidential, and copyrighted information (68 FR 18836; Apr. 17, 2003). Section 2.390 now incorporates these amendments. The final rule also reflects the addition of a footnote to paragraph (a), which provides that "final NRC records and documents'' do not include handwritten notes, nor do they include any drafts. Drafts which are protected from disclosure include

documents prepared by NRC personnel, as well as documents prepared by contractors retained by the NRC.

Section 2.1206--Informal Hearings

Section 2.1206 specifies that informal hearings under the new Subpart L will be oral hearings unless all the parties agree to a hearing consisting of written submissions (this is a significant change from the existing Subpart L which generally involves hearings consisting of written submissions). No motion to hold a hearing consisting of written submissions may be entertained absent unanimous consent of the parties.

Document Availability

It is NRC's policy to make all publicly available documents mentioned in *Federal Register* notices accessible to the public in the Publicly Available Records System (PARS) Library, which is the public subset of documents in the Agency-wide Documents Access and Management System (ADAMS) Main Library. The complete procedures for ensuring public availability in ADAMS of documents mentioned in *Federal Register* notices can be found on the *NRC Rulemaker* web site.

You must include a statement in the Supplementary Information section of the preamble to proposed rules that indicates how an interested person may obtain a copy of any document concerning the proposed rule that is being made available to the public, including any referenced material.

Example

Availability of Documents

The NRC is making the documents identified below available to interested persons through one or more of the following methods as indicated.

Public Document Room (PDR). The NRC Public Document Room is located at 11555 Rockville Pike, Rockville, Maryland.

Rulemaking Website (Web). The NRC's interactive rulemaking website is located at http://ruleforum.llnl.gov. These documents may be viewed and downloaded electronically via this Website.

NRC's Agency-wide Documents Access and Management System (ADAMS). The NRC's PARS Library is located at http://www.nrc.gov/reading-rm/adams.html.

The NRC staff contact <Provide the name, address, and telephone number of the NRC staff contact.>

Document	PDR	RuleForum	ADAMS	NRC Staff
Comments received	X	X	X	
Regulatory Analysis	X	X	ML00024600	X
Environmental Assessment	X	X	ML00012300	X
Backfit Analysis	X	X		X
Draft NUREG-XXXX	X	X		
NUREG-XXXX	X	X		
RG-XXX	X	X		X
Draft Regulatory Guide	X			X

A free single copy of draft NUREG-[XXXX] may be obtained by writing to the Office of Information Services, Reproduction and Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or E-mail: DISTRIBUTION@nrc.gov, or Facsimile: (301) 415-2289.

Copies of NUREGS may be purchased from The Superintendent of Documents, U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-0001; Internet: bookstore.gpo.gov; (202) 512-1800. Copies are also available from the National Technical Information Service, Springfield, VA 22161-0002; www.ntis.gov; 1-800-533-6847 or, locally, (703) 605-6000. Some publications in the NUREG series are included in the document collections in the Electronic Reading Room on NRC's Website at http://www.nrc.gov/reading-rm.html.

Plain Language

On June 1, 1998 (63 FR 31883), a Presidential memorandum entitled "Plain Language in Government Writing" was published in the *Federal Register*. This action directed that the Government's documents, including rulemaking actions, be written in clear and accessible language. The NRC's Plain Language Action Plan website, http://www.internal.nrc.gov/NRC/PLAIN/index.html, provides guidance, examples, and links to external websites that are designed to help the NRC staff comply with the plain language initiative in preparing regulatory and other documents. Include a statement concerning compliance with the plain language initiative in the Supplementary Information section of the preamble to the proposed rule.

If existing regulatory text has been reorganized or rewritten to improve the organization and readability of the material, include the following statement.

Plain Language

The Presidential memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883) directed that the Government's documents be written in clear and accessible language. To comply with this directive, the NRC has made editorial changes to improve the organization and readability of the existing language of the paragraphs being revised. These types of changes are not discussed further in this document. The NRC requests comments on the proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the NRC as explained in the ADDRESSES caption of this notice.

If existing regulatory text has not been reorganized or rewritten to improve the organization and readability of the material, include the following statement.

Plain Language

The Presidential memorandum "Plain Language in Government Writing" published June 10, 1998 (63 FR 31883) directed that the Government's documents be in clear and accessible language. The NRC requests comments on the proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the NRC as explained in the ADDRESSES caption of this notice.

Comment Analysis

Every time the NRC publishes a rulemaking document for comment, the comments received are discussed in the Supplementary Information section of the preamble to the rule. Comments presenting substantive changes or suggestions are discussed in detail.

A substantive comment is any comment that is a serious attempt to address an issue that was raised in the document for comment. Nonsubstantive, editorial, corrective comments, as well as those that request clarification or present exhortations, may simply be acknowledged.

In presenting the analysis of public comments you must:

- Indicate any substantive change made in the rulemaking document as a result of public comment and the reasons for accepting the suggestion.
- Indicate any new material or information relevant to the rulemaking received as a result of public comment.
- Discuss any substantive comments that were not accepted and the reasons for rejecting them.

If substantive changes are made in a final rule as a result of public comment on a proposed rule, your comment analysis must go beyond addressing the public comment in a general manner. The comment analysis must reaffirm the factual and policy predicates on which the final rule is based, explain any connection with or changes from the proposed rule, and present a reasoned argument in support of the final version of the rule. This action is necessary if a court is to determine that a change in the final rule is a "logical outgrowth" of the rulemaking proceeding. If the anticipated changes do not meet the "logical outgrowth" standard, the rule may have to be reissued in proposed form to provide the public with an opportunity to comment on the changes. The "logical outgrowth" standard emphasizes:

- The NRC's explanation for selecting the final version of the rule from the alternatives considered.
- The breadth of alternatives first mentioned in the proposed rule.
- The magnitude of the changes.
- The factual reasons for the change.

Generally, the most effective method of presenting comment analysis in the Supplementary Information section of the preamble is to present an issue-by-issue discussion. Substantive comments are presented by summarizing the issue addressed and the commenter's reasoning and then stating the NRC's response and its reasons for accepting or rejecting the comment. Each individual comment need not be addressed separately. If several comments raise the same substantive issue, they may be treated in the aggregate and addressed in the comment analysis.

Specific commenters need not be identified, although it may be helpful to characterize the commenter by affiliation or organization (i.e., licensee, vendor, environmental concern, or private citizen).

Fairness is essential in responding to public comments. This is true both in characterizing the comment and in explaining why the comment was accepted or rejected. Comment analysis is not a vote count. Logic and reasoning are more important than numbers.

Comments of a minor or clarifying nature may be acknowledged and should be discussed in the aggregate in the comment analysis.

The comment discussion should indicate any new information or suggested alternatives presented by public comments and indicate any substantive changes made in the proposed rule as a result of these comments. In addition, this discussion should indicate the substantive comments received that were not adopted and NRC's reasons for rejecting those comments.

ANPRM Comment Analysis

When the NRC publishes an Advance Notice of Proposed Rulemaking (ANPRM) or uses an enhanced public participation process to seek comment on draft rule text, the comments received are discussed in the Supplementary Information section of the preamble to the proposed rule. If your rulemaking provides for enhanced public participation but is also on an expedited schedule, consolidate comments on draft rule text with those received on the proposed rule and discuss all public comments in the preamble to the final rule.

Agreement State Comments

Each proposed rule that affects the Agreement States because of compatibility concerns must contain a discussion of the opportunities afforded to the Agreement States for their early and substantive participation in the rulemaking process. Your discussion must present the views, concerns, and comments that have been raised by the Agreement States during the development of the proposed rule. This discussion should contain sufficient detail to provide the Agreement States with an additional opportunity to review NRC's rationale in response to their comments. The discussion should be presented as a readily identifiable portion of the general discussion in the Supplementary Information section of the preamble to the proposed rule.

For listings of NRC regulations that have compatibility designations and a full explanation of Agreement State compatibility, see 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," and Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs."

Indian Tribe Comments

Comments received from Indian Tribes, like those from Agreement States, are presented as a readily identifiable portion of the general comment discussion in the Supplementary Information section of the preamble.

Comment Presentation

The NRC may prepare an analysis of the public comments received as an appendix to the Commission paper on a significant or controversial final rule. This analysis consists of a detailed examination of the comments received and the NRC's intended response to them. If a separate comment analysis has been prepared, you may summarize the analysis in the comment response section of the Supplementary Information portion of the preamble. In this discussion, you should indicate that a detailed analysis has been prepared and is available for public inspection on RuleForum and in ADAMS.

Example

Comments on the Proposed Rule

The Commission received 26 letters commenting on the proposed rule. Copies of those letters and an analysis of the comments are available for public inspection on the NRC's rulemaking website located at http://ruleforum.llnl.gov and in the NRC's Agency-wide Documents Access and Management System (ADAMS).

A number of commenters stated that the proposed rule would extend the NRC activities beyond the regulatory area of radiological working conditions that is applicable to all licensees. The commenters interpreted the rulemaking preamble as a Commission attempt to become involved in antitrust, safety, and security matters of all licensees. This was not the Commission's intent. Matters pertaining to radiological working conditions and radiological safety of all licensees are of concern to the Commission. However, antitrust and security matters are relevant only to certain types of licensees. For example, antitrust information is considered by the Commission only with respect to certain production and utilization facilities (primarily nuclear reactors). This rule is not intended to extend the Commission's involvement with antitrust or security matters to licensees with whom these matters are not presently considered. As noted earlier, the final rule involves the Commission in radiological safety aspects of all licensees (and their contractors and subcontractors) that are beyond the area of radiological working conditions. This involvement is appropriate since an individual fabricating a component that is destined for use in connection with a regulated facility or activity may be fabricating this component in a nonradiological work area, but that individual may possess information that indicates that the component, when installed at the regulated facility or activity, may contribute to a degradation of public health or safety. At times, this information has not been readily available from those responsible for component fabrication, for example, licensees and their subcontractors. The Commission, to fulfill its mandate effectively, requires complete, factual, and current information concerning the regulated activities of its licensees. Employees are an important source of information and should be encouraged to come forth with any potential safety-related items without fear of retribution from their employers. The purpose of the final rule is to ensure that employees are aware that employment discrimination for engaging in a protected activity, for example, contacting the Commission, is illegal and that a remedy exists through the Department of Labor (DOL). The organizations subject to the rule should understand that the Commission will not permit any interference with communications between the Commission's representatives and employees. In addition to redress being available to the individual employee, the Commission may, upon learning of an adverse finding against an employer by the DOL, take enforcement action against the employer because the employer is engaged in illegal discrimination.

On the basis of the comments received, the following substantive changes have been incorporated into the final rule.

(1) The definition of discrimination has been revised to more closely track the statutory language (see §30.7(a)).

(2) The statute expressly provides that an employee is not protected from actions taken by the employer when the employer's action is in response to the employee's deliberate action to violate the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This concept was not included in the proposed rule but has been incorporated in the final rule for completeness (see §30.7(a)).

(3) The statement of available NRC enforcement actions that are derived from the Atomic Energy Act, as amended (see §30.7(c)), has been revised to more clearly state the policy of enforcement in the event of unlawful discrimination.

(4) A new §30.7(d) has been added to clarify the fact that all actions taken by an employer that adversely affect an employee are not prohibited by the new regulation.

On the basis of NRC staff comments, the parts of Title 10 that are included in the scope of the rulemaking have been revised to delete Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions," to add Part 60, "Disposal of High Level Radioactive Wastes in Geologic Repositories," and to add Part 72, "Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI)." Part 71 was removed from the scope of the rulemaking since all general licensees under Part 71 are also specific licensees under another part, for example Part 50, and are, therefore, included in this rulemaking. Parts 60 and 70 have been included in the rulemaking as conforming amendments so that all specific licensees will have similar responsibilities under the Employee Protection amendments.

A number of comments from licensees and their consultants stated that the proposed rule would allow individuals to harass the employer with accusations that are false, frivolous, or unwarranted. To prevent this occurrence, it was recommended that either civil penalties be imposed on any individual who knowingly supplies false information or that compensation be provided to an employer to defray the cost of defending against the allegations. The Commission has rejected these comments since the statutory authority of the Commission under Section 210 neither provides for penalties against individuals nor for any reimbursement to an employer. On the basis of a review of the accusations to DOL, it appears that, when an accusation appears to be unwarranted, DOL accomplishes termination of the proceedings at an early stage.

APA Exemptions

The Administrative Procedure Act (APA) generally requires that an agency publish a notice of proposed rulemaking to announce the proceeding to the public and allow an opportunity to comment on the contemplated action before the agency issues the rule in final form (5 U.S.C 553(b)). The APA also generally requires that a final rule not become effective until at least 30 days after the final rule is published in the *Federal Register* (5 U.S.C. 553(d)). An agency may waive either or both of these requirements for a rulemaking action that meets the exceptions to the requirements specified in the APA.

If you have not published a notice of proposed rulemaking, indicate the APA exemption under which it waives notice and comment procedures. Publication of a proposed rule is unnecessary if:

- The rule is an interpretive rule that is not of itself substantive or binding;
- The rule is a general statement of policy that does not establish a binding norm imposing substantive rights or obligations;
- The rule is a rule of agency organization, procedure, or practice; or
- The NRC can show good cause that notice and comment are impracticable, unnecessary, or contrary to the public interest.

You must allow a 30-day post-promulgation comment period for:

- A final rule for which the notice and comment requirements are waived under the good cause exception if the basis of the waiver is that the notice and comment procedure is impractical or contrary to the public interest.
- An interpretative rule or general statement of policy adopted without notice and comment unless the NRC determines that notice and comment procedures serve no useful purpose or would be so burdensome that any foreseeable gain would be outweighed.

If you determine that a proposed rule is not required, insert a statement indicating that decision and the APA exemption under which the NRC waives notice and comment in the Supplementary Information section of the preamble to the final rule.

Example

Because these amendments deal solely with agency practice and procedure, the notice and comment provisions of the Administrative Act Procedure do not apply under 5 U.S.C. 553(b)(A).

