

United States Nuclear Regulatory Commission Regulations Handbook

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



United States Nuclear Regulatory Commission Regulations Handbook

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M.T. Lesar

**Division of Administrative Services
Office of Administrative Services
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001**



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FOREWORD

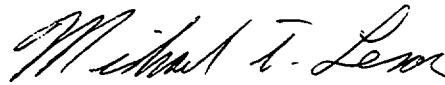
The *NRC Regulations Handbook* is designed to assist the NRC staff in drafting and preparing rulemaking documents for publication in the *Federal Register*. The handbook contains procedures, requirements, and background information essential to those who develop or review rulemaking actions for the NRC. The handbook was first published in August 1982 as NUREG/BR-0053; supplements to the handbook were issued in April 1983, June 1984, and September 1985; and it was revised in its entirety in November 1987, December 1989, June 1995, and September 1997. This is the fifth complete revision of the handbook. This revision reflects amendments to Management Directive 6.3, "The Rulemaking Process," which was necessary to reflect the transfer of NRC rulemaking responsibility from the Office of Nuclear Regulatory Research to the Office of Nuclear Material Safety and Safeguards and the Office of Nuclear Reactor Regulation. This revision also reflects significant changes that have occurred since September 1997 in the rulemaking process and NRC procedures.

The handbook is intended to serve as a guidance tool for the professional staff who prepare, review, and coordinate rulemaking items; it provides the information relevant to each step in the rulemaking process. Because some of the information is similar at successive steps in the rulemaking process, there is occasional duplication. Our experience has shown that this format is most helpful to users because it allows them to find all of the needed information concerning a particular step in the process in one place rather than having to follow a system of cross-references. In addition, we have used all odd numbers in designating parts and sections to illustrate one suggested method of leaving room to accommodate future changes.

The handbook also provides guidance to the staff who prepare packages containing a *Federal Register* rulemaking document for transmittal to the Office of the Federal Register. The handbook contains information and examples that may prove helpful to administrative, program

support, and clerical personnel involved in the preparation or tracking of rulemaking packages. Because the rulemaking process changes continuously, the handbook is designed to incorporate future supplements. Specific instructions to update the handbook will accompany any revised material.

Please direct questions concerning the use of the handbook or the rulemaking process, suggestions for improving the content or format of the handbook, or corrections of any errors or inconsistencies in the handbook to me (301-415-7163) or by e-mail (MTL).

A handwritten signature in cursive script, reading "Michael T. Lesar".

Michael T. Lesar, Chief
Rules and Directives Branch
Office of Administration

PART 1 - NRC RULEMAKING: BACKGROUND

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1.1 Administrative rulemaking.

(a) The Administrative Procedure Act.

(1) The Administrative Procedure Act of 1946 (APA) (5 U.S.C. 551, et seq), as amended, presents the minimum procedural requirements that Federal agencies are required to follow when they promulgate rules and conduct adjudicatory proceedings. The APA --

- (i) Provides the public, with stated exceptions, the right to participate in the rulemaking process by commenting on proposed rules;
- (ii) Requires that the effective date of a regulation be not less than 30 days from the date of publication unless there is good cause for an earlier date;
- (iii) Provides for the publication of agency statements of organization and procedural rules; and
- (iv) Establishes the standard of judicial review of administrative actions.

(2) The primary goal of the APA is to ensure that agencies observe procedural due process (i.e., fairness) in conducting their regulatory and administrative affairs. Appendix B to this handbook sets out the provisions of the APA that govern notice and comment rulemaking (5 U.S.C. 553).

(3) In establishing minimum procedural requirements, the APA permits agency flexibility in developing additional procedural requirements. These requirements can be found for each agency in the *Code of Federal Regulations* (CFR). The additional rulemaking policies for the NRC appear in Management Directive (MD) 6.3, "The Rulemaking Process." A description of the legal requirements for rulemaking and NRC's basic internal procedures are discussed in more detail in this part of this handbook.

(4) Enabling legislation for an agency, specific acts that an agency administers, or judicial decisions resulting from legal challenges to agency actions may require the agency to follow additional procedural requirements in developing its regulations.

(b) The *Code of Federal Regulations*.

(1) The CFR is a codification of the regulations promulgated by Federal agencies. The CFR is edited annually to present the regulations effective as of the revision date of the volume. The CFR, used in conjunction with the daily *Federal Register*, provides a current version of an agency's regulations.

(2) The CFR is divided into 50 titles according to subject matter. These titles are divided into chapters, chapters are divided into parts, and parts are divided into sections. NRC regulations are contained in 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.

(c) The *Federal Register*.

(1) 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 agendas of regulations, meeting announcements, and other agency documents concerning the conduct of public business. These documents are discussed in subsequent sections of this handbook.

- (2) The publication of a document in the *Federal Register* has certain legal effects.
 - (i) Publication provides official notice of a document's existence and content.
 - (ii) Publication creates a rebuttable presumption that the text is a true copy of the original document and that the document was duly issued, prescribed, and promulgated.
 - (iii) The contents of the *Federal Register* are judicially noticed by a court of law.
- (3) The OFR's publication requirements for the different types of documents published in the *Federal Register* are covered in this handbook. However, the OFR may occasionally modify these requirements. Questions regarding the most current OFR requirements for publication or special publication requests should be directed to the Rules and Directives Branch (RDB), Office of Administration (415-7163).

1.3 NRC rulemaking.

(a) The NRC may develop a regulation in response to --

(1) Congressional promulgation of a new statute requiring new regulatory requirements;

(2) Commission, Advisory Committee on Reactor Safeguards, or NRC staff initiatives indicating a need for further regulation to resolve a safety, safeguards, or environmental problem;

(3) The receipt of a petition for rulemaking; or

(4) The need for a conforming, corrective, or other type of administrative action.

(b) The NRC complies with the APA and all other laws applicable to the rulemaking process as it develops a regulation (see 10 CFR Part 2, Subpart H). The handbook contains an appropriate discussion of each basic statutory requirement that affects rulemaking where relevant. In like manner, the NRC prepares rulemaking documents in accordance with the regulations established by the OFR (1 CFR Chapter 1).

(c) The NRC has established policy on and objectives for the rulemaking process in MD 6.3. The policies established in the management directive and the procedures of this handbook are intended to ensure that --

(1) Responsibilities are established for all NRC offices and employees who are involved in the rulemaking process;

(2) Schedules for rulemaking actions, including the significant steps for a rulemaking as outlined in paragraph (d) of this section, are established and met;

(3) Coordination occurs among NRC offices during the development of a rulemaking action;

(4) NRC staff resources are used efficiently in developing rules; and

(5) Agreement States are provided an early opportunity to comment on draft rulemaking plans and rulemaking actions.

(d) This paragraph provides a brief narrative overview of the significant steps in an NRC rulemaking action. A significant step is the approval of the rulemaking plan or the publication of a document in the *Federal Register* concerning the rulemaking.

(1) Notice and comment rulemaking. The vast majority of NRC rulemakings are developed in compliance with the notice and comment requirements of the APA (5 U.S.C. 553). The significant steps in this process, as implemented by the NRC, are --

- (i) Rulemaking plan;
- (ii) Proposed rule; and
- (iii) Final rule.

(2) Enhanced public participation. The Commission may direct that a rulemaking be developed using enhanced public participation (see Part 9 of this handbook). The significant steps in this process are --

- (i) Rulemaking plan;
- (ii) Advance notice of proposed rulemaking or other, less formal, notification of the contemplated action and request for public comment or other form of public participation;
- (iii) Proposed rule;
- (iv) Announcement of a meeting, hearing, or workshop, if applicable;
- (v) Extension of comment period, if applicable;
- (vi) Final rule.

(3) Direct final rule. If the NRC determines that it is not likely to receive significant adverse comment on a noncontroversial action, the NRC may choose to develop the rulemaking as a direct final rule. The significant steps in this process are --

- (i) Direct final rule and companion proposed rule;

(ii) If no significant adverse comments are received, a document confirming the effective date;

(iii) If significant adverse comments are received --

(A) Withdrawal of direct final rule before its effective date or revocation of the regulation imposed by the direct final rule after its effective date; and

(B) Subsequent final rule.

1.5 Commission rulemaking authority.

(a) Rulemaking authority for the NRC is vested in the Commission by the Atomic Energy Act, as amended by the Energy Reorganization Act (42 U.S.C. 2201). The Commission has delegated specific rulemaking authority to the Executive Director for Operations (EDO) and the Chief Financial Officer (CFO) (see Sections 1.7 and 1.9 of this handbook). The Commission has retained exclusive authority to issue regulations concerning --

(1) A significant question of policy (see Sections 1.7(b) and (c) of this handbook for more information on determining whether an action constitutes a significant question of policy);

(2) 10 CFR Parts 7, 8, and 9 (Subpart C) concerning matters of policy; or

(3) 10 CFR Part 2 if the Office of the General Counsel (OGC), the Office of Commission Appellate Adjudication, or the Atomic Safety and Licensing Board Panel fail to concur on the action.

(b) A rulemaking action is forwarded for the Commission's consideration via a Commission paper submitted through the EDO or the CFO. The EDO Procedures Manual provides guidance as to the type of Commission paper that should be used for a particular type of action.

(c) When the rulemaking action is forwarded to the Commission for consideration, the Office of the Secretary (SECY) schedules it for the Commission's consideration, with or without oral presentations, at a Commission meeting. Usually, Commission meetings on these matters are open to the public under the Government in the Sunshine Act. In some cases, such as those involving classified or safeguards matters, the meeting may be closed to the public. Copies of the Commission paper are sent to every Commission-level office

that may have an interest in the regulation. The Commission may approve the regulation as submitted by the EDO or the CFO, approve the regulation subject to specified changes, disapprove the regulation entirely, or direct that the regulation be revised and issued or revised and resubmitted to the Commission for reconsideration.

(d) The Commission's decision on a regulation is reflected in a staff requirements memorandum (SRM) issued by SECY. If the Commission orders changes to be made in the regulation, the SRM describes these changes and establishes the deadline for resubmission for Commission consideration or submission for signature and publication.

1.7 EDO rulemaking authority.

(a) The EDO has certain rulemaking authority delegated by the Commission (see the final rule published in the *Federal Register* on March 19, 1982 [47 FR 11816], as amended on October 18, 1985 [50 FR 42145] and MD 9.17, "Organization and Functions, Office of the Executive Director for Operations"). Subject to general policy guidance from the Commission, the EDO has the authority to issue all proposed or final rules except those involving --

- (1) A significant question of policy;
- (2) 10 CFR Parts 7, 8, or 9 (Subpart C) concerning matters of policy; or
- (3) 10 CFR Part 2 if OGC, the Office of Commission Appellate Adjudication, or the Atomic Safety and Licensing Board Panel fails to concur on the action.

(b) (1) A rule involves a "significant question of policy" and must be submitted to the Commission for approval and issuance if it --

- (i) Represents a major change in existing Commission policy;
 - (ii) Represents a major new issue; or
 - (iii) Results in a major commitment of resources by a class of licensee.
- (2) In determining whether a rule is considered to involve a significant question of policy, the lead office should consider the --
- (i) Impact of the action on licensees and the public;
 - (ii) Degree of controversy that may be associated with the action;
 - (iii) Existence of significant public health, safety, environmental, or common defense and security questions;
 - (iv) Applicability of existing precedent; and
 - (v) Resources that will be required for implementation.

(c) The following types of rules should be submitted to the EDO for signature unless they fall within one of the excepted parts of 10 CFR Chapter I.

(1) A rule involving a minor change in policy. This type of rule involves a situation in which existing policy is essentially followed with minor modifications to fit a particular situation.

(2) A rule involving a minor new issue. This type of rule involves a situation in which-

(i) The issue was previously considered by the Commission in a similar context;

(ii) The rule has limited impact;

(iii) The rule does not present important health, safety, environmental, or safeguards or security questions; or

(iv) The rule requires limited resources to implement.

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

(d) (1) A final rule may be submitted for the EDO's signature if the Commission has considered all significant questions of policy in connection with the proposed rule and--

(i) No significant adverse questions or comments have been received on the proposed rule; or

(ii) No substantial changes in regulatory text are necessary.

(2) The lead office should take care to ensure that important new rules involving significant public interest are brought before the Commission if comments received suggest that the Commission might wish to reconsider certain provisions of the proposed rule even when the lead office determines that no changes to regulatory text are necessary. For this reason, final rules that implement the Nuclear Waste Policy Act must be forwarded for the Commission's review.

(e) If the rule falls within the scope of the EDO's rulemaking authority, the office director of the lead office shall forward it to the EDO by memorandum. The memorandum must explain the basis and purpose of the rule. In addition, the lead office shall include a certification statement (the approved-for-publication page), prepared for the EDO's signature, that appears after the office director's signature. This statement must identify the rule and explain how it falls within the scope of the EDO's rulemaking authority. If appropriate, the statement should reference earlier Commission policy decisions that relate to the subject of the rule. See Section 19.5 of this handbook for a sample memorandum and certification statement for a rule prepared for the EDO's signature.

(f) The EDO shall obtain concurrence from the CFO indicating that the CFO has no resource-related objection to the rulemaking. The lead office shall obtain the required CFO concurrence before the rulemaking is submitted to the EDO for signature.

(g) The EDO shall inform the Commission of each time he or she exercises his or her rulemaking authority.

(1) The EDO shall notify the Commission of each proposed rule he or she issues for publication in the *Federal Register* through a Weekly Information Report entry for the proposed rule. The lead office shall prepare the Weekly Information Report entry and include it with the memorandum forwarding the proposed rule for EDO signature. See Section 19.5 of this handbook for a sample Weekly Information Report entry. After the proposed rule has been signed, the lead office shall forward the completed rulemaking package to RDB for final action (see Appendix A of the handbook for document submittal procedures).

(2) The EDO shall notify the Commission before forwarding a final rule for publication in the *Federal Register* through a Notice of Final Rule Signed by the EDO (formerly the Daily Staff Notes entry for the final rule). The lead office shall prepare the Notice of Final

Rule Signed by the EDO and include it with the memorandum forwarding the final rule for the EDO's EDO signature. See Section 19.5 of this handbook for a sample entry. The EDO will forward a copy of the Notice of Signature and the final rule for circulation in the Commission's reading file, and return the signed rule to the lead office. A rule signed by the EDO may not be forwarded to the Office of the Federal Register for publication for 5 working days after the date it was signed. This practice provides the Commission with an opportunity to review the action before it is issued as an official agency action. When the 5-working-day period has elapsed, the lead office shall forward the completed rulemaking package to RDB for final action (see Appendix A of the handbook for document submittal procedures).

1.9 CFO rulemaking authority.

(a) The CFO has certain rulemaking authority delegated by the Chairman (see the memorandum from the Chairman to the Acting CFO dated February 18, 1997). The CFO has the authority to develop and issue rules needed to carry out his or her responsibilities, including the revisions to the annual fee regulations in Parts 170 and 171.

(b) The CFO's rulemaking authority does not extend to the promulgation of proposed or final rules that involve significant questions of policy. For rules that raise policy issues, the CFO shall consult with the Commission or, in cases involving the Chairman's rulemaking authority, with the Chairman.

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

(d) The CFO shall inform the Commission of each time he or she exercises his or her rulemaking authority.

(1) The CFO shall notify the Commission of each proposed rule he or she issues for publication in the *Federal Register* through a Weekly Information Report entry for the proposed rule. The CFO shall prepare the Weekly Information Report entry and include it with the memorandum forwarding the proposed rule for the CFO's signature. See Section 19.5 of this handbook for a sample Weekly Information Report entry. After the proposed rule has been signed, the CFO shall forward the completed rulemaking package to RDB for final action (see Appendix A of the handbook for document submittal procedures).

(2) The CFO shall notify the Commission before forwarding a final rule for publication in the *Federal Register* through a Notice of Final Rule Signed by the CFO. The CFO shall prepare the Notice of Final Rule Signed by the CFO and include it with the memorandum

forwarding the final rule for the CFO's signature. See Section 19.5 of this handbook for a sample entry. The CFO will forward a copy of Notice of Final Rule Signed by the CFO and the final rule for circulation in the Commission's reading file, and return the signed rule to the lead office. A rule signed by the CFO may not be forwarded to the Office of the Federal Register for publication for 5 working days after the date it was signed. This practice provides the Commission with an opportunity to review the action before it is issued as an official agency action. When the 5-working-day period has elapsed, the CFO shall forward the completed rulemaking package to RDB for final action (see Appendix A of the handbook for document submittal procedures).

PART 3 - NRC RULEMAKING: PROCEDURES

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3.1 Rulemaking initiation.

(a) **Rulemakings initiated by the NRC staff.** Each program office is responsible for initiating and developing each element of a rulemaking action in the subject areas for which the office is responsible and becomes the lead office for that rulemaking. An office that wishes to initiate a rulemaking action shall prepare a rulemaking plan as described in Section 3.3 of this handbook and shall obtain approval to proceed with the rulemaking as described in paragraph (c) of this section.

(b) **Rulemakings initiated by the Commission.** If the Commission directs the staff to undertake a rulemaking action, the lead office shall develop a rulemaking plan for the action to the extent practicable.

(c) **Rulemaking plan approval.**

(1) The Commission approves or denies the rulemaking plan, or major modifications to a plan, for any rulemaking that is not within the authority delegated to the Executive Director for Operations (EDO) or the Chief Financial Officer (CFO) (see Section 1.5 of this handbook). A rulemaking plan is forwarded for the Commission's consideration through the EDO or the CFO, as appropriate.

(2) The EDO approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the EDO by the Commission (see Section 1.7 of this handbook). The EDO provides a copy of the draft rulemaking plan to the Commission via a Commission note and a final rulemaking plan via a negative consent paper.

(3) The CFO approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the CFO

by the Chairman (see Section 1.9 of this handbook). The CFO provides a copy of the draft rulemaking plan to the Commission via a Commission note and a final rulemaking plan via a negative consent paper.

(e) Rulemaking plan unnecessary.