If you determine that a final rule should become effective when it is published in the *Federal Register*, indicate the APA exception under which it waives the deferred effective date requirement. The NRC may waive the deferred effective date requirement:

- For a substantive rule granting or recognizing an exception or relieving a restriction;
- For an interpretative rule;
- For a statement of policy;
- When the NRC can show good cause for making the rule effective immediately.

If you determine that the deferred effective date requirement may be waived for a final rule, insert a statement indicating that decision and the APA exception under which the NRC waives the deferred effective date requirement in the Supplementary Information section of the preamble to the final rule.

Example

The NRC finds that good cause exists to waive the 30-day deferred effective date provisions of the Administrative Procedure Act (5 U.S.C. 553(d)). Delaying the effective date of this rule would be contrary to the public interest because physicians would not be able to provide the added diagnostic services for patient care described in this rule immediately. Therefore, the rule is effective upon publication in the Federal Register.

If the NRC determines that both the notice and comment procedure and the deferred effective date requirement may be waived for a final rule, the NRC may combine the statements indicating these waivers and the provisions of the APA under which the NRC waives the notice and comment procedure and the deferred effective date requirement in a single statement inserted in the Supplementary Information section of the preamble to the final rule.

Example

Because these are amendments dealing with agency practice and procedure, the notice and comment provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553 (b)(A). The amendments are effective upon publication in the Federal Register. Good cause exists to dispense with the usual 30-day delay in the effective date because the amendments are of a minor and administrative nature dealing with a matter of agency conduct, a change in the price of making copies of documents in the PDR.

Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires executive agencies to assess the impact of proposed agency actions on family well-being. For each rule that may affect family well-being, the agency is required to conduct a seven-factor assessment that is contained in the statute. The act also requires the head of each agency to certify to the OMB and to Congress that an assessment has been conducted for those policies and regulations having a potential effect on family well-being. The certification

also must provide an adequate rationale for implementing those policies and regulations that may negatively affect family well-being.

The act does not impose any restrictions on the effective date of any rule or policy. For any final rule that may have a negative effect on family well-being insert the following statement in the Supplementary Information section of your preamble, directly above the Voluntary Consensus Standards heading:

Example

Assessment of Federal Regulations and Policies on Families

In accordance with Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277), the NRC has assessed this action against the seven factors set forth in that act. The NRC has determined that this action may negatively affect family well-being. <Include rationale for implementing the regulation in spite of the potential impact on family well-being.>

Use the following statement for any final rule that may affect family well-being but won't have a negative impact.

Example

Assessment of Federal Regulations and Policies on Families

In accordance with Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277), the NRC has assessed this action against the seven factors set forth in that act. The NRC has determined that this action will not negatively affect family well-being.

A statement is not required in the final rule if the NRC determines that the action does not have an effect on family well-being.

A simple process for assuring compliance with the requirements of the act can be found on the *NRC Rulemaker* web site. Questions concerning this act may be directed to OGC.

Placement of Procedural Reviews in the Preamble

It is at this point in the supplementary information, after the background discussion of rule changes, disposition of public comments, and the section-by-section analysis, that the rule writer should include statements for each of the required statutory reviews or analyses needed for both proposed and final rules. These procedural requirements are discussed at length in Chapter Four, but the general order of the statements is as follows:

1. National Technology Transfer Advancement Act
2. National Environmental Policy Act and 10 CFR Part 51
3. Paperwork Reduction Act

4. Unfunded Mandates Act (when applicable)
5. Regulatory Analysis
6. Regulatory Flexibility Act
7. Backfit Analysis
8. Congressional Review Act (Final Rules Only)

Federal Register's Subject Index Terms

The OFR requires each agency to include a list of subject index terms for each part affected in a proposed or final rule document (1 CFR 18.20). The list of terms is intended to identify the major topics of the rule and the categories of persons affected by it in a standard fashion. These terms are contained in the *Federal Register Thesaurus of Indexing Terms*. The terms provide a common vocabulary for indexing the rulemaking documents of all agencies and form the basis for the CFR Index.

Place the list of subject index terms for each CFR part affected as the last item in the Supplementary Information section of the preamble for each proposed or final rule document submitted for publication in the *Federal Register*. Present the list of subject index terms in alphabetical order.

Example (a document citing a single CFR part)

List of Subjects in 10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

Example (a document citing two or more CFR parts)

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalties, Government contracts, Hazardous materials transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 70

Criminal penalties, Hazardous materials transportation, Nuclear control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

Use the list of subject index terms developed by RDB and approved by the OFR in your list of subject index terms provided for each part. A list of the approved subject index terms for each part in 10 CFR Chapter I can be found on the *NRC Rulemaker* web site. If an originating office wishes to use additional terms, it should consult with RDB.

A list of subject index terms is not required for a final rule that:

- Does not contain regulatory text;
- Only presents nomenclature changes; or
- Corrects a previous document.

Words of Issuance

The words of issuance describe the general effect of the document and present the general rulemaking authority of the agency. The words of issuance directly precede the heading of the first CFR part the document amends or adds (or proposes to amend or add). Use the following words of issuance,s with a listing of each 10 CFR part affected, in each rulemaking:

Example

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 <for final rules add: *and 553* >, the NRC is <*proposing to adopt* or *adopting*> the following amendments to 10 CFR Parts 30, 50, and 73.

Amendatory Language

A final rule document makes changes or additions to the CFR, a proposed rule suggests changes or additions. The regulatory text of a rulemaking document published by the NRC must fit into the existing text of 10 CFR Chapter I. Amendatory language uses standard terms to give instructions to the OFR on how to change the CFR.

Amendatory language must be exact. The amendatory language for each change must:

- Identify the specific CFR unit being amended by its complete numerical and alphabetical designation;
- Use one of the standard terms to describe how the CFR unit is being changed;
- Address all the regulatory text set out in the document.

The OFR requires that the following terms be used in amendatory language to describe how the CFR unit is being changed. Each term is a precise instruction that alters a CFR unit in a prescribed manner. Misuse of these terms, or use of an inappropriate term, could cause unintended or incorrect changes in the CFR that will require the preparation and publication of a correction. Consult RDB for guidance on correct use of these terms.

Added

"Added" means that a unit of new material, such as a paragraph, section, part, or chapter, is inserted in the CFR.

Example

Part 53 is added to read as follows: <An entire new CFR part is added>.

Example

Section 50.47 is added to read as follows: <An entire new CFR section is added to a CFR part>.

Example

In §50.54, paragraph (f) is added to read as follows: <A paragraph is added to a CFR section>.

In limited situations, a word or number may be added to a CFR unit without setting out the text of the unit. The number of the section containing the change must be set out, followed by the word "Amended" in square brackets. The amendment is then presented in the form of an instruction. RDB generally determines when an amendment may be presented in this fashion.

Example

§19.3 [Amended]

In §19.3, add ", 61," between "60" and "70."

Amended

"Amended" means that an existing CFR unit is changed. Because "amended" is a general term compared to other terms used to describe a type of change, it is used with other amendatory terms that describe the specific nature of the change.

Example

Part 73 is amended by revising §§73.17 and 73.50 to read as follows:

Example

10 CFR Chapter I is amended by revising Part 100 to read as follows:

Example

Section 73.97 is amended by removing paragraph (e).

Corrected

"Corrected" means that a clerical or typographical error in a published document is fixed. An error in regulatory text must be corrected before the effective date of the final rule. Once the final rule becomes effective, a formal amendment in the form of a technical amendment is necessary to make the change. A correction is not an amendment and may not be used to write in "second thoughts." Any "fine tuning" of a published regulation must be in the form of a formal clarifying amendment.

Example

In the issue of March 15, 2001 (66 FR 12345), 10 CFR 39.10 is corrected by changing the reference in the second line from "§44.10" to "§44.20."

Example

In the issue of May 3, 2001 (66 FR 98765), the delegation of authority is corrected in the first paragraph of the second column by changing "Director" to read "Administrator."

Redesignated

"Redesignated" means that an existing CFR unit is transferred to a vacant position and renumbered. If the newly redesignated CFR unit is also revised, this change is specifically stated in the amendatory instruction.

Example

In §30.15, paragraphs (e) and (f) are redesignated as paragraphs (d) and (e).

Example

Part 33 is redesignated as Part 75.

Example

Section 73.11 is transferred to Part 100 and redesignated as §100.71.

Example

In §54.12, paragraph (d) is redesignated as paragraph (e) and revised to read as follows:

Removed

"Removed" means that an existing CFR unit is being taken out of the CFR. Although a number of different terms, including "revoked," "rescinded," and "deleted," have been used to indicate subtle legal differences for removing material, the OFR recognizes "removed" as the appropriate term for use in amending the CFR.

Example

Part 110 is amended by removing §110.70.

Example

In §20.25, paragraphs (d)(2) and (f) are removed.

Republished

"Republished" means that an unchanged unit of CFR text is set out for the convenience of the reader to provide the context for an amendment. This term is mostly used with the introductory text of a section or paragraph. Because all regulatory text that is published or republished in a rule document is used to update the CFR, you must be precise when presenting any republished text.

Example

§2.1, the introductory text of paragraph (a) is republished and paragraphs (a)(1) and (3) are revised to read as follows:

Revised

"Revised" means that an existing CFR unit is changed and the new text of the unit is set out in its entirety. This is the most common method of amending the CFR. "Revised" is the term used whenever the new text of a unit is completely set out, whether the unit has been completely rewritten or only partially changed.

Example

In §20.25, paragraph (f) is revised to read as follows:

Example

Section 9.9 is revised to read as follows:

Example

Part 19 is revised to read as follows:

Nomenclature change

"Nomenclature change" means that a term or phrase is changed throughout a CFR unit. It is mostly used to change an office designation or the title of an agency official. The OFR may require that a set of marked CFR pages accompany a nomenclature change. The marked pages indicate exactly where in CFR text the desired changes occur and how they are to appear. RDB determines, in consultation with the OFR, when marked pages must accompany a nomenclature change.

Example

In 10 CFR Chapter I, all references to the "Atomic Energy Commission" are changed to read "Nuclear Regulatory Commission" and all references to "AEC" are changed to read "NRC."

Suspended

"Suspended" means that the effectiveness of a CFR unit is stayed temporarily or indefinitely. "Suspended" is not a true amendatory term because it does not actually change the content of the CFR; it simply reflects the changed status of a particular CFR unit. During the suspension, the CFR unit is not in effect or enforceable. You should avoid an open-ended suspension whenever possible by stating the duration of the suspension in the document announcing the action. The suspended provision continues to appear in the CFR; however, the OFR will insert an editorial note explaining the status of the provision. The NRC is responsible for issuing the follow-up document necessary to remove the suspended provision or to lift the suspension.

Example

In §2.712, the provisions of paragraph (f) are suspended until further action by the Commission.

Example

Section 123.77 is suspended from July 1, 1995, to October 1, 1996.

Withdrawn

"Withdrawn" has a different connotation in a final rule document than in a proposed rule document. In a final rule, "withdrawn" is used to indicate that a final rule with a pending effective date will not go into effect. In a proposed rule, "withdrawn" is used to indicate that a previously published proposed rule will not be issued as a final regulation.

Multiple Amendments

If an amendment makes several changes within a section, the amendatory language must clearly identify each change. All changes to the section must be described in one amendatory instruction. If several different types of amendments are being made within the section, the different types of amendments must be listed within a single instruction.

Example

Amend §73.3 as follows:

a. Revise paragraphs (d) and (f);

b. Redesignate paragraphs (h) and (i) as paragraphs (j) and (k);

c. Add new paragraphs (h) and (i).

Example

10 CFR 50.20 is amended by revising paragraphs (a)(5)(iii), (c), (c)(3)(iv), and (d) to read as follows:

If a document amends several nonconsecutive CFR sections within a part, the changes to each section must be described in a separate amendatory instruction.

The complete part heading, including its numerical designation and title, must precede the list of amendatory instructions changing sections within the part.

The authority citation for the part must appear directly after the part heading.

The following example shows a series of amendments within a part and the proper placement and sequence of the required elements.

Example

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 33.

PART 33 - SPECIFIC DOMESTIC LICENSES OF

BROAD SCOPE FOR BYPRODUCT MATERIAL

1. The authority citation for Part 33 continues to read as follows:

AUTHORITY: 42 U.S.C. 2111, 2201, 2232, 2233, 5841.

2. Section 33.13 is revised to read as follows:

§33.13 Applications for specific licenses of broad scope.

Applications for specific licenses of broad scope should be filed on Form NRC 313, “Application for Byproduct Material License,” in accordance with the provisions of §30.32 of this chapter.

3. Paragraph (c) is added to §33.15 to read as follows:

§33.15 Requirements for the issuance of a Type C specific license of broad scope.

* * * * *

(c) The applicant has established administrative controls and provisions relating to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review necessary to ensure safe operations.

Authority Citations

Each rule document must contain a citation of the legal authority under which the NRC is amending the CFR. Each change (or proposed change) to the regulations presented in the document must be authorized by the citation of authority contained in the document.

The NRC is responsible for maintaining accurate and current citations of authority in 10 CFR Chapter I. The authority citation for a part must be verified and, if necessary, revised each time the part is amended. The document must present the complete authority citation for each part it amends.

A change to an authority citation is made by formally amending the citation. An amendment to an authority citation must be made in the same form as an amendment to regulatory text. Each change in an authority citation must be presented as a revision of the authority citation for the part.

Example

1. The authority citation for Part 35 is revised to read as follows:

AUTHORITY: 42 U.S.C. 2111, 2201, 2232, 2233, 5841.

RDB maintains a complete list of the currently effective authority citations for each part in 10 CFR Chapter 1 on the Drafting page of the NRC Rulemaker web site. OGC is responsible for determining whether a change to the currently effective authority citation is required by the amendment.

When amending an entire CFR part, the authority citation must be placed directly after the table of contents and before the regulatory text.

Example

PART 19 - NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTION AND INVESTIGATIONS

Sec.