(1) A rulemaking plan is not required if the Commission specifically directs the initiation of a rulemaking action. The lead office may develop a modified rulemaking plan to aid in guiding the process.

(2) A rulemaking plan is not required if the issue to be resolved is of sufficient urgency that the office directors, the Office of the General Counsel (OGC), and the EDO or the CFO will exercise direct oversight in the development of the rule. Because a rule developed in this type of situation would normally be issued by the Commission, the EDO or the CFO formally notifies the Commission of the rulemaking activity via a Commission note, provides a rationale for proceeding without a rulemaking plan, obtains the Commission's approval for the action, and provides the plans for notifying Agreement States, when applicable.

(i) Each proposed rule developed under these conditions must be submitted to the Commission for approval.

(ii) The need to obtain the Commission's approval for proceeding without preparing a rulemaking plan does not diminish the authorities specifically delegated to the EDO, OGC, and office directors regarding matters that are a significant threat to public health and safety.

(3) A rulemaking plan is not required if the issue is to be addressed through the issuance of a direct final rule.

(4) A rulemaking plan is not required if the rulemaking action is purely administrative in nature.

3.3 The rulemaking plan.

(a) Except as provided in Section 3.1(e) of this handbook, the lead office, in consultation with OGC and the other offices that will participate in the rulemaking, shall develop a proposed rulemaking plan for each contemplated rulemaking, including situations in which the NRC staff is recommending that a petition for rulemaking be granted. The rulemaking plan provides a preliminary outline of the scope and impact of the contemplated action sufficient for the approving official to determine that the contemplated rule is needed and desirable and to approve the continuation of the action before the agency expends resources on the project. The rulemaking plan also provides a framework for completing the contemplated action and a mechanism for obtaining early substantive input from the Agreement States.

(b) The proposed rulemaking plan must contain the following types of information:

(1) The plan must define the regulatory problem or issue that is to be resolved through the rulemaking action. This definition may identify a safety concern, the need to facilitate the licensing process, or the need to provide relief of an unnecessary regulatory burden. The definition must include --

(i) A description of the existing regulatory framework; and

(ii) An explanation of why the NRC or the licensees cannot take actions to resolve the problem effectively within the existing regulatory framework or why the necessary actions under the existing framework are burdensome.

(2) An initial determination of whether the rulemaking will be developed using risk-informed, performance-based criteria;

(3) An analysis of legal sufficiency provided by OGC that must demonstrate that there are no known bases for legal objection to the contemplated rulemaking. The analysis also must describe any potential legal complications identified by OGC that should be anticipated.

(4) The general basis for believing that the contemplated rulemaking is likely to be cost-effective and will meet backfit criteria, if appropriate. This conclusion should be reached by considering the preliminary analysis of available information.

(5) An indication of whether there are any known problems that could affect Agreement State implementation of the contemplated rulemaking action. If the rulemaking may affect Agreement States, the plan must include a suggested Agreement State compatibility classification for the proposed rule. If the compatibility classification for Agreement State regulations is "C" or "H and S," the plan must identify the essential objectives of each section of the proposed rule. (See Office of State and Tribal (STP) Internal Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.") Agreement States will be provided an opportunity to comment on the draft rulemaking plan through the procedures presented in Section 3.9 of this handbook.

(6) An identification of the supporting documents that are expected to be developed to complete and to implement the contemplated rulemaking action. Supporting documents could include a generic environmental impact statement (GEIS); the clearance package necessary to obtain Office of Management and Budget (OMB) approval of new or amended information collection requirements; regulatory impact analyses, including information sufficient either to constitute a regulatory flexibility analysis or to support a certification that the proposed regulation will not have a significant economic impact on a substantial number of small entities as required by the Regulatory Flexibility Act; and other related documents such as regulatory guides, NUREGs, inspection plans, or enforcement guidance.

(7) An indication of whether the contemplated rulemaking will be a major rule, as defined by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (Pub. L. 104-121) and a basis for the determination. (See Appendix F to this handbook for a definition of "major rule" and an explanation of the requirements of the SBREFA.)

(8) An indication of whether a technical standard developed by a voluntary consensus standards body is appropriate for use instead of a Government-unique standard as required by the National Technology Transfer and Advancement Act of 1995 or whether there are no applicable standards (see Section 5.13 of this handbook).

(9) The resources that are expected to be necessary to complete and implement the contemplated rulemaking action, including the resources needed to develop the supporting documents identified in paragraph (b)(6) of this section. The discussion must indicate whether these resources are included in the projected budget for the next 2 years. This discussion must also identify the office(s) that will be responsible for each activity.

(10) An indication of whether the EDO or the CFO may issue the rule under the rulemaking authority delegated to the EDO or the CFO by the Commission.

(11) The name of the lead office staff and the key staff within each office who will be involved in the contemplated rulemaking action.

(i) The senior manager designated by each office director to concur for that office. Each designee is responsible for keeping the office director informed of key policy issues related to the rulemaking action.

(ii) An indication of whether a steering group or a working group format will be used to develop the contemplated rulemaking action (see Section 3.5 of this handbook for a discussion of the working group concept).

(12) A discussion of whether enhanced public participation, as described in Section 3.7 of this handbook, should be employed in the rulemaking process. The plan also must describe

any special measures or procedures to be employed in the rulemaking process such as the use of negotiated rulemaking.

(13) A schedule for preparing the necessary supporting information, completing the proposed rule, analyzing public comments, and completing the final rule.

(i) The schedule must be established on the basis of --

(A) The priority or importance given to the action;

(B) The complexity of the issues to be resolved;

(C) The number and complexity of supporting documents, such as regulatory guides or a GEIS, or technical tools, such as computer codes needed for implementation; and

(D) The degree of interaction or negotiation with interested parties needed to complete the rulemaking.

(ii) Unless the contemplated rulemaking action would require the development of a resource-intensive technical analysis or guidance document, every effort should be made to complete the rulemaking action within 18 months from the date the rulemaking plan is approved.

(iii) A rulemaking plan should not be submitted when there are significant gaps in the technical basis for formulating or implementing the rule unless the necessary nature and extent of these gaps, and the likelihood of closing them, are explicitly addressed in the rulemaking plan.

(c) The lead office shall make the rulemaking plan available to the appropriate advisory committees and to the Committee To Review Generic Requirements. Each appropriate committee may be included as a cc on the concurrence memorandum.

(d) The following actions are taken after the Commission, the EDO, or the CFO has approved a rulemaking plan.

(1) The Office of Administration (ADM) shall make the approved rulemaking plan available to the NRC staff through the interactive rulemaking website (<http://ruleforum.llnl.gov>).

(2) ADM shall include a new regulatory agenda entry in the next edition of the *NRC Regulatory Agenda* and on the NRC internal Website. If the intended action will be a major rule, ADM shall include an entry for it in the *NRC Regulatory Plan* that is submitted to the OMB as required by Executive Order 12866. (See Section 5.1(a)(4) of this handbook for additional information concerning the regulatory agenda.)

(3) The lead office shall prepare an entry for inclusion in the Rulemaking Activity Plan.

(4) Each participating office will implement the plan as approved by the Commission, the EDO, or the CFO. The office representative for each office will oversee the activities of his or her office so that the schedule is maintained.

(e) A rulemaking plan should be revised when it becomes apparent that there is a significant change in one of the fundamental premises underlying the contemplated rulemaking sufficient to alter the projected scope, outcome, resource expenditures, and time frame of the action. A revision to a rulemaking plan must be approved at the same level that the original rulemaking plan was approved.

3.5 Working group.

(a) The lead office may establish a working group for a particular rulemaking action. When appropriate, a working group may be formed before a rulemaking plan is approved. Working groups are especially helpful in facilitating staff action on significant rulemaking endeavors. Staff from the lead office, concurring offices, and OGC generally comprise the working group for a specific rulemaking action. The working group should have –

- (1) A task leader from the lead office who serves as the project manager and is responsible for completing the action;
- (2) A member from other units within the lead office that have program responsibilities related to the rulemaking;
- (3) A member from OGC to provide legal advice and support;
- (4) A member from other staff offices, as appropriate. If the involvement of another staff office in a rulemaking is limited to a specific area, such as matters related to regulatory flexibility, information collection, Agreement State compatibility, inspection, or enforcement, the involvement of the working group member from that office may be limited to that specific area;
- (5) An Agreement State representative, as appropriate.

(b) The working group for a specific rulemaking action is responsible for –

- (1) Assessing the scope of the rulemaking action, identifying the tasks necessary to complete the rulemaking action, identifying members who will be responsible for completing these tasks, and developing schedules and resource estimates for completing each stage of the rulemaking action;
- (2) Assisting the lead office in preparing the rulemaking plan, the proposed and final rule packages, and all necessary supporting documents;

(3) Addressing comments, estimating the information collection burden, and preparing briefing materials;

(4) Reviewing contractor reports or monitoring contractor effort if contract support is necessary;

(5) Preparing associated guidance, including licensing, inspection, and enforcement guidance, as appropriate, and coordinating the completion of the guidance so that the final guidance is available when the final rule becomes effective; and

(6) Facilitating the concurrence process by keeping his or her management informed of the significant issues of concern to that office and assisting in developing an appropriate resolution of those issues.

(c) A steering group may be established for certain significant rulemaking actions. The steering group is composed of senior managers from the affected offices and OGC. The steering group resolves significant questions of policy and facilitates concurrence of the rulemaking plan.

3.7 Enhanced public participation.

(a) The NRC may designate certain significant rulemakings for enhanced public participation throughout their development and publish an advance notice of proposed rulemaking (ANPR) (see Part 11 of this handbook) or other less formal types of documents to invite public participation. The publication of an ANPR or any other type of document announcing enhanced public participation does not represent a commitment by the NRC to issue a proposed or final rule on the matter in question. This issue remains a matter of agency discretion unless Congress has mandated rulemaking concerning the contemplated action. Public response to the enhanced public participation initiative is a factor in determining whether or not the rulemaking proceeding continues beyond this preliminary stage and, if continued, the direction taken in developing the proposed and final rule.

(b) **ANPR.** An ANPR is the most formal method of beginning an enhanced public participation rulemaking. In an ANPR, the NRC generally describes a problem or situation and may present an outline of the anticipated regulatory response to the problem. The NRC may propose several alternative solutions in an ANPR and request public comment on each alternative. Although regulatory text is not essential in an ANPR, the NRC may choose to present its anticipated action as an amendment to the regulations in 10 CFR Chapter I to direct public attention to and encourage public comment on the changes under consideration. If regulatory text is not presented, NRC may describe its intended approach in narrative fashion and present a list of questions and issues for comment to direct public attention to the type and nature of the changes under consideration.

(c) The NRC has used a number of other types of vehicles, most of which are less formal than an ANPR, to encourage enhanced public participation in developing a proposed

rule. These same actions may be used to encourage further public participation when developing a final rule after a proposed rule has been published.

(1) **Negotiated rulemaking.** Negotiated rulemaking is a formal process that is used to bring interested parties into the regulatory process, including the drafting of regulatory text, at an early stage under circumstances that encourage cooperation to solve regulatory problems. The interested parties are brought together under the direction of a facilitator and attempt to reach consensus on the text of a proposed rule that is acceptable to each party. The sponsoring agency is represented by a senior official who is authorized to speak on behalf of the agency.

(2) **Interactive rulemaking.** The Commission may direct the NRC staff, as part of an enhanced public participation initiative, to conduct an interactive rulemaking with the public. In this type of proceeding, a special entry for the action would appear in Ruleforum, a World Wide Web site developed by the NRC to further public access to and participation in its rulemaking actions. The site for this rulemaking would contain additional information concerning the action, such as contemplated regulatory text in draft form or the regulatory approach that is under consideration, and would request public responses.

(3) **Requests for comment or participation.** The NRC frequently requests public comment or participation in a particular rulemaking action through a more informal medium than an ANPR. In these instances, the NRC publishes a document in the *Federal Register* that explains NRC's anticipated action and requests public comment on its intent. In developing its proposed revision of the medical licensing regulations, the NRC solicited informal public input on the development of proposed rule language and associated documents.

(4) **Meetings or workshops.** The NRC may conduct a series of public meetings or workshops to obtain public input on a regulatory issue or an area of the regulations that may be

a candidate for rulemaking or language that may be considered at either the proposed rule or the final rule stage.

(d) Please see Part 11 of this handbook for the requirements applicable to the preparation of a document beginning an enhanced public participation rulemaking.

3.9 Agreement State review.

(a)(1) If a rulemaking may affect the Agreement States and Agreement State review is necessary (see Section 5.9 (e) of this handbook), the lead office provides a copy of the draft rulemaking plan to STP after offices have concurred in the rulemaking plan and the EDO or the CFO provides a copy of the draft rulemaking plan to the Commission via a Commission note. The copy must be marked in block form "PREDECISIONAL DRAFT INFORMATION, FEDERALLY PROTECTED, NOT FOR PUBLIC DISCLOSURE." STP provides a copy of the draft rulemaking plan to the Agreement States by placing it on the Technical Conference Forum (<http://techconf.llnl.gov>) that is dedicated to Agreement States. Agreement States have 45 days in which to submit any comments.

(i) Some rulemaking plans may be sent to the Commission for its consent before they are made available to the Agreement States if the contemplated rulemaking involves controversial policy issues.

(ii) If a rulemaking plan is not required, STP notifies the Agreement States of the rulemaking action.

(2) At the same time, the lead office notifies the Conference of Radiation Control Program Directors (CRCPD) Council Chair that is responsible for suggested State regulations through the Technical Conference Forum (<http://techconf.llnl.gov>).

(b) After consulting with the appropriate NRC offices and the OGC, the lead office revises the draft rulemaking plan in response to comments submitted by the Agreement States and the CRCPD. The revised plan is submitted to the Commission, the EDO, or the CFO, as appropriate, for approval. The submittal package must address Agreement State comments or contain an attachment that indicates the staff's disposition of Agreement State and CRCPD

comments. Note that if significant comments are received from the Agreement States, the rulemaking plan may have to be resubmitted for office concurrence.

(c)(1) If the rulemaking plan is approved, the lead office informs the Agreement States and the public of the staff's intention to proceed with the development of a proposed rule through the Technical Conference Forum.

(i) The lead office creates an entry for the *NRC Regulatory Agenda* and forwards the entry to ADM for inclusion in the next edition of the *NRC Regulatory Agenda* and the *Unified Agenda of Regulatory and Deregulatory Actions*.

(ii) The lead office notifies the CRCPD Council Chair responsible for suggested State regulations of the plan's approval through the Technical Conference Forum so that the parallel development of a suggested State regulation could begin, if such an action is desired.

(2) If the Commission does not approve the rulemaking plan, the lead office notifies STP and the CRCPD Council Chair responsible for suggested State regulations through the Technical Conference Forum that the plan was not approved.

(d) If a draft proposed rule is clearly applicable to Agreement State interests (see Section 5.9(e) of this handbook), Agreement State involvement will be sought on preliminary versions of the draft proposed rule. Agreement State involvement may be sought through working group participation and posting preliminary versions of the draft proposed rule on the Technical Conference Forum for comment.

3.11 Advisory committee review.

(a) When a proposed rule is sent for office concurrence, the lead office shall forward it to the appropriate advisory committee for review in accordance with its own procedures. The proposed rule may be forwarded to the appropriate committee as a cc to the concurrence request memorandum. The advisory committees are the --

- (1) Advisory Committee on Reactor Safeguards;
- (2) Advisory Committee on Nuclear Waste; and
- (3) Advisory Committee on the Medical Uses of Isotopes.

(b) The lead office shall formally document and respond to any consensus comments or recommendations from the advisory committee concerning the rulemaking action. The analysis and response to public comment must be presented in the Supplementary Information section of the proposed or final rule, as appropriate.

(c) If an individual committee member participates in a rulemaking apart from the committee, the comments received from the individual are maintained as part of the rulemaking record.

(d) The lead office shall meet with the appropriate committee, at the committee's request, at any time during the rulemaking process to discuss its rationale for the proceeding.

3.13 Coordination with the Office of Public Affairs: Press release.

(a) Shortly before the proposed or final rule is forwarded for office concurrence, the lead office shall contact the Office of Public Affairs (OPA) concerning whether a press release is to be prepared for the rulemaking. The lead office provides the OPA with a draft of the proposed or final rule that will be forwarded for office concurrence, as well as draft versions of any supporting documents developed for the action.

(1) OPA determines whether a press release is necessary or desirable for a proposed or final rule.

(2) If a press release is necessary or desirable for a proposed or final rule, OPA prepares the draft press release. The lead office reviews the draft press release and provides its comments to OPA.

(3) If a press release is prepared, a paper copy of the draft press release is included in the concurrence package with the Commission paper or attached to the memorandum requesting the signature of the EDO or the CFO. The press release is not listed as an attachment in the Commission paper or the memorandum itself. The press release and the draft congressional letters are forwarded to the Commission separately from the Commission paper.

(4) If OPA determines that a press release is not necessary or desirable, a note to that effect is included in the Commission paper or the memorandum requesting the signature of the EDO or the CFO.

(b) The lead office shall inform OPA of any change in the proposed or final rule resulting from the concurrence process, EDO or CFO review, or Commission action that would

require a change in the press release or the preparation of a press release if one was originally determined to be unnecessary.

(c) When the staff requirements memorandum (SRM) is prepared, the Office of the Secretary (SECY) will inform OPA of any changes to the press release directed by the Commission in its action on the paper. After making these changes, OPA will review the press release with the lead office to make sure that the changes are technically accurate, that no other changes are needed to reflect the SRM, and that no other actions need to be taken before the press release is issued. The lead office shall continue to coordinate with the OPA until the proposed or final rule is submitted for publication and the press release is issued.

(d) If possible, the lead office shall notify OPA shortly before the SRM is issued for a proposed or final rule or when the EDO or the CFO has signed the proposed or final rule. This action allows OPA to issue the press release at the earliest appropriate time.