19.1 Purpose.

19.2 Scope.

19.3 Definitions.

19.4 Interpretations.

19.5 Communications.

19.11 Posting of notices to workers.

19.13 Notifications and reports to individuals.

19.14 Presence of representatives of licensees and workers during inspections.

19.15 Consultation with workers during inspections.

19.16 Requests by workers for inspections.

19.17 Inspections not warranted; informal review.

19.30 Violations.

19.31 Application for exemptions.

19.32 Discrimination prohibited.

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Even if a document amends only certain sections within a CFR part, a complete citation of authority must be presented. If the authority for issuing an amendment is the same as the authority listed for the whole CFR part, simply restate the entire authority. The restated authority citation is placed before the first item in the list of amendments to the part.

Example

PART 160 - TRESPASSING ON COMMISSION PROPERTY

1. The authority citation for Part 160 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended, sec. 229, 70 Stat. 1069 (42 U.S.C. 2201, 2278a); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. Section 160.3 is revised to read as follows:

§160.3 Trespass.

Unauthorized entry upon any facility, installation, or real property subject to this part is prohibited.

If the authority for issuing an amendment is not included in or changes the authority citation for the whole CFR part, the authority citation for this part must be revised to reflect the new or changed authority. The authority citation is revised in its entirety and placed as the first item in the list of amendments to the part.

Example

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

1. The authority citation for Part 71 is revised to read as follows:

AUTHORITY: Secs. 53, 57, 62, 63, 81, 161, 182, 183, 68 Stat. 930, 932, 933, 935, 948, 953, 954, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201,2232, 2233, 2297f); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 71.97 also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789-790.

2. Section 71.2 is revised to read as follows:

§71.2 Scope.

The regulations in this part apply to each person authorized by specific license issued by the Commission to receive, possess, use, or transfer licensed materials if he or she delivers licensed materials to a carrier for transport or transports licensed material outside the confines of his or her plant or other place of use.

If a section is issued under a specific authority that differs from the overall authority for the part, a specific authority citation may be presented for the section. Authority citations for specific sections are presented in a separate paragraph within the part authority citation.

Example

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

1. The authority citation for Part 40 is revised to read as follows:

AUTHORITY: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95-604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97-415, 96 Stat. 2067 (42 U.S.C. 2022); sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

Section 40.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152).

Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234).

Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

Regulatory Text: CFR Codification

Amending the CFR

The regulatory text of a proposed rule document, will, if adopted as a final rule, be codified in the CFR. NRC regulations are codified in 10 CFR Chapter I. The regulatory text of each NRC rulemaking document must be presented as an amendment to 10 CFR Chapter I. Your regulatory text must:

- Be drafted exactly as it is to appear in the CFR;
- Conform to the structure and terminology of the CFR.

CFR Structure

The basic structure of the CFR consists of a hierarchy of designated CFR units. The major components of this structure are illustrated in the following table.

CFR Unit	CFR Designation	Description
Title	10	Broad area subject to Federal regulation
Chapter	I	Regulations of a single issuing agency
Part	10	Unified body of regulations concerning a single function or specific subject
Section	10.1	Short presentation of one regulatory proposition

A chapter or part may be subdivided into subchapters and subparts. These subordinate units are useful in providing additional organizational levels. Subchapters and subparts are designated alphabetically.

The section is the basic CFR unit. Most amendments are expressed in terms of how they affect a section or a group of sections. The content of a section is limited to a short, simple presentation of a single regulatory proposition. Each section number includes the number of the part, followed by a period and a sequential number. For example, the first section in Part 25 is expressed as "§25.1." Sections in a new or revised part need not be numbered consecutively. If you use all odd or even sequential numbers in designating sections within a new or revised part, you leave future rule writers room for expansion.

If internal division of a section is necessary, the section may be divided into paragraphs. Each paragraph within a section must be designated for reference and future amendment. The paragraph structure within a section is as follows:

Term	Symbol
Paragraph	(a), (b), (c), . . .
For further subdividing of a paragraph	(1), (2), (3) , . . . (i), (ii), (iii) , . . . (A), (B), (C) , . . .
Note: Numbers and letters at the fifth and sixth level are italicized. To prevent confusion, staff should avoid these levels of designation.	(*1*), (*2*), (*3*) , . . . (*i*), (*ii*), (*iii*) , . . .

Stated another way, the CFR structure permits the internal division of a paragraph to six levels of designation.

Paragraph symbol	(a)	(1)	(i)	(A)	(*1*)	(*i*)
Level of Designation	1	2	3	4	5	6

The level of designation is the number of paragraph symbols necessary to identify a subdivision within a section. For CFR purposes, each subdivision within a paragraph also is considered a paragraph. The term "subparagraph" may not be used when referencing a subdivided paragraph within the regulatory text of a *Federal Register* document.

Example

Three symbols are necessary to identify paragraph (a)(1)(i) of §1.1.

When a paragraph is subdivided, the alphanumeric designators should highlight the organization of the paragraph. In the same manner as an outline, ideas of equal weight should reflect the same level of designation. Supporting or secondary concepts should be designated at levels subordinate to the central concepts.

Example

§30.63 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of –

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of —

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

You can avoid overly detailed subdivision within a section by dividing a long, complex section into a series of smaller, more compact sections. Divisions below the third level of designation generally indicate that too much material is included within the section. As a result, the user will have more difficulty locating the important material that is buried within a section. The user finds information within a regulation primarily through the section heading. If sections are too long, there are fewer headings, and those headings cannot adequately reflect the material contained in the section.

The OFR no longer permits the use of an undesignated concluding paragraph.

Example [This type of construction is forbidden]

Each boiling- or pressurized-light-water nuclear power reactor fuel with oxide pellets within cylindrical Zircaloy or ZIRLO cladding must, as provided in paragraphs (b) through (d) of this section, include means for control of hydrogen gas that may be generated following a postulated loss-of-coolant accident (LOCA) by –

(1) Metal-cladding reaction involving the fuel cladding and the reactor coolant;

(2) Radiolytic decomposition of the reactor coolant; and

(3) Corrosion of metals.

This section does not apply to a nuclear power reactor facility for which the certifications required under § 50.82 (a)(1) have been submitted.

Paragraph designations are not required in a definitions section. The defined terms are presented in alphabetical order. If a defined term must be subdivided, begin with the second level of designation within the term.

Example

Common defense and security means the common defense and security of the United States.

Nuclear reactor means an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission in a self-supporting chain reaction.

Produce, when used in relation to special nuclear material, means —

(1) To manufacture, make, or refine special nuclear material;

(2) To separate special nuclear material from other substances in which special nuclear material may be contained; or

(3) To make new special nuclear material.

The OFR no longer permits the use of hyphenated numbers (§117-2.1 or §11-7.201) or numbers with alpha characters (Part 115a, §115a.1, or §115.1a) in designating units within the CFR system.

You may, if necessary, continue to use a hyphenated number or alpha character in a CFR part that already contains a unit designated in this fashion.

Any deviation from standard CFR designation must be approved in advance by the Director of the OFR. A request for approval should be made before extensive drafting has begun. The request must include the contemplated structure and indicate the reasons for the requested deviation.

Any questions on the assignment of new section or part numbers should be directed to RDB (415-7163). In addition, the assignment of any new part or section numbers should be made after consultation with RDB to prevent confusion resulting from duplicative or overlapping part or section numbers.

Plan for the Future

You should structure a regulation in a manner that allows future changes to be made easily and permits new material to be added in appropriate locations. The writer may leave room for future growth by skipping every other number in designating parts and sections and leaving a few slots vacant at the end of each subpart or group of related sections. These devices permit greater flexibility in revising or adding to a regulation should changes be necessary after the final rule has been become effective.

Full Text Amendment

Present each amendment in a final rule document as a full text amendment to the CFR. Full text means that the complete text of the designated CFR unit being amended is presented in the document. The CFR unit is any block of text that can be identified by its number or letter designation. The unit of text presented may be as small as a paragraph. Nomenclature changes or amendments to a table are the only exceptions to this rule.

Footnotes

You should avoid the use of footnotes in the text of a regulatory document. Explanatory notes and references should be presented within document text. If a footnote is essential, the manner and form in which it is designated and presented in regulatory text is critical. Incorrectly designated footnotes cause errors when a document is printed in the *Federal Register* and again when regulatory text is codified in the CFR. You must follow these guidelines when presenting footnotes in the text of a regulatory document.

Material in text to which a footnote is keyed must be numbered with Arabic numerals presented in the fashion 1, 2, 3, or in superscript. You may not use asterisks or other symbols to designate footnotes within regulatory text.

Footnotes must be consecutively numbered throughout the part, appendix, or table where they appear in regulatory text.

Documents containing footnotes numbered consecutively by the page are unacceptable for publication in the *Federal Register* because five to six typed pages make up one *Federal Register* page.

If both the preamble and the regulatory text of a document contain footnotes, you must use a separate numbering sequence in each. The preamble is not retained in the CFR.

Footnotes in the CFR are numbered consecutively throughout the part. An amendment to existing text that adds or removes a footnote may affect the numbering of any other footnotes contained in the amended part. It may not be necessary to redesignate existing footnotes to reflect added or removed footnotes. Contact RDB for assistance in designating footnotes in amended text (415-7163).

Footnotes are a part of the CFR unit where the footnote designator appears. An amendment to regulatory text containing a footnote affects the status of the footnote. If the portion of a section containing a footnote designator is amended, the text of the footnote also must be set out in presenting the amendment.

Regulatory Text: Headings

Each CFR unit larger than a paragraph is given a brief heading that describes the content of that unit. Each heading must be brief, accurate, and useful to an individual seeking specific information. A good heading describes the content of a unit in a manner that allows the user to readily identify needed information.

Part Headings

The part heading is a concise statement that describes the content or effect of the regulatory program contained in the part. You should use subject terms in the part heading that are consistent with terms used by other agencies to identify similar material. NRC drafters may consult NRC's list of subject index terms or the *Federal Register Thesaurus of Indexing Terms* to identify subject terms appropriate for use in a part heading.

Section headings

Descriptive section headings function as signposts by helping the user identify particular regulatory provisions that apply to him or her.

Section headings combine with part and subpart headings to provide an overall picture of the regulation. The headings in the following example allow a person to find information necessary to complete an application and prepare a package of radioactive material for shipment. Note particularly that the description of package standards begins with the general requirements applicable to all packages and then provides the particular requirements that specific types of packages must meet.

Example

Part 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

* * * * *

Subpart D - Application for Package Approval

71.31 Contents of application.

71.33 Package description.

71.35 Package evaluation.

71.37 Quality assurance.

71.39 Additional information.

Subpart E - Package Standards

71.41 Demonstration of compliance.

71.43 General standards for all packages.

71.45 Lifting and tie-down standards for all packages.

71.47 External radiation standards for all packages.

71.49 Additional requirements for Type B packages.

71.51 Fissile material categorization and exemptions.

71.53 General requirements for all fissile material packages.

71.55 Specific standards for a Fissile Class I package.

71.57 Specific standards for a Fissile Class II package.

71.59 Specific standards for a Fissile Class III shipment.

* * * * *

Section headings may be constructed to indicate that material in a series of sections is related. The strategic repetition of the key or common term followed by a specific description of unit content is a technique for showing the unified relationship of different requirements in a simple style.

Example

Subpart C - General Licenses

71.12 General license: NRC-approved package.

71.14 General license: DOT specification container.

71.16 General license: IAEA package.

71.18 General license: Type A, Fissile Class II package.

71.20 General license: Restricted, Fissile Class II package.

71.22 General license: Type A package, Fissile Class III shipment.

71.24 General license: Restricted, Fissile Class III shipment.

Paragraph Headings

Headings may be used at the paragraph level to identify significant material within a section. If paragraph headings are used, they are underscored in the document submitted for publication. Paragraph headings are printed in italics in the *Federal Register* and the CFR. Paragraph headings are not listed in a table of contents; they appear only in the text of the regulation.

Example

§2.730 Motions.

(a) Presentation and disposition. All motions must be addressed to the Commission or, when a proceeding is pending before a presiding officer, to the presiding officer. All written motions must be filed with the Secretary and served on all parties to the proceeding.

b) Form and content. Unless made orally on the record during a hearing, or the presiding officer directs otherwise, a motion must be in writing, specifically state the grounds and the relief sought, and be accompanied by any affidavits or other evidence relied on, and, as appropriate, a proposed form or order.

(c) Answers to motions. Within 10 days after service of a written motion, or any other period as the Secretary or the Assistant Secretary specifies....

* * * * *

Form of Amendment: Section Level

Each amendment made at the section level requires three elements. These elements must appear in the following order —

- Proper amendatory language;
- The section heading of the section being changed; and
- The regulatory text of the section being changed.

In addition to these elements, the part heading and the authority citation of each part affected must be set out and the words of issuance for the document must precede the amendments contained in the document.

If the full text of the section being changed is set out, the following format must be used.

Example

Words of issuance	For the reasons set out in the preamble and under authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 35.
Part heading	**PART 35 - HUMAN USES OF BYPRODUCT MATERIAL**
Unchanged authority citation	1. The authority citation for Part 35 continues to read as follows: AUTHORITY: 42 U.S.C. 2111, 2201, 2232, 2233, 5841.
Amendatory language	2. Section 35.2 is revised to read as follows:
Section heading	§35.2 License requirements.
Revised text	A person subject to these regulations may not receive, possess, use, or transfer byproduct material for any human use unless in accordance with a specific or general license issued under the regulations in this part and Parts 30 and 32 or 33 of this chapter.

If the entire section is not being revised, the NRC may set out the full text of only the paragraphs being amended by using asterisks in place of unchanged material. The asterisks in regulatory text indicate the codified material within the section that is not altered by the amendments. The asterisks provide a CFR format in which only the full text of the amended paragraph is presented. This format may be used to present several changes within a section without setting out the complete text of the section.

Five asterisks in a row indicate that one or more paragraphs are not being amended. Space the five asterisks evenly across the page.

Three asterisks in a row represent text within a paragraph that is not being amended. Three asterisks are used with the paragraph designator to indicate levels of designation that are not affected by an amendment to a paragraph below the first level of designation. Separate the indented paragraph designator and the three asterisks with two spaces.

A document may present a series of section-level amendments within one or more CFR parts. If a document makes a series of section-level amendments within one or more parts, the following four elements must be included:

(1) The heading of each part in which an amendment is made must be set out in capital letters.