3.15 Concurrences on and legal review of a rulemaking action.

(a) The lead office shall obtain appropriate concurrences for each significant action taken during the development of the rulemaking. At a minimum, appropriate concurrences must be obtained for –

- (1) Each rulemaking plan before it is submitted for approval;
- (2) Each proposed rule package before the proposed rule is submitted to the Commission for consideration or to the EDO or the CFO for signature and publication;
- (3) Each final rule package before the final rule is submitted to the Commission for consideration or to the EDO or the CFO for signature and publication; and
- (4) Each document relating to the rulemaking before it is submitted for signature and publication.

(b) An office director and the General Counsel shall sign for his or her office regarding concurrence on rulemaking actions or delegate concurring authority to a working group member or other appropriate official.

(c) The office director of each office affected by a rulemaking action and the General Counsel shall designate an office representative and an alternate for that rulemaking action.

- (1) The designee, or his or her alternate in the designee's absence, is responsible for --
 - (i) Keeping office management informed of the policy issues that could affect office interests or constitute a basis for legal objection and of the designee's proposed position regarding these issues;
 - (ii) Speaking or signing for his or her office on the rulemaking regarding concurrence or conditions for concurrence or a determination of no legal objection by writing the concurrence

letter or identifying specific issues that prevent concurrence and determination of no legal objection; and

(iii) Overseeing office review of factual matters in the concurrence document and providing timely feedback during the document development process.

(2) The office designee may interact in the concurrence process in either the traditional manner or as a member of a working group.

(d) Office concurrence means that --

(1) The office agrees with the overall approach, objective, technical content, and resource impacts of the draft rulemaking document and applicable supporting information.

(2) The office believes that the rulemaking action does not or will not adversely affect or conflict with other NRC programs or policies.

(3) The office agrees with material that is presented as factual and for which the office has a programmatic basis for judging the accuracy of the material.

(4) The office has reviewed the rulemaking action and agrees that it is consistent with current rules and other authoritative statements of agency policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards.

(e) OGC review of rulemaking actions will be consistent with OGC Policy and Procedure Directive 14, which governs OGC review and approval of papers and provides for either concurrence or a determination of no legal objection.

(1) From OGC's standpoint, concurrence means that the recommended action is legally sufficient, is consistent with existing policy or is sound future policy, and is supported by OGC. A rulemaking document is considered legally sufficient when all relevant facts are presented and these facts are considered in light of applicable laws or agency policy. Applicable laws or policy include the Constitution, treaties, statutes, regulations, Executive orders, judicial

decisions, agency adjudicatory decisions, contracts and agreements, and binding Commission policy and SRM.

(2) No legal objection means that the recommended action is legally sufficient and that OGC is not taking a position with respect to the policy aspects of the recommendation.

(3) If the reviewing attorney disagrees with the recommendation on policy grounds, OGC shall formally communicate the basis for the policy disagreement and the supporting reasons, in writing, to the lead office, branch chief or above, or the proposed signer of the document, as appropriate, and to appropriate OGC management.

(f)(1) An office may not withhold office concurrence or the determination of no legal objection on the basis of questions concerning material that is presented as factual except for parts of the material for which the office has a programmatic basis for judging the accuracy of the material. However, the concurring office may provide timely questions or concerns regarding any technical analysis or information that may invalidate or raise doubts about the proposed rule.

(2) An office may not withhold office concurrence or the determination of no legal objection on the basis of editorial style or manner of presentation that does not affect the policy recommendations of the rulemaking action. However, the concurring office may provide timely suggestions for revised wording for the optional use of the lead office.

(3) An office may not withhold office concurrence or the determination of no legal objection on the basis of policy disagreements that do not have a legal or technical basis.

3.17 Concurrences needed.

(a) At the rulemaking plan, proposed rule, and final rule stages, the lead office formally requests concurrences from all other NRC offices that are affected by or interested in the rulemaking action; OGC; the Rules and Directives Branch (RDB), ADM; the Office of the Chief Information Officer (OCIO); the Office of the Chief Financial Officer (OCFO); and the Office of Enforcement (OE).

(1) OGC reviews rulemaking actions to ensure that the action is legally sufficient, is consistent with existing policy, or is sound future policy

(2) OCFO reviews rulemaking actions to ensure that the resources required to complete and to implement the rulemaking have been properly addressed and to ensure that rulemakings that could affect the NRC's license and annual fee schedules have been coordinated.

(3) OCIO reviews rulemaking actions to ensure that potential information technology impacts have been properly addressed and to coordinate OMB approval of any new or amended information collection requirements.

(4) OE reviews rulemaking actions to ensure that an appropriate criminal penalty statement is included. OE will determine whether the "criminal penalties" section for each part affected by the rulemaking action must be amended to reflect the rulemaking action. OE also will determine whether any changes to the Enforcement Policy are warranted.

(5) RDB reviews rulemaking actions to ensure that the rulemaking document meets Office of the Federal Register (OFR) publication requirements and complies with the Regulatory Flexibility Act, the SBREFA, and the Commission's Plain Language Initiative.

(b) Although the Office of the Inspector General (OIG) does not concur on rulemaking actions, a copy of each rulemaking action is forwarded to the OIG for its review. The OIG

reviews rulemaking actions for the purpose of making recommendations concerning the impact of the rulemaking on the economy. The OIG also makes recommendations concerning efficiency in the administration of programs and operations administered or financed by the agency and concerning the prevention of fraud and abuse in these programs. The OIG forwards its comments to the lead office or to the Commission, as appropriate.

3.19 Concurrence procedures.

(a) At the rulemaking plan, proposed rule, and final rule stages, the lead office formally shall transmit each rulemaking action to the offices that need to concur simultaneously (see Section 3.17 of this handbook).

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

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

(2) Concur or provide a determination of no legal objection with the condition that specific policy or legal recommendations of the concurring office can be accommodated;

(3) Work with the lead office to resolve any policy reasons for withholding concurrence;

(4) State the policy reasons for withholding concurrence or for the legal objections that are not resolved at the staff level and present the suggested solutions that would result in concurrence, and send a copy of this memorandum to the Office of the Executive Director for Operations (OEDO); or

(5) State the reasons for being unable to respond on schedule and send a copy of this memorandum to the OEDO.

(c) After receiving the concurrence memoranda, the lead office shall --

(1) Provide a revised rulemaking proposal, including the rulemaking plan, proposed rule, or final rule, to the EDO; or

(2) Hold a meeting with the designated representatives of participating offices, or their alternates, with the appropriate Deputy Executive Director for Operations to resolve any impasse that is preventing the presentation of the rulemaking for the EDO's review.

(d) Within 7 calendar days of receipt of a proposed or final rule, the EDO shall --

(1) Transmit the proposed or final rule for Commission consideration;

(2) Notify the Commission of the intent to issue the rule under the rulemaking authority delegated to the EDO (see Section 1.7 of this handbook);

(3) Return the rulemaking proposal to the lead office for modification or resolution of questions within a specified schedule; or

(4) Instruct the lead office not to proceed with the rulemaking.

3.21 Processing a proposed or final rule for publication.

(a)(1) If the Commission approves a proposed rule or a final rule, the lead office prepares the proposed rule or the final rule for publication by making any changes the Commission directed and any remaining editorial or format changes. The lead office then prepares the rulemaking package, consisting of the proposed rule or the final rule and all necessary accompanying documents. (For additional information on submitting a rulemaking package for publication, see Appendix A to this handbook.) The lead office submits the rulemaking package to RDB at least 2 working days before the due date established in the SRM.

(2) RDB conducts a final review of the rulemaking package to ensure compliance with the publication requirements of the OFR, to verify that the regulation is complete, and to ensure that all necessary accompanying documents are attached and accurate. RDB then transmits the regulation to SECY for signature and transmittal to the OFR for filing and publication.

(b) If the proposed rule or final rule is signed by the EDO, the CFO, or the CIO under delegated rulemaking authority, it is routed through RDB for transmittal to the OFR (see Appendix A to this handbook).

(c) The lead office prepares the required congressional letters and, for final rules, the standard forms to the Speaker of the House, the President of the Senate, and the General Counsel for the General Accounting Office necessary to comply with congressional notification procedures of the SBREFA. RDB forwards letters being sent to appropriate congressional committees, with enclosed copies of the regulation, to the Office of Congressional Affairs (OCA) to ensure that these committees having oversight responsibility for the NRC are notified

of the agency's regulatory activities. For a final rule, RDB also forwards the SBREFA compliance forms to OCA.

(d) The lead office coordinates the preparation and issuance of the public announcement with OPA so that the release of the public announcement coincides with the publication of the proposed or final rule in the *Federal Register* (see Section 3.11 (c) and (d) of this handbook).

(e) If a proposed rule constitutes a major Federal action significantly affecting the quality of the human environment, the lead office ensures that the draft or final GEIS, prepared as required under the National Environmental Protection Act and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," is made available for public comment. If an environmental assessment and finding of no significant impact was prepared for a proposed rule, the lead office ensures that the environmental assessment is made available for public comment. Brief environmental assessments may be incorporated in the proposed rule or the final rule; larger environmental assessments may be referenced in the proposed rule and made available in a separate document.