(2) The complete authority citation for each part in which an amendment is made is placed under the part heading. If the authority citation is revised, the amendatory instruction necessary to indicate the revision is placed as the first item in the list of amendments for the part.

(3) The proper amendatory language is included for each change. Amendatory instructions, including the instruction for a revised authority citation, are numbered consecutively throughout the document.

(4) The section heading and amended text for each changed section follow the amendatory language.

The following example illustrates both the proper method of presenting a series of section-level amendments within a document and the correct use of asterisks to indicate unchanged text.

Example

Words of issuance	For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 20 and 21.
Part heading	PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION
Unchanged authority Citation	1. The authority citation for Part 20 continues to read as follows: AUTHORITY: 42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 5841, 5842, 5846.
Amendatory language	2. In §20.1101, paragraph (b) is revised to read as follows:
Section heading Indicates that paragraph (a) is unchanged	§20.1101 Radiation protection programs. * * * * *
Revised text	(b) The licensee shall use, to the extent practicable, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
Indicates that the rest of the section is unchanged	* * * * *

Amendatory language

3. In §20.1204, paragraph (c)(1) is revised to read as follows:

Section heading

§20.1204 Determination of internal exposure.

Indicates that paragraphs (a) and (b) are unchanged

* * * * *

Indicates that the introductory text of paragraph (c) is unchanged

(c) * * *

Revised text of paragraph (c)(1)

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

Indicates that the rest of the section is unchanged

* * * * *

Amendatory language

4. Section 20.2201 is amended by revising paragraph (b)(1)(iii) and adding paragraph (b)(1)(vi) to read as follows:

Section heading

§20.2201 Reports of theft or loss of licensed material.

Indicates that paragraph (a) is unchanged

* * * * *

Indicates that the introductory text of paragraphs (b)(1) and (b)(1)(i) and (ii) are unchanged. [The paragraph designation and three asterisks are necessary to place this amendment in paragraph (b)(1)]

(b) * * *

(1) * * *

Revised text of paragraph (b)(1)(iii)

(iii) A statement of disposition or probable disposition of the licensed material involved;

Indicates that paragraphs (b)(1)(iv) and (b)(v) are unchanged

* * * * *

Added text of paragraph (b)(1)(vi)

(vi) Procedures or measures that have been or will be adopted to prevent a recurrence of the loss or theft of licensed material.

Indicates that the rest of the section is unchanged

* * * * *

Part heading

PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

Amendatory language

5. The authority citation for Part 21 is revised to read as follows:

Revised authority citation

AUTHORITY: 42 U.S.C. 2201, 2282, 5846

Amendatory language

6. In §21.21, paragraph (c) is revised to read as follows:

Section heading

§21.21 Notification of failure to comply or existence of a defect.

Indicates that paragraphs (a) and (b) are unchanged

* * * * *

Revised text of paragraph (c)

(c) Individuals subject to paragraph (b) of this section may be required by the Commission to supply additional information related to the defect or failure to comply.

No asterisks. Indicates that there is no more text in §21.21

Form of Amendment: Part and Subpart Level

Each amendment made at the part level requires the following elements. The elements must appear in the following order:

- Proper amendatory language;
- The part heading;
- A table of contents for the part;
- The authority citation;
- Regulatory text.

Example

Amendatory language	Part 160 is revised to read as follows:
Part heading	PART 160 TRESPASSING ON COMMISSION PROPERTY
Table of contents	Sec 160.1 Purpose. 160.2 Scope. 160.3 Trespass. 160.4 Unauthorized introduction of weapons or dangerous material. 160.5 Violations. 160.6 Posting. 160.7 Effective date of prohibition on designated locations. 160.8 Effect on other laws.
Authority citation	AUTHORITY: 42 U.S.C. 2278a, 5841.
Regulatory text	§160.1 Purpose. The purpose of this regulation is to protect and secure Nuclear Regulatory Commission property.

(The complete text of any revised part must be set out in its entirety. The remainder of Part 160 is not necessary for the purpose of this example.)

Amendments also may be made at the subpart level. An amendment at the subpart level follows the same format and content requirements as an amendment at the part level.

The table of contents at the part level lists section numbers and headings contained in a part presented in numerical order. A table of contents is required in a document that:

- Adds a new part or subpart;
- Revises an existing part or subpart; or
- Adds or revises two or more sections grouped under a centered heading.

Proper Cross-Referencing Techniques

A "cross-reference" is a reference from one unit of the CFR to another unit. A cross-reference may only be used to reference an existing unit of CFR text. Cross-referencing is not to be confused with incorporation by reference, a legal device that may be used to give material the force and effect of law without printing the material in the *Federal Register*.

The OFR requires that each agency publish the full text of its regulations (1 CFR 21.21(c)). Therefore, the OFR generally prohibits an agency from using a cross-reference to the regulations of another agency as a substitute for publishing the regulations in full text in its regulations. The OFR may permit an agency to cross-reference the regulations of another if the OFR finds that:

- The reference is required by court order, statute, Executive order, or reorganization plan;
- The reference is to regulations promulgated by an agency with the exclusive legal authority to regulate in a subject matter area but the referencing agency needs to apply these regulations to its own programs;
- The reference is informational or improves clarity and does not impose a requirement;
- The reference is to test methods or consensus standards produced by a Federal agency that have replaced or preempted private or voluntary test methods or consensus standards in a subject matter area; or
- The reference is to the department level from a subagency.

Identify the CFR unit being cited by the proper CFR unit designation in each cross-reference. Avoid using nonspecific references, such as "herein," "above," or "below," which require interpretation by the user and may result in ambiguity.

The following table covers the most common cross-reference situations and illustrates the proper style for each cross-reference.

References to a different TITLE	
A chapter	1 CFR Chapter I
A part	1 CFR Part 2
A section	1 CFR 2.7
A paragraph	1 CFR 2.7(a)(2)
References within the same CHAPTER	
A part	Part 30 of this chapter
A section	§30.19 of this chapter
A paragraph	§30.19(a) of this chapter

References within the same PART

A section	§20.15
A paragraph	§20.15(a)

References within the same SECTION

A paragraph	Paragraph (b) of this section
A subdivision within a paragraph	Paragraph (b)(1)(i) of this section

Incorporation by Reference

Incorporation by reference was established by statute as a means of allowing an agency to meet the requirement to publish regulations in the Federal Register by referring to materials already published outside of the Federal Register publishing system. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register. This material, like any other properly issued regulation, has the force of law.

For incorporation by reference to be valid, it must be approved by the Director of the Office of the Federal Register. OFR requirements for approval of incorporation by reference appear at 1 CFR Part 51. Material is eligible for incorporation by reference if it meets the following criteria:

- It is published data, criteria, standards, specifications, techniques, illustrations, or similar material.
- It does not detract from the legal or practical attributes of the *Federal Register* publishing system established by the *Federal Register* Act, the Administrative Procedure Act, and 1 CFR Chapter I. This means that the appropriate method for issuing agency rules is the publication of the full text of the rule in the *Federal Register* for codification in the CFR. The Director of the Office of the *Federal Register* will normally subject any request by an agency to incorporate by reference any material that the agency generates to greater scrutiny than material that is generated by an independent standard-setting organization.
- It benefits the Federal Government and members of affected classes by substantially reducing the volume of matter printed in the *Federal Register*. Generally, the material must be the equivalent of at least 10 pages in the *Federal Register* or contain highly specialized, technical matter that may pose difficulties in composition or printing.
- It is reasonably available to and useable by the class of people affected by it. This means that, to the extent necessary to ensure fairness and uniformity in the administrative process, the material is available to the public for purchase or inspection. Generally, material is considered available if the public may purchase or inspect it with minimum effort. To meet this criterion, a person must be able to inspect the material at the OFR, the agency's central and regional offices, or in depository libraries; and purchase the material from the publisher or the agency at reasonable cost.

Statements of incorporation by reference contained in regulatory text must meet specific drafting standards. Each statement of incorporation by reference must:

- Include the words "incorporation by reference";
- Identify the standard and/or material to be incorporated by title, date, edition, author, publisher, and identification number;
- Contain a brief subject description;
- Contain a statement of availability; and
- Refer to 5 U.S.C. 552(a) and 1 CFR Part 51 and include a statement indicating that the Director of the Federal Register approves the incorporation by reference.

Example

(b) The ASME Boiler and Pressure Vessel Code, which is referenced in the following paragraphs, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A notice of any changes made to the material incorporated by reference will be published in the Federal Register. Copies of the ASME Boiler and Pressure Vessel Code may be purchased from the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, NY 10016. It is also available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20852-2738, and the Office of the Federal Register, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to http: www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

(1) As used in this section, references to Section III of the ASME Boiler and Pressure Vessel Code refer to Section III, Division 1, and include editions through the 1977 Edition and addenda through the Summer 1979 Addenda.

(2) As used in this section, references to Section XI of the ASME Boiler and Pressure Vessel Code refer to Section XI, Division 1, and include editions through the 1977 Edition and addenda through the Summer 1979 Addenda subject to the following limitations and modifications:

Any questions on the suitability of material for incorporation by reference and the requirements necessary to obtain OFR approval should be directed to RDB (415-7163). RDB will coordinate each request for incorporation by reference with the OFR.

In each final rule document that contains an incorporation by reference that has been approved by the Director of the Office of the Federal Register, you must include the term "incorporation by reference" in the list of subject index terms for the part that contains the incorporation by reference; and include the following language under the DATES caption of the preamble to the final rule:

Example

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of [INSERT THE EFFECTIVE DATE OF THE DOCUMENT].

The OFR requires that a written request for each incorporation by reference approval be submitted to the Director of the Office of the Federal Register at least 20 working days before the final rule is submitted for publication. Each request for approval must contain:

- A letter requesting approval of the incorporation;
- A copy of the material to be incorporated; and
- A copy of the draft final rule document that uses proper language of incorporation.

Signature Block

Each rulemaking document must contain a complete signature block. The signature block usually appears on the last page of the document in the following format:

Example

Dated at Rockville, Maryland, this ___ day of _____, 2004.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Always include at least three lines of text with the signature block; the signature block may not appear on a page by itself.

Chapter 4 Procedural Requirements

Background

This section of the handbook discusses the procedural requirements the NRC considers when developing and issuing proposed and final rules. You will need to review your rule pursuant to each of these procedural requirements and include a summary of the review in the Supplementary Information section of the preamble. Your reviews ensure that the NRC considers the impact of regulatory alternatives in the rulemaking process. For all rulemakings you must prepare:

- A determination 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.
- An assessment of the environmental impact of the rule under the National Environmental Policy Act and 10 CFR Part 51.
- OMB approval for each new or amended information collection requirement under the Paperwork Reduction Act.
- A regulatory analysis prepared in accordance with the Regulatory Analysis Guidelines approved by the Commission and issued as NUREG/BR-0058, Revision 4. A regulatory analysis examines the economic impact, in terms of costs and benefits, of alternatives considered in developing the rule.
- An analysis of the economic impact of the rule on small entities under the Regulatory Flexibility Act.
- A backfit analysis prepared in accordance with 10 CFR 50.109, 70.76, 72.62, or 76.76.

In addition, for final rules, you must comply with the congressional review procedures established by the Congressional Review Act (CRA).

Timing of Procedural Reviews

The preparation of the environmental assessment and the regulatory analysis should precede, or at least be drafted concurrently, with the development of the proposed rule. These documents should not be developed after the proposed rule is drafted. These analyses help you to determine the necessity, extent, and direction of the rulemaking proceeding and should be an integral part of each step of the rulemaking. As the rulemaking progresses you may need to adjust or develop the analyses in greater detail.

While the regulatory action can and should be re-evaluated and adjusted in terms of more extensive analyses before it is issued as a final rule, after the draft analyses are made available for comment, any changes to them that are not the result of the public comment process require that the revised draft analyses be re-issued for comment.

Of critical timing importance is any rulemaking action that adds or amends an information collection requirement affecting 10 or more persons. The clearance package necessary to obtain OMB approval must be prepared at the same time a rule is prepared.

Rulewriters should be aware of these deadlines:

- **For Proposed rules**: The NRC may not submit a proposed rule that adds or amends an information collection requirement for signature and publication until the clearance package requesting OMB approval has been forwarded to OMB.
- **For Final Rules**: Information collection requirements must be approved by OMB before a final rule may be submitted for signature and publication.

Note that the procedural requirements pertaining to regulatory analysis and information collection overlap to some extent. Section 5.1 of the Regulatory Analysis Guidelines requires that factors needed to obtain OMB approval be addressed in the regulatory analysis. The analyses required under the Commission's Regulatory Analysis Guidelines and the Regulatory Flexibility Act (RFA) are similar in content. The RFA permits a regulatory flexibility analysis to be combined with any other analysis as long as it meets the requirements of the act. Section 5.2 of the Regulatory Analysis Guidelines requires that factors necessary to evaluate the economic impact on small entities be addressed in the regulatory analysis. Finally, the NRC's Regulatory Analysis Guidelines have been developed so that a regulatory analysis that conforms to the guidelines will also meet the requirements of the backfit rule.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) requires Federal agencies to consult with and to participate in the development of consensus standards. The act also requires that Federal agencies use standards developed by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or is otherwise impractical. A voluntary consensus standard is a standard developed or adopted by a domestic or an international voluntary consensus body.

Voluntary consensus bodies are those that agree to make their standards (intellectual property) available on a nondiscriminatory, royalty-free, or reasonable-royalty basis to all interested parties. These bodies are further characterized by openness, balance of interest, due process, an appeals process, and consensus (general agreement but not necessarily unanimity). For more detailed information on this subject, please see OMB Circular A-119, "Federal Participation in the Development and Use of Consensus Standards" (63 FR 8545; February 19, 1998).

The preamble of each proposed rule must contain a statement that requests comment and contains appropriate information concerning the use of voluntary standards. The preamble for final rules must repeat the statement that appeared in the proposed rule and acknowledge, summarize, and respond to any comments received, and explain the NRC's final decision.

If your rulemaking uses a voluntary consensus standard, the preamble must contain a statement that identifies the standard.

If your rulemaking uses a Government-unique standard instead of a voluntary consensus standard, the preamble must contain a statement that:

- Identifies the standard and explains the rationale for using the Government-unique standard instead of a voluntary consensus standard.
- Explains why using the voluntary consensus standard would be inconsistent with applicable law or is otherwise impractical; and, for proposed rules, invites comments that identify any voluntary standard that has not been used and requests explanation why the standard should be used.

If your rulemaking uses a Government-unique standard and does not identify any voluntary consensus standard, the preamble must contain a statement to that effect.

If your rulemaking does not constitute the establishment of a standard containing generally applicable requirements it must contain a statement to that effect and a basis for this determination.

Include the following statement addressing the use of voluntary standards in the Supplementary Information section of the preamble:

Example (for a proposed or final rule)

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this <*proposed* or *final*> rule, <insert one of the following options>

<Option 1 - Proposed rule> The NRC proposes using the following voluntary consensus standard: <identify the standard by name, developing organization, and date issued> The NRC invites comment on the applicability and use of other standards.

<Option 1 - Final rule> The NRC is using the following voluntary consensus standard: <identify the standard by name, developing organization, and date issued> The following alternative voluntary consensus standards were identified but are not used in this final rule <identify the standard(s) by name, developing organization(s) and date(s) issued>

<Option 2 - Either Proposed or Final Rule> The NRC <*proposes using* or *is using*> the following Government-unique standard: <identify the standard by name, developing organization, and date issued> NRC <*proposes using* or *is using*> this standard instead of the following voluntary consensus standard: <identify the standard by name, developing organization, and date issued> The NRC has determined that using a Government-unique standard is justified because [provide an explanation such as *using the voluntary consensus standard would be impractical or inconsistent with applicable law*>

<Option 3 - Proposed rule> The NRC proposes to use the following Government-unique standard: <identify the standard by name, developing organization, and date issued> The NRC is not aware of any voluntary consensus standard that could be used instead of the proposed Government-unique standard. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain how the voluntary consensus standard is comparable and why it should be used instead of the proposed Government-unique standard.

<Option 3. - Final rule> The NRC is using the following Government-unique standard: <identify the standard by name, developing organization, and date issued> No voluntary consensus standard has been identified that could be used instead of the Government-unique standard."

<Option 4. - Final rule> The NRC is <describe the action being taken in the final rule> This action does not constitute the establishment of a standard that contains generally applicable requirements."

If the proposed or final rule concerns NRC's approval of a standard design certification, you must include the following statement addressing the use of voluntary standards in the Supplementary Information section of the preamble.

Example

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this <*proposed* or *final*> rule, the NRC <*proposes to approve* or *is approving*> the <name> standard plant design for use in nuclear power plant licensing under 10 CFR Parts 50 and 52. Design certifications are not generic rulemakings establishing a generally applicable standard with which all Parts 50 and 52 nuclear power plant licensees must comply. Design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certifications are initiated by an applicant for rulemaking, rather than by the NRC. For these reasons, the NRC concludes that the act does not apply to this <*proposed* or *final*> rule.

If the NRC staff recommends partially adopting a voluntary consensus standard, the Commission paper must explicitly identify those portions of the voluntary consensus standard that are not being adopted. In addition, your Commission paper must contain a justification for why the portions of the standard that are not recommended for adoption are inconsistent with applicable law or are otherwise impractical.

Guidance concerning compliance with the requirements of the National Technology Transfer and Advancement Act appears in Management Directive MD 6.5, "NRC Participation in the Development and Use of Consensus Standards," and OMB Circular A-119. For these documents and additional information concerning compliance with the Act, please see NRC Standards Development on the public web site at http://www.nrc.gov/what-we-do/regulatory/standards-dev.html.

National Environmental Policy Act (NEPA)

Overview

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.) requires each Federal agency to prepare an environmental impact statement on each major Federal action significantly affecting the quality of the human environment. The intent of the Act is to build the consideration of environmental aspects of agency actions into the decision-making process of the agency.

The NRC must assess the environmental impact of each proposed and final rulemaking action and include a statement concerning the environmental impact in the Supplementary Information section of the preamble to each rulemaking.

Staff must make a preliminary determination as to the environmental impact of a rulemaking action when the proposed rule is being developed. Unless the NRC receives significant public comment on the draft environmental assessment (or environmental impact statement) and the proposed rule, it is unlikely that the NRC's determination as to the environmental impact of the action will change. Therefore, subject to the review of public comment, you should complete all consultation requirements before the final environmental action is issued.

If a rulemaking belongs to a category of actions that the Commission has declared by rule to be a categorical exclusion (10 CFR 51.22(c)), an environmental impact statement (EIS) or an environmental assessment is not required for the regulatory action. However, even if your rulemaking qualifies for a categorical exclusion, you should still do an EIS if you think there will be significant impact on the human environment.

If your rulemaking is not eligible for one of the categorical exclusions listed in 10 CFR 51.22(c), you must prepare an environmental assessment. A draft environmental assessment prepared for a proposed rule can be updated for the final rule to reflect any changes resulting from public comment or new information received from any other source.

If you complete the environmental assessment and find that the rule is not a major action significantly affecting the quality of the human environment, you do not need to prepare an environmental impact statement. Instead you prepare and publish in the Supplementary Information section a finding of no significant impact (FONSI; see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119). This finding includes a statement that the NRC has determined that it is not necessary to prepare an environmental impact statement for the action and explains why the NRC believes that the action will not have a significant effect on the quality of the human environment.

If your rulemaking is not eligible for one of the categorical exclusions listed in 10 CFR 51.22(c) and you find through the environmental assessment that the rule is a major action significantly affecting the quality of the human environment, then you must prepare an environmental impact statement on the rule (see 10 CFR 51.20(a)(1)). The draft environmental impact statement prepared for the proposed rule must be updated for the final rule to reflect any changes resulting from public comment or new information received from any other source.

The NRC also prepares an environmental impact statement if the rule involves a matter that the Commission has determined should be covered by an environmental impact statement (see 10 CFR 51.20(a)(2) and (b)).

Categorical Exclusions

An environmental impact statement or an environmental assessment is not required for any rulemaking action that is eligible for a categorical exclusion. A rulemaking is eligible for a categorical exclusion if the action belongs to a category of actions that the Commission has declared by rule to be categorically excluded from the Environmental Analysis requirement because such actions do not individually or cumulatively have a significant effect on the human environment.

The types of rulemaking actions that have been determined to fall under a categorical exclusion are listed in 10 CFR 51.22(c).

If you determine that your rulemaking is eligible for a categorical exclusion, include the following statement in the Supplementary Information section of the preamble to the rule.

Example

Environmental Impact: Categorical Exclusion

The NRC has determined that this <*proposed* or *final*> rule is the type of action described in categorical exclusion 10 CFR 51.22(c) <Insert the paragraph number within 10 CFR 51.22(c) that precisely identifies the appropriate categorical exclusion>. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this <*proposed* or *final*> rule.

In order to fulfill a commitment made to the Council on Environmental Quality, the NRC consults with the States on environmental issues before issuing an environmental assessment and documents the consultation in the environmental assessment. Procedures for consultation with the States during the preparation of an environmental assessment for a rulemaking action can be found on the *NRC Rulemaker* web site.

Environmental Justice

The Commission's "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions," (69 FR 52040; August 24, 2004) confirmed that the legal basis for NRC's analysis of environmental justice matters, including impacts of a proposed licensing or regulatory action on minority or low-income communities, is NEPA. While NRC supports the general goals of Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," NRC will meet these goals through the normal and traditional NEPA review process. Office guidance on how to incorporate environmental justice in the NEPA review process can be found in NMSS NUREG-1748 "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs (August 22, 2003) ML032450279 and NRR LIC-203, Rev. 1, "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues" (May 24, 2004) ML033550003.

Environmental Analysis Statements

If you have evaluated the environmental impact of your rulemaking action and have prepared an environmental impact statement, use the following statement in the Supplementary Information section of the preamble to your rule:

Example

Environmental Impact Statement: Availability

As required by the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, the NRC has prepared a <*draft* or *final*> environmental impact statement for this <*proposed* or *final*> rule. <Insert Proposed or Final Rule Language>

<Proposed rule language:>

The NRC requests public comment on the draft environmental impact statement, including any environmental justice considerations related to this proposed rule. The NRC has committed to complying in all its actions with Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11, 1994. The NRC uses the following working definition of "environmental justice": the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of environmental justice may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the Environmental Impact Statement and this proposed rule to every State Liaison Officer and requested their comments on the draft statement. Comments on the draft statement may be submitted to the NRC as indicated under the ADDRESSES heading.

<Final rule language:>

The NRC requested the views of the States on the environmental impact statement for this rule. <Indicate whether comments were received concerning environmental justice considerations and whether the final rule or the environmental impact statement has changed as a result.> <Indicate whether the States' comments have been addressed and whether the environmental impact statement has changed as a result of the States' comments.>

Finding of No Significant Impact (FONSI)

Unless your rulemaking action is eligible for one of the categorical exclusions listed in 10 CFR 51.22(c), you must prepare an environmental assessment on each licensing and regulatory action, including proposed and final rules for which an environmental impact statement has not been prepared (see 10 CFR 51.21, 51.30, and 51.31). If after completing your environmental assessment for a proposed or final rule you determine that an environmental impact statement need not be prepared, you must prepare and publish a finding of no significant impact (FONSI; see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119).

A FONSI includes a statement that the NRC has determined not to prepare an environmental impact statement for the action and explains why the NRC believes that the action will not have a significant effect on the quality of the human

environment. You may either include the text of the environmental assessment in the Supplementary Information section of your preamble to the proposed or final rule or summarize the environmental assessment and indicate how interested persons may obtain a copy of it.

If you determine that a FONSI is appropriate for a proposed or final rule and are including the environmental assessment in the Supplementary Information section of the preamble, you must include the following statement:

Example (proposed rule language)

Finding of No Significant Environmental Impact:
Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis for this determination reads as follows:

<insert the text of the environmental assessment>

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC is seeking public participation. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

Example (final rule language)

Finding of No Significant Environmental Impact:
Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis for this determination reads as follows:

<insert the text of the environmental assessment>

The NRC requested the views of the States on the environmental assessment for this rule. <Indicate whether the States' comments have been addressed and whether the environmental assessment has changed as a result of the States' comments.>

If you determine that a FONSI is appropriate for a proposed or final rule and are presenting the environmental assessment in a separate document, you must include a statement indicating this finding and summarize the environmental assessment in the Supplementary Information section of the preamble to your rule.

Example (proposed rule language)

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51 that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. <Include a discussion that briefly presents the reasons why the action will not have any significant environmental impact, summarizes the environmental assessment, and notes any other related environmental documents.>

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC is seeking public participation. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

Example (final rule language)

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. <Include a discussion that briefly presents the reasons why the action will not have any significant environmental impact, summarizes the environmental assessment, and notes any other related environmental documents.>

The NRC requested the views of the States on the environmental assessment for this rule. <Indicate whether the States' comments have been addressed and whether the environmental assessment has changed as a result of the States' comments.>

Absent special circumstances, you need not conduct a separate environmental justice review for an environmental assessment that results in a FONSI. However, as discussed in the Environmental Justice Policy Statement (69 FR 52040; August 24, 2004), if there is a clear potential for significant offsite impacts from the proposed action, then an appropriate environmental justice review may be needed to provide the basis for a FONSI. For these special cases include the following statement in the Supplementary Information section of the preamble to your rule.

Example (proposed rule language)

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51 that this rule, if adopted, would not be a major Federal action

significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. <Include either the text of the environmental assessment (EA) or a discussion that briefly presents the reasons why the action will not have any significant environmental impact, summarizes the environmental assessment and the environmental justice review, and notes any other related environmental documents.>

The NRC has committed to complying with Executive Order (E.O.) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11, 1994. E.O. 12989 describes environmental justice as "identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations." In the case of most environmental assessments, there are little or no offsite impacts, and therefore, an EJ review is generally not necessary to make a FONSI. However, where a proposed action has a clear potential for offsite impacts to minority or low-income communities, an EJ review is conducted as part of the EA. While the proposed rule has a clear potential for offsite impacts to minority and low-income communities associated with the proposed rule, the NRC has conducted an environmental justice review for the EA and has determined that there are no disproportionate high and adverse impacts on minority and low-income populations.

In the letter and spirit of E.O. 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. Comments on any aspect of the environmental assessment and the environmental justice review may be submitted to the NRC as indicated under the ADDRESSES heading.

Example (final rule language)

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51 that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. <Include a discussion that briefly presents the reasons why the action will not have any significant environmental impact, summarizes the environmental assessment, and notes any other related environmental documents>

The NRC requested public comments on any environmental justice considerations that may be related to this rule. <Indicate whether public comments have been addressed and whether the environmental assessment has changed as a result of public comment> The NRC requested the views of the States on the environmental assessment for this rule. <Indicate whether the States' comments have been addressed and whether the environmental assessment has changed as a result of the States' comments>

Paperwork Reduction Act (PRA)

The Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.) is intended to minimize the burden on regulated parties resulting from the collection of information by and for the Federal Government. The PRA also is intended to maximize the public benefit and practical utility of information created, collected, disclosed, maintained, used, shared, and disseminated by or for the Federal Government. The PRA requires each Federal agency to obtain approval from OMB for each information collection activity that affects 10 or more persons.

The factors necessary to obtain OMB approval must be addressed in the regulatory analysis [see Chapter Four of this handbook]. The NRC complies with the PRA in a manner consistent with its responsibilities to ensure that public health and safety is adequately protected. An approved information collection request must display the OMB clearance number, a public protection notification, and, where appropriate, the expiration date. The Records and FOIA/Privacy Services Branch, Information and Records Services Division, Office of Information Services (OIS), is responsible for coordinating NRC activities necessary to comply with the Paperwork Reduction Act.

The PRA applies to any action that imposes an information collection requirement, such as a recordkeeping, application, reporting, or third-party disclosure requirement, on 10 or more persons. You must obtain OMB clearance for both voluntary and mandatory information collection requirements. An information collection request that is submitted to nine or fewer people must contain a statement that the request is not subject to the Paperwork Reduction Act. An OMB clearance is not required for a request for public comment in connection with a rulemaking proceeding.