(f) If a proposed rule or a final rule is subject to the Regulatory Flexibility Act, RDB sends a copy of the regulation and any related analyses to the Chief Counsel for Advocacy of the Small Business Administration.

3.23 Post-publication responsibilities.

(a) After the proposed or final rule is published in the *Federal Register*, the lead office is responsible for placing the document in the Agencywide Documents Access and Management System (ADAMS) and declaring it an official agency record. The lead office is also responsible for placing earlier drafts of the proposed or final rule and all supporting documents in ADAMS.

(b) After the proposed or final rule is published in the *Federal Register*, ADM coordinates with OCIO to ensure that copies of the published document are sent to all affected licensees as well as any interested person who has asked to be placed on a mailing list for NRC notices. The lead office shall coordinate any special distribution requests with RDB.

(c) After the proposed or final rule is published in the *Federal Register*, the lead office is responsible for compiling the complete regulatory history for the rulemaking. See Appendix D to this handbook for instructions on complying with the NRC's regulatory history procedures.

PART 5 - PROPOSED RULE

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5.1 Proposed rule documents: Description.

(a) Each document the NRC prepares for publication in the Proposed Rules section of the *Federal Register* must meet the format requirements specified in 1 CFR Chapter I. The requirements applicable to a proposed rule are discussed in this part. 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. Documents published in the Proposed Rules section generally announce contemplated amendments to the agency's regulations or anticipated agency rulemaking actions and provide the public with an opportunity to comment on the proposed changes. 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. The OFR classifies the following types of NRC documents for publication in the Proposed Rules section of the *Federal Register*.

(1) **Proposed rules.** These documents are required to be published by the notice and comment provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553) and other applicable statutory authority. Proposed rules suggest amendments to the NRC regulations contained in 10 CFR Chapter I and request public comment on the suggested changes.

(2) **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 --

- (i) Extend a comment period;
- (ii) Announce a public hearing or meeting on a proposed regulation;
- (iii) Publish or announce the availability of information supplemental to a rulemaking;
- (iv) Withdraw a proposed rule;
- (v) Terminate a proposed rule proceeding; or
- (vi) Correct a previously published proposed rule.

(3) **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*.

(i) Advance notices of proposed rulemaking. These documents generally describe a problem or situation and may outline NRC's anticipated regulatory response. In an advance notice of proposed rulemaking, 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 advance notice of proposed rulemaking and solicit public comment on each alternative.

(ii) 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*.

(iii) 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*.

(4) **Regulatory agendas.** The NRC publishes an agenda of regulations under agency development in the *Federal Register* each April and October. 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), the Chief Financial Officer, or the Chief Information 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*. The NRC also issues an update of its agenda of regulations

approved by the EDO for development each January and July (NUREG-0936). The NRC agenda also includes a summary of petitions for rulemaking pending before the Commission (10 CFR 2.802(g)). The NRC announces the availability of its agenda in a document published in the Proposed Rules section of the *Federal Register* and places a copy of the updated agenda in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland, and places an electronic copy into the Agencywide Documents Access and Management System.

(5) **Policy statements.** The APA (5 U.S.C. 552(a)(1)(D)) requires that each agency publish in the *Federal Register* "statements of general policy or interpretations of general applicability formulated and adopted by the agency." Therefore, each draft policy statement prepared by the NRC should comply with the format requirements specified in Section 5.7 of this handbook. The Rules and Directives Branch (RDB) should review each draft policy statement to determine whether it meets all procedural and format requirements for publication and can be properly integrated into the *NRC Rules and Regulations* after it is published in the *Federal Register*.

(b) NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Proposed Rules section of the *Federal Register*. Within NRC, the originating office has the primary responsibility for identifying and correcting errors that appear in a published proposed rule document. See Section 13.5 of this handbook for information on preparing a correction document. The originating office shall coordinate the preparation of a correction notice with RDB.

(c) 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. See Section 7.9(f) of this handbook for more information on issuing a rule in final form without requesting public comment. If a noncontroversial regulatory amendment could be issued under the "good cause" exemption of the

APA and the NRC does not expect to receive significant adverse comment on the action, the NRC may issue a direct final rule and request public comment on the action in a companion proposed rule. See Section 9.1(a)(2) of this handbook for more information on issuing a direct final rule.

(d) The APA does not specify a minimum public comment period for a proposed rule. However, Executive Order 12889, which implemented the North American Free Trade Agreement, mandated a 75-day comment period for technical regulations issued under 5 U.S.C. 553 and certain other Federal measures of general application. OGC has indicated that exemptions to this requirement will generally not be approved.

(e) The following document format requirements are applicable to each proposed rule submitted for publication in the *Federal Register*.

(1) The NRC billing code, [7590-01-P], must appear in the upper right-hand corner on the first page of the document.

(2) Document text must be double-spaced.

(3) Document text may appear on only one side of the page.

5.3 Proposed rule documents: Anatomy.

This section examines a typical proposed rule document. Each essential element of a proposed rule is identified to help a writer meet the required elements of a proposed rule and create a complete and correct document. The number of the section in this handbook that discusses each required element in detail is indicated in parentheses. The format used in this and other examples to present document text generally reflects the format used in printing the *Federal Register*. The format used in the sample proposed rule document (see Section 19.3 of this handbook) reflects the format for a typed *Federal Register* document.

SAMPLE: PROPOSED RULE

Agency Heading	NUCLEAR REGULATORY COMMISSION
HEADINGS: CFR Citation Heading (5.5)	10 CFR Part 50
RIN Heading	RIN 3150-AA11
Subject Heading	Reporting Changes to the Quality Assurance Program
PREAMBLE: Captioned Headings (5.7)	AGENCY: Nuclear Regulatory Commission. ACTION: Proposed rule. SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to permit power reactor licensees to make certain quality assurance (QA) changes without obtaining NRC review and approval of these changes in advance. The proposed rule would allow licensees to make routine or administrative changes that should not have an adverse impact on the effectiveness of their QA programs. This action is intended to reduce the financial and administrative burden on power reactor licenses without adversely impacting public health and safety. DATES: Submit comments (insert date 75 days after publication in the <i>Federal Register</i>). Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

Statement of
Considerations
(5.9)

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

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm Federal workdays.

You may also provide comments via the NRC's interactive rulemaking Website at <http://ruleforum.llnl.gov>. This site provides the capability to upload comments as files (any format), if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, (301) 415-5905 (e-mail: CAG@nrc.gov).

To inspect or obtain documents related to this rulemaking, see the Availability of Documents heading in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-0123; e-mail xxx@nrc.gov.

SUPPLEMENTARY INFORMATION:

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to permit power reactor licensees to make certain changes to their QA programs without obtaining NRC approval in advance.

Note: If a proposed rule contains an extensive Supplementary Information discussion, The Supplementary Information section must begin with a table of contents for the Supplementary Information section (see Section 5.9 (b) of this handbook).

The Supplementary Information section must include a section-by-section analysis of the substantive provisions of the proposed regulatory text.

The Supplementary Information section must contain a discussion of the views, concerns, and comments raised by Agreement States during the development of each proposed rule that would amend 10 CFR Parts 30, 34, 35, 40, 61, or 70, or their State equivalent.

Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the Government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in these proposed revisions 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 reflectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of the preamble.

PROCEDURAL
REGULATORY
REQUIREMENTS: National
Technology
Transfer and
Advancement
Act (5.13)

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that agencies use technical standards that are developed or adopted by voluntary consensus bodies unless the use of such a standard is inconsistent with applicable law or is otherwise impractical. In this proposed rule, the NRC is proposing to allow its power reactor licensees to make certain types of changes to their quality assurance program without obtaining NRC approval in advance. This proposed action would relax regulatory requirements and does not constitute the establishment of a standard that contains generally applicable requirements.

National
Environmental
Policy Act
(5.15)

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; therefore, an environmental impact statement is not required. (Briefly present the reasons why the action will not have any significant environmental impact, summarize the environmental assessment, and note any other related environmental documents.)

The determination of this environmental assessment is that there will be no significant offsite impact on the public from this action. However, the general public should note that the NRC is seeking public participation. Submit comments on any aspect of the environmental assessment 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.

Paperwork
Reduction Act
(5.17)

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collection requirements.

The burden to the public for this information collection is estimated to average ___ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-xxxx), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the *Federal Register*). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory
Analysis
(5.19)

Regulatory Analysis

The Commission has prepared a draft regulatory analysis for 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 analysis as indicated under the ADDRESSES heading.

Regulatory
Flexibility Act

Regulatory Flexibility Certification

(5.21)

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).

Backfit Analysis
(5.23)

Backfit Analysis

As required by 10 CFR 50.109, the Commission has completed a backfit analysis for the proposed rule. The Commission has determined on the basis of this analysis that backfitting to comply with the requirements of this proposed 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: (Here insert the text of the backfit analysis.)

SUBJECT INDEX TERMS
(5.25)

List of Subjects In 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire prevention, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

WORDS OF ISSUANCE
(5.27)

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 Part 50.

PART HEADING

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY CITATION

AUTHORITY: (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2239, 5841, 5842, 5846).