Information Quality Act

The Information Quality Act (IQA) (Public Law No. 106–554,515(a)) was developed as a supplement to the Paperwork Reduction Act. The IQA requires the Office of Management and Budget (OMB) to issue guidelines for Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies. While few NRC rulemakings are affected by the IQA, any "Influential Scientific Information" that provides the basis for a substantive rulemaking that has substantial impact on an industry must be peer reviewed. A discussion of the peer review report must be included in the preamble to any related rulemaking and included in the Regulatory History for the rule. To find the most recent guidance on Information Quality issues, including Peer Review compliance, see *The NRC Rulemaker*.

NRC Regulations

Each new information collection requirement appearing in an added or amended regulation or the deletion of a requirement from an existing regulation must be approved by OMB before it becomes effective. In addition, each of the following existing 10 CFR Chapter I information collection requirements must be re-approved by OMB when the current OMB clearance expires:

- Recordkeeping.
- Application.
- Reporting.
- Third-party disclosure.

An information collection requirement appearing in NRC regulations is invalid and unenforceable unless it is approved by OMB or the Commission overrides an OMB denial.

Preparation of an OMB Clearance Package - Proposed Rule

If your proposed rule contains a new or amended information collection requirement, you must develop the clearance package necessary to obtain OMB approval at the same time you draft the proposed rule. An OMB clearance package is needed even when the proposed amendments reduce the burden imposed by an information collection requirement or delete an information collection requirement. The proposed rule and the clearance package must be developed along parallel tracks so that when the proposed rule is submitted for signature and publication, the necessary concurrences have been obtained for the clearance package and it is ready for transmittal to OMB. You may not submit a proposed rule that contains a new or amended information collection requirement for publication until the clearance package necessary to obtain OMB review and approval has been approved by OIS for submittal to OMB.

Preparation of an OMB Clearance Package - Final Rule

A clearance package necessary to obtain OMB approval must be developed and submitted to OMB for a final rule that:

- Was not first issued as a proposed rule and contains an information collection requirement;
- Was submitted to OMB as a proposed rule but the information collection requirement was not approved by OMB; or
- Was submitted to OMB as a proposed rule but the information collection requirements contained in the proposed rule have been amended in the final rule or new information collection requirements have been added to the final rule.

A revised clearance package must be developed and submitted for OMB approval if a final rule contains an information collection requirement that has been added or amended since the clearance package for the proposed rule was submitted for OMB approval. An OMB clearance package is required even if the changes from the proposed rule reduce the burden imposed by an information collection requirement.

You may not submit a final rule that contains a new or amended information collection requirement for publication until OMB approval has been obtained for each information collection requirement contained in the final rule, including those requirements that have been added or amended since the proposed rule was published.

Standard Statements

There is a unique PRA statement for each type of rulemaking action. You must include the appropriate PRA statement in the Supplementary Information section of the preamble for your rulemaking action. You can find formatted versions of these PRA statements on the *NRC Rulemaker* web site.

Each statement contains a specific OMB approval number for the information collection requirements that are contained in the affected parts. Each approval number starts "3150," which identifies NRC as the issuing agency, and has a specific four-digit number that is assigned to represent a particular part within 10 CFR Chapter I. The Records and FOIA/Privacy Services Branch, OIS, will identify the appropriate identification number for each rulemaking action.

Guidance

The Office of Information Services (OIS) is responsible for coordinating the activities necessary to comply with the PRA. Written OIS guidance appears in MD 3.54, "Collection of Information and Reports Management." In addition, each office has appointed an Information Management Coordinator who provides advice, direction, and assistance in meeting PRA Requirements. Specific questions concerning the procedures and requirements of the PRA may be directed to the Chief, Records and FOIA/Privacy Services Branch.

Regulatory Analysis

The Commission's Regulatory Analysis Guidelines, NUREG/BR-0058, Rev. 4, were revised in September 2004. These guidelines establish a framework for:

- Analyzing the need for and consequences of a proposed regulatory action.
- Selecting a preferred alternative from potential courses of action.
- Documenting the analysis in an organized and understandable format.

The regulatory analysis for a final rule is based upon the draft regulatory analysis that is prepared in support of the proposed rule. The draft regulatory analysis must be updated to reflect any additional information received through the public comment process. The draft regulatory analysis must also be amended to reflect and support any changes that are made to the proposed regulation when it is adopted as a final rule.

The regulatory analysis is intended to ensure that NRC decisions that impose regulatory burdens on licensees are based on adequate information concerning the extent of these burdens and the resulting benefits. The regulatory analysis also ensures that decisions are made through a systematic and disciplined process that is clear to all participants and affected parties. Ultimately, the regulatory analysis ensures that the regulatory burdens imposed are needed, justified, and the minimum necessary to achieve regulatory objectives.

Components of a Regulatory Analysis

NUREG/BR-0058 discusses the impacts to be addressed by each regulatory analysis. These include:

- Direct costs or savings to licensees, the NRC, and State and local government agencies.
- Non-radiation risk-related costs or savings to the general public.
- Averted onsite impacts.
- Changes in regulatory efficiency or scientific knowledge needed for regulatory purposes.

Each regulatory analysis must include the following standard elements:

- A statement of the problem and NRC's objectives for the regulatory action.
- An identification and analysis of alternative approaches to resolving the problem.
- A discussion of the basis for inclusion or exclusion of individual requirements (see NUREG/BR-0058 for details on aggregation or "bundling" of requirements in a regulatory analysis.)
- An estimate and evaluation of the values and impacts for the selected alternatives, including the uncertainties that affect these estimates.
- The conclusion reached concerning the evaluation of values and impacts and a safety goal evaluation, where appropriate.
- The decision rationale for the selected regulatory action.
- A tentative implementation schedule and implementation instrument for the regulatory action.

A regulatory analysis must accompany each mechanism used by the NRC staff to establish or communicate generic requirements, guidance, requests, or NRC staff positions that would place a burden on licensees.

Regulatory analysis requirements for a given action may be eliminated at the discretion of the Commission, the EDO, a Deputy EDO, or the responsible NRC office director.

A more limited regulatory analysis may be prepared when justified by case-specific circumstances. In these situations, the regulatory analysis should be limited only in terms of depth of discussion and analysis. It should not be limited by reducing the scope of the analysis or the need to justify the action.

Regulatory Analysis Relative to Other Procedural Requirements

To the extent possible, the regulatory analysis must contain or summarize the analyses or information necessary to comply with other procedural requirements for rulemaking.

NEPA. If an environmental impact statement has been prepared and forms the basis for a proposed or final rule, a summary of the environmental impact statement is an appropriate substitute for the information and analysis requirements identified in NUREG/BR-0058, Revision 4, Sections 4.1-4.3.

Paperwork Reduction Act. If the rule would impose collection requirements that require obtaining OMB approval under the Paperwork Reduction Act [see

Chapter Four of this handbook], the draft or final OMB clearance package must be prepared or revised on a parallel track so that OMB has approved the information collection requirement before the *Federal Register* notice is submitted for signature and publication.

Regulatory Flexibility Act. If the rule is likely to have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis must be prepared. The regulatory flexibility analysis is included as an appendix to the regulatory analysis and as part of the rule. The regulatory flexibility analysis may reference information discussed in the body of the regulatory analysis. If the NRC certifies that the rule does not have a significant economic impact on a substantial number of small entities, the regulatory analysis must contain sufficient information concerning the potential impact of the rule on small entities to support this certification.

Backfit Rule. If a backfit analysis is required for a rule, the regulatory analysis must contain the information required by the Commission's backfit rule. The NRC's Regulatory Analysis Guidelines have been developed so that a regulatory analysis prepared according to the guidelines will meet the requirements of the backfit rule. See "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 4, and Management Directive 8.4, "Management of Facility-specific Backfitting and Information Collection."

Information Quality Act. If a rule relies on "Influential Scientific Information" and has substantial impact on an industry, it must be peer reviewed. A discussion of the peer review report must be included in the preamble to any related rulemaking. For the most recent guidance on Information Quality issues, see *The NRC Rulemaker*.

Required statements.

You must include a statement concerning the regulatory analysis in the Supplementary information section of the preamble to the rule.

Example (proposed rule)

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

If you have prepared a draft regulatory analysis for the proposed rule and are including it in the text of the Supplementary Information section of the preamble to the proposed rule, present it as follows:

Example (proposed rule)

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission.

<Insert the draft regulatory analysis.>

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

If a draft regulatory analysis has not been prepared for the proposed rule, insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Example (proposed rule)

Regulatory Analysis

A draft regulatory analysis has not been prepared for this proposed regulation. <Include a statement that indicates why a regulatory analysis is not necessary for the proposed regulatory action.>

If a regulatory analysis has been prepared for the final rule as a separate document, insert the following statement in the Supplementary Information section of the preamble to the final rule.

Example (final rule)

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available as indicated under the Availability of Documents heading of the Supplementary Information section.

If a draft regulatory analysis has been prepared for the final rule and is included in the text of the Supplementary Information section of the preamble to the final rule, present it as follows:

Example (final rule)

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. <Insert the draft regulatory analysis.>

If a draft regulatory analysis has been not prepared for the proposed rule, insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Example (final rule)

Regulatory Analysis

A regulatory analysis has not been prepared for this regulation. <Include a statement that indicates why a regulatory analysis is not necessary for the regulatory action.>

Regulatory Flexibility Act

Purpose

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), as amended by the Congressional Review Act (CRA), requires that each Federal agency consider the impact of its rulemakings on small entities and evaluate alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition. In essence, the RFA requires that each agency analyze the impact of the rulemaking on different size entities, estimate the effectiveness of the regulatory action in addressing the source of the problem, and consider alternatives that would minimize compliance costs. For NRC regulatory actions, the RFA primarily impacts regulations that would affect byproduct, source, and special nuclear material licensees.

Applicability

The RFA applies to each rulemaking subject to notice and comment under the APA (5 U.S.C. 553 (b)). Therefore, the requirements of the RFA apply to each proposed rule developed by the NRC. The RFA exempts a final rule for which a proposed rule was not issued. If the action is issued as a direct final rule, the direct final rule must contain a regulatory flexibility certification statement in case the direct final rule must be withdrawn and a subsequent final rule issued.

Requirements

In order to comply with the RFA's basic requirement that an agency regulate in a manner that does not unduly burden a particular sector because of size, the NRC must consider the potential impact of its regulatory actions on small entities.

If you believe that a rulemaking action will have a "significant economic impact on a substantial number of small entities," the RFA requires preparation of a regulatory flexibility analysis (called an "initial" regulatory flexibility analysis in a proposed rule). The act also requires that this analysis, or a summary of the analysis, be published in the *Federal Register* for public comment. The regulatory flexibility analysis may be combined with other analyses as long as it meets the requirements of the RFA. The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, Revision 4) require that factors necessary to evaluate the economic impact of the proposed rule on small entities be addressed in the regulatory analysis that considers the costs and benefits of the proposed rule.

The act permits the NRC to dispense with the preparation of a regulatory flexibility analysis if:

- The NRC determines that the rulemaking action will not have a significant economic impact on a substantial number of small entities.
- The Commission certifies this to be the case.
- The certification and the factual basis for the certification are published in the proposed rule.

Size Standards

The NRC has established size standards which you must use to determine which NRC licensees qualify as small entities. The NRC size standards are codified in 10 CFR 2.810. These size standards state:

A small business is a for-profit concern and is a:

- Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $5 million or less over its last 3 completed fiscal years; or
- Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

A small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of $5 million or less.

A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

A small educational institution is one that is:

- Supported by a qualifying small governmental jurisdiction; or
- Not state or publicly supported and has 500 or fewer employees.

For the purposes of this section, the NRC uses the Small Business Administration definition of receipts (13 CFR 121.402(b)(2)). A licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of this section.

Standard Statements

Your rulemaking must include a statement concerning the RFA in the Supplementary Information section of the preamble.

If you have prepared an initial regulatory flexibility analysis, you must include one of the following statements.

Use this standard statement to seek public comment and announce availability:

Example (proposed rule)

Regulatory Flexibility Analysis

The NRC has prepared an initial regulatory analysis of the impact of this proposed rule on small entities. The preliminary analysis indicates that although the proposed rule will have an economic impact of $1500-1750 annually on medical licensees, of which 18 percent are small entities, the proposed alternative is the least costly alternative that provides adequate protection from radiation exposure for patients and workers. A summary of this analysis appears as Appendix A to this document.

The NRC requests written comments on the analysis. Send comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

If you find you need more information on how the proposed rule will actually affect small entities or on how a rule may be modified to alleviate significant economic impact upon them, you can request directed comments. Use the following statement:

Example (proposed rule)

Regulatory Flexibility Analysis

The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from small entities (i.e., small businesses, small organizations, and small jurisdictions under the Regulatory Flexibility Act) as to how the regulations will affect them and how the regulations may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Those small entities that offer comments on how the regulations could be modified to take into account the differing needs of small entities should specifically discuss —

(a) The size of their business and how the proposed regulations would impose a significant economic burden on them as compared to larger organizations in the same business community;

(b) How the proposed regulations could be modified to take into account their differing needs or capabilities;

(c) The benefits that would accrue or the detriments that would be avoided if the proposed regulations were modified as suggested by the commenter;

(d) How the proposed regulations, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individuals or groups; and

(e) How the proposed regulations, as modified, would still adequately protect the public health and safety.

The comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

If an initial regulatory flexibility analysis is not required, you must include the necessary certification statement. This statement must certify that the proposed rule will not have a significant economic impact on a substantial number of small entities, and provide the factual basis for this certification. The statement must contain sufficient information to support the conclusion, including information on the number and type of small entities involved and the potential effect of the rule on them. A simple, unsubstantiated conclusion is insufficient.

If your proposed rule would affect licensees that are not nuclear power plant licensees, use the following type of certification statement.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The proposed rule would affect about 1,150 specific licensees under 10 CFR Part 35. These licenses are issued principally to medical institutions. Small business entities as defined by 10 CFR 2.810, primarily physicians in private practice, comprise about 280 of these special medical licensees. Because the affected licensees currently assay radiopharmaceutical dosages as a license condition, they have the equipment, personnel, time, and expertise to comply with the proposed rule. Although most licensees already maintain similar records, an additional expense might be incurred for the time required to keep the detailed measurement records proposed in the rule. The annual recordkeeping burden imposed by the proposed rule is estimated to be 19 hours for the average licensee.

The potential gains in patient protection significantly outweigh the economic impact on small medical licensees. However, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which small medical licensees operate.

Any small entity subject to this regulation that determines, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this opinion in a comment that indicates —

(a) The licensee's size and how the proposed regulation would impose a significant economic burden on the licensee as compared to the economic burden on a larger licensee;

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(c) The benefits that would accrue or the detriments that would be avoided if the proposed regulations were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect public health and safety.

If your proposed rule would affect nuclear power plant licensees, use the following statement.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

Initial Regulatory Flexibility Analysis

The RFA requires that the initial regulatory flexibility analysis, or a summary of the analysis, be published in the *Federal Register* with the proposed rule. The analysis or summary is presented as an appendix to the document. If you only publish a summary of the analysis, it must contain sufficient detail concerning the cost and benefits of the proposed rule to enable a small entity to determine how the proposed rule will affect it, and whether it requires the more detailed information contained in the analysis. Your initial regulatory flexibility analysis must contain the following information:

- A description of the reasons why the agency is considering regulatory action. Include a short paragraph explaining the statutory, policy, program, or practical reasons for the rule or amendment. Cite the preamble for more details.
- A succinct statement of the objectives of, and legal basis for, the proposed rule. Include a brief statement of objectives and cite the preamble for details. If the rule is being issued under new statutory authority, cite it here; otherwise, reference the authority citation contained in the proposed rule document.
- A description and, where feasible, an estimate of the number of small entities to which the proposed rule will apply. Describe the type and number of licensees affected. If a specific number of licensees is not known, use realistic estimates. To the extent possible, the NRC should—

  Provide a profile of the affected entities that is divided into size segments;

  Cite the NRC's size standard rule 10 CFR 2.180 to identify the steps taken to develop a definition of a small entity that is different from the RFA's definition; and

  Identify the small entities expected to experience more significant impacts as a result of the rule.

- Description of projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and

the type of professional skills necessary for preparation of reports or records.

- Describe these requirements generally. Reference the more detailed statement of requirements in the preamble or codified text. Obtain detailed analyses of costs and administrative burdens associated with reporting and recordkeeping from the paperwork burden analysis prepared to comply with the Paperwork Reduction Act.
- Indicate the type of small entity subject to each requirement, for example, field radiographers, private physicians, manufacturers of certain equipment. Indicate the type of professional skill needed to prepare the report, for example, that of a radiographer, a lab technician, a production manager, a general administrative expert.
- To the extent possible, analyze the long- and short-term costs of the proposed requirements and the classes of small entities that will be subject to them. These costs should include direct compliance costs as well as reporting, recordkeeping, or other administrative costs. Compare the costs of compliance for large and small entities as well as the ability of small entities to pass on these costs as price increases or user fees. Consider the resulting effects, if any, the proposed requirements may have on closures, production, operating costs, employment, or other relevant factors.
- An indication, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule. Indicate "none" if there is no duplication or conflict. However, if you are aware of any duplication, indicate the provision and explain why the duplication is necessary.
- A description of the significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize the rule's economic impact on small entities. Include a description of any significant alternative regulatory provisions that were considered. Alternatives that may be considered include:

  The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

  The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities;

  The use of performance rather than design standards; and

  An exemption from coverage of the rule, or any part of the rule, for small entities.
- Economic impact of rule. Summarize the economic cost of the rule to small entities, the impact of the rule on their ability to compete within the affected industry, and the overall impact of the rule on the affected business community considering such factors as employment, business failures, and the concentration of firms in the market.

If you have prepared a final regulatory flexibility analysis, insert the following statement in the Supplementary Information section of the preamble to the final rule.

Example (final rule)

Regulatory Flexibility Analysis

The NRC has prepared a final regulatory analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis indicates that although the final rule has an economic impact of $1,500-$1,750 annually on medical licensees, of which 18 percent are small entities, the selected alternative is the least costly alternative that provides adequate protection from radiation exposure to patients and workers. The analysis is available as indicated under the Availability of Documents heading of the Supplementary Information section.

If you determine that a final regulatory flexibility analysis is not required, include the necessary certification statement in the Supplementary Information section of the preamble to the final rule. This statement must certify that the regulation does not have a significant economic impact on a substantial number of small entities and include a succinct statement of the reasons for this certification. This statement must contain sufficient information to provide the factual basis for this conclusion. The statement must include detailed information on the number and type of small entities involved and why the rule will have no or minimal effect on them. A simple, unsubstantiated conclusion is insufficient.

If your final rule affects licensees that are not nuclear power plant licensees, use the following type of certification statement.

Example

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The regulation affects about 2,000 specific licensees under 10 CFR Part 35. These licenses are issued principally to medical institutions. Small business entities, primarily physicians in private practice, comprise about 280 of the specific medical licensees. Because the affected licensees currently assay radiopharmaceutical dosages as a license condition, they have the equipment, personnel, time, and expertise to comply with the regulation. Although most licensees already maintain similar records, an additional expense might be incurred for the time required to keep the detailed measurement records required by the rule. The annual recordkeeping burden imposed by the rule is estimated to be 19 hours for the average licensee. The potential gains in patient protection significantly outweigh the economic impact on small medical licensees.

If a final rule affects nuclear power plant licensees, use the following statement.

Example (final rule)

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

Final Regulatory Flexibility Analysis: Content

The final regulatory flexibility analysis is an updated version of the initial analysis. The final analysis must reflect any new information received through public comment or any other source. The RFA requires that the final regulatory flexibility analysis contain —

- A succinct statement of the need for, and the objectives of, the rule.
- A summary of the issues raised by public comment on the initial regulatory flexibility analysis, a summary of NRC's assessment of those issues, and a statement of any changes made in the rule as a result of public comment.
- A description of the type of small entities and an estimate of the number of small entities to which the rule applies or an explanation of why no such estimate is available.
- A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that are subject to the requirement and the type of professional skills necessary for preparation of the report or record.
- A description of the steps the NRC has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule that affect the impact on small entities was considered by the NRC and rejected.

Emergency Provisions

The RFA permits the NRC to delay the completion of a regulatory flexibility analysis for a rule issued in response to an emergency that makes timely compliance with the requirement to prepare an analysis impractical.

- The NRC may not delay the preparation of a regulatory flexibility analysis for more than 180 days after completion of the final rule. If an analysis is not prepared within 180 days, the rule lapses and has no effect.
- The delay must be supported by a written finding that is published in the *Federal Register* no later than the publication date of the final rule.

- The NRC should limit its interpretation of "emergency situation" to something that could have an immediate and significant impact on public health and safety.

Questions concerning the Regulatory Flexibility Act may be directed to the Chief, Rules and Directives.

Backfitting Statement

Overview

The NRC has established standards for the management of backfitting requirements imposed on power reactors (10 CFR 50.109). Analogous provisions have been established to manage backfitting requirements imposed on —

- Gaseous diffusion plants (10 CFR 76.76)
- Independent spent fuel storage installations or monitored retrievable storage installations (10 CFR 72.62)
- Special nuclear material licensees (10 CFR 70.76).

A brief overview of the Backfitting process follows; for detailed guidance consult "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 4, and Management Directive 8.4, "Management of Facility-specific Backfitting and Information Collection."

Backfitting is a process that can include both plant-specific changes and generic changes applied to one or more classes of regulated entities. The definition of backfitting has four components.

The first component is the modification of or addition to:

- Systems, structures, components, or design of a facility;
- The design approval or manufacturing license for a facility; or
- The procedures or organization required to design, construct, or operate a facility.

The second component is that the modification or addition is the result of either:

- A new or amended provision of the Commission's regulations; or
- A regulatory NRC staff position interpreting these regulations that is either new or different from a previously applicable NRC staff position.

The third component concerns the timing of the new or amended regulation or NRC staff position that brought about the modification or addition. The fourth component is that the modification or addition must be imposed as a mandatory requirement and where current practices or activities would not satisfy the modification or addition.

The NRC prepares a systematic and documented backfit analysis for each backfit that it seeks to impose by rulemaking action. The Commission may impose a backfit on a facility that already provides adequate protection of public health and safety and common defense and security only if the backfit analysis indicates that:

- There would be a substantial increase in the overall protection to the public health and safety or the common defense and security derived from the backfit; and
- The direct and indirect costs that would result from the implementation of the backfit are justified.

Exceptions

A backfit analysis is not required and the "substantial increase" and "cost justification" standards do not apply if:

- A backfit is necessary to ensure adequate protection of public health and safety or the common defense and security (typically, this exception applies to Orders and licensing activities;
- A backfit is necessary to bring a facility into compliance with a license, a licensee's written commitments, or the rules and orders of the Commission;
- The backfit involves defining or redefining adequate protection (typically, this exception applies only in the context of a rulemaking).

For each backfit analysis excepted, the NRC prepares a "documented evaluation" that includes a statement of the objectives of and the reasons for the backfit, and the basis for treating it as an exception to the backfit analysis requirements.

Backfit Analysis Content

A backfit analysis prepared in support of a backfit contained in a rulemaking must contain:

- A statement of the specific objectives that the backfit is designed to achieve;
- A general description of the activity that would be required of the licensee or the applicant to complete the backfit;
- The potential change in the risk to the public from the accidental offsite release of radioactive material;
- The potential impact on the radiological exposure of facility employees;
- The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;
- The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;
- The estimated resource burden on the NRC associated with the backfit and the availability of NRC resources;
- The potential impact of differences in facility type, design, or age on the relevance and practicality of the backfit; and
- Whether the backfit is interim or final and, if interim, the justification for imposing the backfit on an interim basis.

Include a statement concerning the applicability of the backfitting requirements set out in 10 CFR Chapter I in the Supplementary Information section of the preamble to your rulemaking. If your rulemaking (either proposed or final) contains a backfit requirement that would substantially increase safety beyond adequate protection and would do so at a justifiable cost, insert the following statement.

Example

Backfit Analysis

As required by 10 CFR 50.109 <or 70.76, 72.62, or 76.76, as appropriate>, the Commission has completed a backfit analysis for the <*proposed* or *final*> rule. The Commission has determined, on the basis of this analysis, that backfitting to comply with the requirements of this <*proposed* or *final*> rule will provide a substantial increase in protection to public health and safety or the common defense and security at a cost that is justified by the substantial increase. The basis for this determination reads as follows: <Insert the text of the backfit analysis or reference the regulatory analysis or other publicly available document that contains backfit analysis.>

If your rulemaking (either proposed or final) contains a backfit requirement that is considered necessary to protect public health and safety adequately or to bring licensees into compliance, insert the following statement or an appropriate variation of this statement.

Example

Backfit Analysis

The Commission has concluded, on the basis of the documented evaluation required by 10 CFR 50.109(a)(4) <or 70.76, 72.62, or 76.76 as appropriate> that the backfit requirements contained in this <*proposed* or *final* > rule

<insert one of the following three options:>

option 1 - *are necessary to bring the facilities described into compliance with licenses or the rules and orders of the Commission or into conformance with written commitments by the licensees*

option 2 - *are necessary to ensure that the facilities described in the rule provide adequate protection to the health and safety of the public and are in accord with the common defense and security*

option 3 - *involve defining or redefining what level of protection to the public health and safety or the common defense and security should be regarded as adequate*

and, therefore, a backfit analysis is not required and the cost-benefit standards of 10 CFR 50.109(a)(3) <or 70.76, 72.62, or 76.76, as appropriate> do not apply. The documented evaluation includes a statement of the objectives of and reasons for the backfits that would be required by the <*proposed* or *final*> rule and sets forth the basis for the Commission's conclusion that these backfits are not subject to the cost-benefit standards of 10 CFR 50.109(a)(3) <or 70.76, 72.62, or

76.76, as appropriate>. <Insert the text of the documented evaluation or reference the regulatory analysis or other publicly available document that contains the documented evaluation.>

If the backfit requirements of 10 CFR Chapter I do not apply to your rulemaking, insert the following statement or an appropriate variation of this statement.

Example

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this <*proposed* or *final*> rule; therefore, a backfit analysis is not required for this <*proposed* or *final*> rule because

<insert one of the following three options:>

option 1 - *these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I*

option 2 - *these amendments do not impose more stringent safety requirements on 10 CFR Part 50 [or Part 70, Part 72, or Part 76, as appropriate licensees*

option 3 - *these amendments are mandated by [cite the appropriate act of Congress.*

<Note that Options 1 and 2 require additional text to explain this conclusion>

Congressional Review Act

Among other requirements, the Congressional Review Act (CRA) requires Federal agencies to provide Congress with an opportunity to review agency rules. For each final rule you must submit to Congress a report containing a copy of the final rule, a concise general statement of the final rule (including a statement indicating whether the action is a "major" rule) and the effective date of the final rule. This report is not required for proposed rules.

The report consists of a standard form (GAO-001, Submission of Rules Under the Congressional Review Act) developed by the General Accounting Office (GAO) and OMB, and must be submitted to each House of Congress and the Comptroller General before the rule takes effect. The report must be accompanied by any other relevant information required by another act or by an Executive order, including any cost-benefit analyses, regulatory flexibility analyses, Paperwork Reduction Act statements, and any environmental assessments or impact statements.

With limited exceptions, all final agency rules, policy statements, and agency documents interpreting agency requirements are defined as "rules" under the CRA. The CRA also establishes special congressional procedures for the disapproval of agency rules.

Major Rules

The requirements concerning major rules are applicable to all major final rules promulgated after March 1, 1996. A "major rule" is defined in 5 U.S.C. 804 (2) as a final action that has resulted or is likely to result in:

- An annual effect on the economy of $100,000,000 or more;
- A major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets.