Sec. 50.78 also issued under 42 U.S.C. 2152. Secs. 50.80-50.81 also issued under 42 U.S.C. 2234. Secs. 50.100-50.102 issued under 42 U.S.C. 2236.

AMENDATORY LANGUAGE
(5.29)

2. In §50.54, paragraph (a)(3) is revised to read as follows:

§50.54 Conditions of licenses.

REGULATORY TEXT
(5.33-5.39)

(a) * * *

(3) Each licensee described in paragraph (a)(1) of this section may make a change to a previously accepted quality assurance (QA) program description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce commitments in the program description as accepted by the NRC. Changes to the QA program that do not reduce the commitments made must be submitted to the NRC in accordance with the requirements of §50.71(e). In addition to QA program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(i) The use of a QA standard approved by the NRC that is more recent than the QA standard in the licensee's current QA program at the time of the change;

(ii) The use of a QA alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(iii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(iv) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternately, the use of descriptive text;

(v) The elimination of QA program information that duplicates language in regulatory guides and QA standards to which the licensee is committed; and

(vi) Organizational revisions that ensure that persons and organizations performing QA continue to have requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

* * * * *

SIGNATURE BLOCK
(5.45)

Dated at Rockville, Maryland, this __ day of _____,
2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

5.5 Document headings.

(a) Each proposed rule document the NRC submits for publication in the *Federal Register* begins with a series of headings that --

- (1) Identify NRC as the agency issuing the document;
- (2) Indicate the parts within 10 CFR Chapter I that the document proposes to amend or establish;
- (3) Provide the unique regulation identifier number (RIN) of the proposed rule; and
- (4) Indicate the subject matter of the document.

Example:

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

(b) The "CFR Citation" heading must contain the number of each part the document proposes to amend or establish. Even if the document proposes to amend only one paragraph within a CFR part, that CFR part number must be included in the heading. If a document does not contain proposed new or changed text but is classified as a proposed rule for *Federal Register* publication, this heading must present the number of the CFR part that the subject matter of the document most closely matches. If no CFR part is appropriate, the CFR chapter designation may be used (10 CFR Chapter 1).

(c) 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.

For assistance in determining whether a RIN has been assigned to a proposed rule or to obtain a RIN, contact RDB (415-6863).

(d) The "Subject" heading is a brief statement that describes the content of the document. The CFR part heading may be sufficient for this purpose. However, more specific information may be needed if the part heading is too general or to differentiate between multiple documents amending the same part or parts.

(e) Occasionally, a document that appears in the Proposed Rules section of the *Federal Register* concerns the identical subject matter of a document published previously. This situation usually occurs when followup documents are necessary in a rulemaking proceeding. To emphasize the relationship between the two documents, the OFR requires that the later document repeat the headings of the earlier document. In addition, a word or phrase identifying the action or type of the second document must be 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

5.7 Preambles: Format requirements.

Each proposed rule the NRC prepares for publication in the *Federal Register* must begin with a preamble. Within 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, which are discussed below, arrange basic information in a uniform format that allows a user to scan the beginning of the document for essential information. The OFR will not print a proposed rule document that does not meet the format requirements described in this section.

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

Example:

AGENCY: Nuclear Regulatory Commission.

(b) **ACTION.** This caption identifies the type of document being published more precisely than the publication categories of the *Federal Register* allow. This caption may not be used to summarize the content or amendatory action of the document. Permissible entries under this caption for a proposed rule document are as follows:

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: Petition for rulemaking: Withdrawal.

ACTION: Proposed policy statement.

ACTION: Proposed rule: Availability of supplemental information.

(c) **SUMMARY.** The Summary is a brief description, written in language that a nonexpert will understand, that allows the reader to determine the subject and intended effect of the proposed 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.

(1) The Summary must answer these questions:

(i) What does this document do?

(ii) Why is this action necessary?

(iii) What is the intended effect of this action?

(iv) Who is affected by the proposed rule? (For example, what class of licensee?)

(2) The answers to these questions must be contained in three or four brief sentences and 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.

(3) The Summary must --

(i) Avoid legal citations (e.g., 10 CFR 35.15(c)(2) or 42 U.S.C. 2201);

(ii) Refer to an act of Congress by popular name (e.g., Atomic Energy Act of 1954);

(iii) Avoid qualifications, exceptions, extensive background, or specific details; and

(iv) 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: 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.

(d) **DATES.** This caption identifies the dates within a document that are essential to the rulemaking proceeding.

(1) The following dates may be included in a proposed rule document, when appropriate:

(i) Comment closing deadlines;

(ii) Public hearing or meeting dates; and

(iii) Other dates that may be relevant to public knowledge of the proceeding.

(2) Information concerning public hearing procedures, meeting agenda, 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.

Example:

DATES: The comment period expires December 31, 2001. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date. Public hearings will be held on November 19 and 26, 2000.

(e) **ADDRESSES.** This caption identifies addresses that an interested person needs to participate in the rulemaking proceeding.

(1) Information that may be presented includes the addresses for --

(i) Mailing public comments;

(ii) Hand-delivering public comments;

(iii) Electronic access to published information;

(iv) Submitting comments electronically;

- (v) Attending a public hearing or meeting;
- (vi) Examining any material available for public inspection; or
- (vii) Obtaining other documents referred to in the proposed rule.

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

Example:

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

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking Website at <http://ruleforum.llnl.gov>. This site provides the capability to upload comments as files (any format), if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, (301) 415-5905 (e-mail: CAG@nrc.gov).

To inspect or obtain documents related to this rulemaking, see the Availability of Documents heading in the Supplementary Information section.

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

(f) **FOR FURTHER INFORMATION CONTACT.** This caption identifies a person who can answer questions or provide additional information concerning the document. The name and telephone number of the designated individual must be presented. The NRC may include 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) 415-1111; 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) 415-0102; e-mail xxx@nrc.gov.

5.9 Preambles: Supplementary Information.

The Supplementary Information section of the preamble serves as the published history of the document. The Supplementary Information section in a proposed rule presents the background information and specific details necessary to inform interested persons of the issues involved in the rulemaking proceeding. When preparing the Supplementary Information for a proposed rule, the drafter should remember that the Supplementary Information discussion for the final rule will be exactly the same as the Supplementary Information discussion for the proposed rule except for the comment analysis and where the final rule differs from the proposed rule's recommendation and where necessary to reflect the differing status between a proposed rule and a final rule.

(a) In the Supplementary Information section, the NRC shall, at a minimum, explain its reasoning for developing the proposed regulation in sufficient detail to ensure interested persons of the opportunity to provide meaningful comments on the proposed rule. The items listed in this paragraph provide a general overview of the topics that must be considered to present an adequate explanation of the proposed rule. To provide an adequate basis for the rulemaking on the record in the event of a court challenge to the proposed rule, the Supplementary Information section should include a discussion of --

- (1) The purpose of the proposed regulation;
- (2) The need for the proposed regulation;
- (3) The laws or directives that authorize the proposed regulation;
- (4) The relationship of the proposed regulation to existing regulations;
- (5) The history of the rulemaking proceeding to this point;
- (6) The alternatives considered in developing the proposed regulation;
- (7) 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;

- (8) A section-by-section analysis of the substantive requirements of the proposed regulation on a provision-by-provision basis;
- (9) The issues to be commented on in the proposed regulation;
- (10) Any noncompliance or penalty provisions;
- (11) Whether the proposed rule will use a voluntary consensus standard or a Government-unique standard;
- (12) The views, concerns, and comments raised by Agreement States during the development of the proposed rule; and
- (13) The response to public comment from an advance notice of proposed rulemaking or any other preliminary document that solicited public participation.

(b) The drafter shall use descriptive center headings to divide and describe material in the Supplementary Information section. Center headings help break up long stretches of text and aid the user in finding particular items of interest. The drafter shall provide a table of contents that consists of the headings used in the Supplementary Information portion of the preamble. This table of contents presents the user with a quick overview of the information presented. A table of contents should be provided for all but the briefest rules.

Example: This example illustrates the use of descriptive center headings and a table of contents in a preamble.

SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Rulemaking Initiation.
- III. Proposed Action.
- IV. Basis for Technetium.
- V. Basis for Uranium Limit.
- VI. Specific Licensing Conditions.
- VII. Proposed Findings.
- VIII. Section-by-Section Analysis of Substantive Changes.
- IX. Agreement State Compatibility.

- X. Availability of Documents.
- XI. Plain Language.
- XII. Voluntary Consensus Standards.
- XIII. Finding of No Significant Environmental Impact: Availability.
- XIV. Paperwork Reduction Act Statement.
- XV. Regulatory Analysis.
- XVI. Regulatory Flexibility Certification.
- XVII. Backfit Analysis.

(c) The Supplementary Information section must contain a section-by-section analysis of the substantive provisions of the proposed regulatory text. This analysis provides a substantive description of the changes that would be made in the regulation sufficient to provide the NRC staff, the affected licensees, and the public with the information necessary to determine what would be specifically required by each provision. This description should present a concise description of what the provision intends and provide any necessary clarification concerning the nature of the imposed requirement. The section-by-section analysis should focus on implementation issues such as how specific terms of art would be interpreted and what the NRC's expectations would be in specific situations. The section-by-section analysis should not explain the reasons (basis) why the NRC is considering the adoption of the provision or change in question.