The effective date for all "major" rules may be no earlier than 60 days after the date Congress receives the complete report or 60 days after publication of the final rule in the *Federal Register*, whichever is later.

Under the Congressional Review Act (CRA), the OMB is responsible for determining whether a rule is "major." This impacts the publication schedule for final rules. You must submit a description of your final rule to OMB and OMB must verify the NRC's determination as to whether the final rule is considered a major rule under CRA before your final rule may be submitted for signature and publication.

Use the following statement in the Supplementary Information section of the preamble to your final rule.

Example

Congressional Review Act (CRA)

In accordance with the Congressional Review Act (CRA) of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

You can find additional information concerning the CRA form and instructions for completing it on the *NRC Rulemaker* web site. Questions concerning CRA may be directed to the Chief, Rules and Directives Branch.

Chapter 5 Direct Final Rules

Background

A direct final rule is a regulatory document that is used for non-controversial regulatory amendments. A direct final rule becomes effective in a certain number of days, usually 75 days after publication, unless the NRC receives significant adverse comments within a prescribed comment period, usually 30 days after publication. The NRC publishes a companion proposed rule with each direct final rule and announces in the direct final rule that any significant adverse comments received will be considered as comments on the companion proposed rule and that the NRC will not initiate a separate comment period for the action.

The direct final rule process allows an agency to issue a rule without having to go through the review process twice (i.e., at the proposed and final rule stages), while at the same time offering the public the opportunity to challenge the agency's view that the rule is non-controversial. The former Administrative Conference of the United States (ACUS) endorsed use of the direct final rule process as a means for expediting rulemaking (see ACUS Recommendation 95-4, Procedures for Non-controversial and Expedited Rulemaking (60 FR 43110; August 18, 1995)). Although not explicitly sanctioned by the Administrative Procedure Act (APA), this process complies with the APA under two rationales:

- The process comes within the meaning of the good cause exemption of section 553(b)(B) for bypassing the usual notice-and-comment requirements when public participation is unnecessary; i.e., the rule is non-controversial and unlikely to attract public comment.
- The process includes the essential elements of rulemaking required by the APA-- notice, an opportunity for comment, a statement of basis and purpose, and publication of the rule not less than 30 days prior to its effective date -- although these elements are not achieved exactly in the manner envisioned in the APA.

When to Use a Direct Final Rule

You should consider using the direct final rule process for non-controversial actions on which you do not expect to receive significant adverse comment. You may determine that the proposed rulemaking action is non-controversial if:

- NRC's experience in using notice-and-comment rulemaking for a particular category of rulemaking reveals that no significant adverse comments are received; or
- There is a demonstrated consensus in favor of the rulemaking action by the stakeholders who will be affected; or
- NRC staff articulates a reasonable basis for assuming that significant adverse comments are unlikely.

When you review a rulemaking to determine the likelihood of significant adverse comment you should consider whether the amendments being made by the rule:

- Are of a minor nature;
- Formalize an existing practice;
- Reflect an update to include a new, accepted technology;
- Adopt or update a generally accepted standard;
- Do not constitute a relaxation of current requirements; or
- Otherwise can be shown to be amendments unlikely to generate significant adverse comments.

Two types of NRC rulemakings that typically use the direct final rule process are the issuance of (or amendment to) a Certificate of Compliance listing in 10 CFR 72.214 and rules requiring the use of updated NRC Forms.

Direct Final Rule Procedures

The lead office drafts and publishes concurrently a direct final rule and a companion proposed rule. The direct final rule must contain language that states that any significant adverse comments received will be considered as comments on the companion proposed rule and that, absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a separate comment period for the action.

An NRC direct final rule becomes effective in a certain number of days, usually 75 days after publication, unless the NRC receives significant adverse comments within a prescribed comment period, usually 30 days after publication. The 45-day period between the close of the public comment period and the effective date of the direct final rule is provided to allow the NRC sufficient time to evaluate whether any of the comments received are significant adverse comments and, if so, to prepare and publish a withdrawal of the direct final rule.

If no public comments are received, the NRC publishes a subsequent document that confirms the effective date. (See the NRC Rulemaker web site for a sample document.) The direct final rule becomes effective on the date stated in the direct final rule or at least 30 days after the publication date of the confirmation document, whichever is later, unless the direct final rule grants or recognizes an exemption or relieves a restriction, in which case it becomes effective on the date specified in the direct final rule.

If public comments are received but they are not significant adverse comments, the NRC publishes a similar confirmation document. In this document the NRC may, in special circumstances, choose to explain why the comments received were not considered to be significant adverse comments in order to achieve added transparency to its determinations.

If significant adverse comments are received, the NRC publishes a document in the Federal Register that withdraws the direct final rule in whole or in part before

the specified effective date. If the NRC desires to proceed with the rulemaking, it prepares and publishes a subsequent final rule that addresses the comments received on the companion proposed rule that was published concurrently with the direct final rule.

If significant adverse comments are received and the NRC is unable to publish a document in the Federal Register that withdraws the direct final rule before the specified effective date, the direct final rule goes into effect. Accordingly, the NRC must return the affected regulations to their status before the direct final rule became effective by publishing a final rule document that removes the regulatory text codified by the direct final rule from the Code of Federal Regulations. If the NRC wishes to proceed with the rulemaking, it prepares and publishes a subsequent final rule that addresses the comments received on the companion proposed rule that was published concurrently with the direct final rule.

Direct Final Rule Document

Your direct final rule must meet the all of the procedural and format requirements outlined for final rules.

The direct final rule complies with all Office of the Federal Register (OFR) requirements applicable to publication of a final rule.

- Document headings.
- Preamble format requirements.
- List of subject index terms.
- Words of issuance.
- Amendatory language.
- Authority citation.
- Regulatory text: CFR codification.
- Regulatory text: Headings.
- Form of amendment: Section level or Part level.

The Supplementary Information section in a direct final rule provides the background discussion and specific information necessary to explain the basis and purpose of the regulation. You must included sufficient information in the Supplementary Information section to provide an adequate basis for the rulemaking on the record in the event of a court challenge to the final rule. The Supplementary Information section also explains the basis for NRC's conclusion that the rulemaking action is non-controversial and no significant adverse comments are anticipated. In addition, you must always include a standard paragraph describing the direct final rule process.

Example

Because NRC considers this action to be non-controversial, the NRC is using the direct final rule process for this rule. The amendments in this rule will become effective on [INSERT DATE 75 DAYS AFTER PUBLICATION IN THE

FEDERAL REGISTER] However, if the NRC receives significant adverse comments on this direct final rule by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published elsewhere in this Federal Register. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when —

(A) The comment causes the staff to reevaluate (or reconsider) its position or conduct additional analysis;

(B) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(C) The comment raises a relevant issue that was not previously addressed or considered by the staff.

(2) The comment proposes a change or an addition to the rule and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the staff to make a change (other than editorial) to the rule.

When you develop and issue a direct final rule, you must comply with all the legal and procedural requirements applicable to a final rule. The issues that you typically must address in a direct final rule document include:

National Technology Transfer and Advancement Act. A direct final rule may adopt a new, generally accepted consensus standard or update a previously accepted general consensus standard.

National Environmental Policy Act (NEPA). A direct final rule either qualifies as a categorical exclusion under 10 CFR 51.22(c) or you must prepare an environmental assessment and make a finding that the action has no significant impact (10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119).

Paperwork Reduction Act (PRA). A direct final rule does not impose a new information collection requirement or make a significant change to an existing information collection requirement. See the NRC Rulemaker web site for the appropriate PRA statement to include in your preamble. Note that there is a different PRA statement for each of these conditions:

- If the direct final rule does not affect Office of Management and Budget (OMB) clearance for an existing information collection requirement.
- If the direct final rule makes an insignificant change to existing information collection requirements.

- If the direct final rule and the current CFR Part do not contain an information collection requirement.

Regulatory analysis. A direct final rule is the type of action for which either a limited regulatory analysis is prepared or for which a regulatory analysis may be eliminated at the discretion of the Commission, the Executive Director for Operations (EDO), a Deputy EDO, or the responsible NRC office director. You may either include a statement that a regulatory analysis was not prepared and provide a brief discussion of the reason why a regulatory analysis is unnecessary, or include a statement concerning the regulatory analysis.

Regulatory Flexibility Act. Although the Regulatory Flexibility Act does not apply to a direct final rule because a proposed rule has not been prepared for the action, the NRC typically complies with the requirements of the Act to the extent that it certifies that the direct final rule will not have a significant economic impact on a substantial number of small entities. This practice is a precaution in case the NRC does receive significant adverse comment and must reissue the action as a final rule for which the companion proposed rule solicited public comment.

Backfit analysis. The backfit requirements of 10 CFR Chapter I generally would not apply to the type of rulemaking action for which the direct final rule process is used successfully.

Congressional Review Act. The congressional review provisions of the Congressional Review Act (CRA) apply to a direct final rule. You must submit a report concerning the action to each House of Congress and the Comptroller General. You must also request OMB verification of the determination that the action is not a major rule (as required by CRA) and include a statement to this effect.

Companion Proposed Rule to a Direct Final Rule Document

You must publish a companion proposed rule in the same issue of the Federal Register that contains your direct final rule document. The NRC announces in the direct final rule that any significant adverse comments received will be considered as comments on the companion proposed rule and that absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a separate comment period on the action.

Your companion proposed rule must meet all of the procedural and format requirements outlined for proposed rules. The OFR publication requirements include:

- Document headings.
- Preamble format requirements.
- List of subject index terms.
- Words of issuance.
- Amendatory language.
- Authority citation.
- Regulatory text: CFR codification.
- Regulatory text: Headings.

- Form of amendment: Section level or Part level.

The Supplementary Information section in your companion proposed rule must contain a cross-reference to the concurrently-published direct final rule. This cross-reference should direct the reader to information explaining the basis and purpose of the regulation and information concerning NRC's compliance with the legal and procedural requirements applicable to the rulemaking action. You must also include in the Supplementary Information section the following standard paragraph describing the direct final rule process and the role of the companion proposed rule:

Example

Because NRC considers this action non-controversial, we are publishing this proposed rule concurrently as a direct final rule. The direct final rule will become effective on [INSERT DATE 75 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. However, if the NRC receives significant adverse comments on the direct final rule by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period for this action in the event the direct final rule is withdrawn.

For a sample companion proposed rule to a direct final rule see the NRC Rulemaker web site.

Criteria for Determining a Significant Adverse Comment

The NRC's definition of a significant adverse comment is taken from ACUS Recommendation 95-4. A significant adverse comment is a comment in which the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change.

Use the following criteria to determine whether a comment on a direct final rule constitutes a significant adverse comment.

A comment is not adverse if:

- The comment supports the rule; or
- The comment is beyond the scope of the rule, that is, the comment presents issues or raises questions outside the scope of the changes being implemented by the rule.

A comment is adverse, but not significant, if:

- The comment opposes the rule but provides no reason;

- The comment opposes the rule and provides a reason but the comment does not raise an issue serious enough to warrant a substantive response in a notice-and-comment process (e.g., the reason is frivolous or non-substantive); or
- The comment proposes a change or addition to the rule but there is no indication that the commenter would object to the rule going forward as proposed.

A comment is adverse and significant if the comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

- The comment causes the staff to reevaluate (or reconsider) its position or conduct additional analysis;
- The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or
- The comment raises a relevant issue that was not previously addressed or considered by the staff.

Carefully review any comments you determine to be adverse but not significant. For the purposes of increasing public confidence, you may elect to treat as "adverse" comments that essentially protest or oppose an NRC action, even those that fail to provide a reason or issue that would warrant a substantive response.

In sum, a comment opposing the rule which is material, i.e., relevant to the rule, and which is non-frivolous and non-trivial, is likely a significant adverse comment under these criteria:

- The comment proposes a change or an addition to the rule and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.
- The comment causes the staff to make a change (other than editorial) to the rule.

Withdrawing a Direct Final Rule

If the NRC receives significant adverse comment on a direct final rule, you must publish a document in the Federal Register that withdraws the direct final rule. If the NRC desires to continue with the rulemaking action, the NRC publishes a subsequent final rule in the Federal Register that reissues the action with a new, deferred effective date and responds to any comments received on the direct final rule.

If you are unable to publish a document in the Federal Register that withdraws the direct final rule before the specified effective date, you publish a final rule document that withdraws the direct final rule and removes the regulatory text codified in that action from the Code of Federal Regulations. See the NRC

Rulemaker web site for a sample document that withdraws a direct final rule after the effective date and revokes the regulatory text codified by that action.

The NRC may delay the effective date of a direct final rule by publishing a document in the Federal Register before the specified effective date that announces the action. This document may either specify a new effective date or indicate that the effective date for the action will be established through publication of a subsequent document in the Federal Register. See the NRC Rulemaker web site for a sample document that delays the effective date of a direct final rule.

In special circumstances, you may choose to publish a document in the Federal Register that responds to any comments received on a direct final rule that were not considered to be significant adverse comments and, therefore, did not require that the direct final rule be withdrawn. This document responds to any questions or issues that may have been raised by the commenters and indicates why the NRC did not consider the comments to be significant adverse comments. See the NRC Rulemaker web site for a document that responds to public comments received on a direct final rule that were not considered to be significant adverse comments.

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Michael Lesar
Cindy Bladey

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11. ABSTRACT *(200 words or less)*

The NRC Regulations handbook is designed to assist NRC staff in drafting, preparing, and reviewing rulemaking documents for publication in the Federal Register. The handbook is intended to serve as a guidance tool, and provides information relevant to each step in the rulemaking process. This revision reflects changes resulting from the consolidation of rulemaking policy matters into Management Directive 6.3, "The Rulemaking Process," and the placement of sample documents and some procedures on the NRC Rulemaker web site. This revision also updates various other changes that have occurred in the rulemaking process and in NRC procedures since the last complete revision in 2001.

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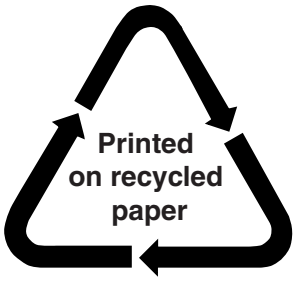

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