Example:

Section-by-Section Analysis of Substantive Changes

Section 170.11 - Exemptions.

This section would be amended to add a new paragraph indicating that amendments to materials portable gauge licenses issued in accordance with NUREG-1556 that change only the name of the Radiation Safety Officer (RSO) would be exempt from amendment fees. This change is consistent with the recent Business Process Redesign (BPR) initiative and NUREG-1556, Volume 1, issued for public comment on October 3, 1996 (61 FR 51729). No amendment fees would be assessed for the amendments issued in accordance with NUREG-1556 to portable gauge licenses because the regulatory program would include commitments from the licensee concerning RSO qualifications; and if those

commitments are included in the amendment application, then there would be no technical review conducted by the NRC.

Section 170.20 - Average cost per professional staff-hour.

This section would be amended to establish two professional staff-hour rates based on FY 1997 budgeted costs--one for the reactor program and one for the nuclear material and nuclear waste program. Accordingly, the NRC reactor direct staff-hour rate for FY 1997 for all activities the fees for which are based on full cost under §170.21 would be \$131 per hour, or \$233,055 per direct FTE. The NRC nuclear material and nuclear waste direct staff-hour rate for all materials activities the fees for which are based on full cost under §170.31 would be \$125 per hour, or \$222,517 per direct FTE. The rates are based on the FY 1997 direct FTEs and NRC budgeted costs that are not recovered through the appropriation from the NWF or the General Fund. The NRC has continued the use of cost center concepts established in FY 1995 in allocating certain costs to the reactor and materials programs in order to more closely align budgeted costs with specific classes of licensees. The method used to determine the two professional hourly rates is as follows:

* * * * *

(d)(1) If the NRC published an advance notice of proposed rulemaking (ANPR) or is using an enhanced public participation process, the comments received on the ANPR or the enhanced public participation initiative must be discussed in the Supplementary Information section of the preamble to the proposed rule. Comments presenting substantive changes or suggestions must be discussed in detail. Nonsubstantive, editorial, corrective comments, as well as those that request clarification or present exhortations, may simply be acknowledged.

(i) Comment analysis is not a vote count. Logic and reasoning are more important than numbers.

(ii) 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.

(iii) 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.

(iv) Comments of a minor or clarifying nature must be acknowledged and should be discussed in the aggregate in the comment analysis.

(v) 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).

(2) 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.

(3) Comments received from Indian Tribes must be presented as a readily identifiable portion of the general discussion concerning any substantive comments received in the Supplementary Information section of the preamble to the proposed rule as discussed in this paragraph.

(e) Each proposed rule that would affect facilities licensed under 10 CFR Parts 30, 34, 35, 40, 61, and 70, or their State equivalent, must contain a discussion of the opportunities afforded to the public and Agreement States for their early and substantive participation in the rulemaking process. This discussion must present the views, concerns, and comments raised by the public and Agreement States during the development of the proposed rule. This discussion should contain sufficient detail to provide the public and Agreement States with an additional opportunity to review NRC's rationale in response to their comments during the public comment period. The discussion should be presented as a readily identifiable portion of the general discussion concerning any substantive comments received in the Supplementary Information section of the preamble to the proposed rule (see paragraph (d) of this section).

(f) The NRC shall include a statement in the Supplementary Information section of the preamble to the proposed rule 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.

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 Public Electronic Reading Room (PERR). The NRC's public electronic reading room is located at www.nrc.gov/NRC/ADAMS/index.html. (Provide accession number for each document.)

The NRC staff contact (NRC Staff). (Provide the name, address, and telephone number of the NRC staff contact.)

Document	PDR	Web	PERR	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		
RGx.xx	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 the Chief Information Officer, 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 posted at NRC's technical document Website www.nrc.gov/NRC/NUREGS/indexnum.html.

(g) 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 writing, including rulemaking actions, be in plain language. The NRC's Plain Language Action Plan Website, <http://www.internal.nrc.gov/NRC/PLAIN/index.htm>, provides guidance, examples, and links to external plain language Websites that are designed to help the NRC staff comply with the plain language initiative in preparing regulatory and other documents. The NRC shall include a statement concerning compliance with the plain language initiative in the Supplementary Information section of the preamble to the proposed rule.

(1) 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 dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). In complying with this directive, the NRC 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 reflectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of the preamble.

(2) 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 dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments on the proposed rule specifically with respect to the clarity and reflectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of the preamble.

5.11 Procedural requirements for rulemaking.

(a) Sections 5.13 through 5.23 of this handbook discuss the portion of the Supplementary Information section of the preamble relating to the procedural requirements the NRC follows in developing and issuing a proposed rule. The requirements are intended to ensure that the NRC considers the impact of each suggested regulatory alternative in the process of developing a proposed rule. The requirements the NRC follows in developing a proposed rule include --

(1) 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 (see Section 5.13 of this handbook);

(2) An assessment of the environmental impact of the proposed rule under the National Environmental Policy Act and 10 CFR Part 51 (see Section 5.15 of this handbook);

(3) OMB approval for each new or amended information collection requirement under the Paperwork Reduction Act (see Section 5.17 of this handbook);

(4) A regulatory analysis prepared in accordance with the Regulatory Analysis Guidelines approved by the Commission and issued as NUREG/BR-0058, Revision 3. A regulatory analysis examines the economic impact, in terms of costs and benefits, of alternatives considered in developing the proposed rule (see Section 5.19 of this handbook);

(5) An analysis of the economic impact of the proposed rule on small entities under the Regulatory Flexibility Act (see Section 5.21 of this handbook); and

(6) A backfit analysis prepared in accordance with 10 CFR 50.109, 70.76, 72.62, or 76.76 (see Section 5.23 of this handbook).

(b) The draft environmental assessment and regulatory analysis should precede, or be prepared concurrently with, the development of the proposed rule. They should not be developed

after the proposed rule is drafted. These documents help determine the necessity, extent, and direction of the rulemaking proceeding and, as such, are an integral part of each step in the rulemaking. As more information becomes available through the rulemaking process, the analyses may be adjusted or developed in greater detail. The intended regulatory action would then be reevaluated in terms of the more extensive analyses and adjusted as necessary.

(c) If the proposed rule would add or amend an information collection requirement affecting 10 or more persons, the NRC must obtain OMB approval of the information collection requirement. The clearance package necessary to obtain OMB approval must be prepared at the same time the proposed rule is being prepared. 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. Please note that the information collection requirements must be approved by OMB before the final rule is submitted for signature and publication. Section 5.1 of the Regulatory Analysis Guidelines requires that factors needed to obtain OMB approval be addressed in the regulatory analysis.

(d) The content of the analyses required under the Commission's Regulatory Analysis Guidelines and the Regulatory Flexibility Act is similar. The act permits a regulatory flexibility analysis to be combined with any other analysis as long as it meets the requirements of the act (see Section 5.21 of this handbook). 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 (see Section 5.19 of this handbook).

(e) The NRC's Regulatory Analysis Guidelines have been developed so that a regulatory analysis that conforms to the guidelines will meet the requirements of the backfit rule.

5.13 National Technology Transfer and Advancement Act.

(a) 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. These bodies have agreed 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).

(b) The preamble of each proposed rule or interim final rule must contain a statement that requests comment and contains appropriate information concerning the use of voluntary standards.

(1) If the rule uses a voluntary consensus standard, it must contain a statement that identifies the standard.

(2) If the rule proposes to use a Government-unique standard instead of a voluntary consensus standard, it must contain a statement that identifies the standards and provides a preliminary explanation for the proposed use of a Government-unique standard instead of a voluntary consensus standard.

(3) If the rule proposes to use a Government-unique standard and no voluntary consensus standard has been identified, it must contain a statement to that effect and an invitation to identify any voluntary standard and to explain why the standard should be used.

(4) If the rule does not constitute the establishment of a standard containing generally applicable requirements, it must contain a statement to that effect.

(c) The NRC shall include the following statement addressing the use of voluntary standards in the Supplementary Information section of the preamble to each proposed rule or interim 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 rule, (insert one of the following options):

Option 1. "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 2. "The NRC proposes using the following Government-unique standard: (identify the standard by name, developing organization, and date issued). NRC proposes 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 a preliminary explanation such as 'using the voluntary consensus standard would be impractical or inconsistent with applicable law')."

Option 3. "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 4. “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.”

(d) If the proposed rule concerns the NRC’s approval of a standard design certification, the NRC shall include the following statement addressing the use of voluntary standards in the Supplementary Information section of the preamble.

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 rule, the NRC proposes to approve 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 rule.

(e) 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, the 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.

(f) Written 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 the NRC's standards Website: www.nrc.gov/NRC/REFERENCE/Standards/index.html.

5.15 National Environmental Policy Act (NEPA).

(a) 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 proposed actions into the decisionmaking process of the agency.

(b) The NRC shall assess the environmental impact of each proposed regulatory action and include a statement concerning the environmental impact in the Supplementary Information section of the preamble to each proposed rule.

(1) If a proposed rule 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 or an environmental assessment is not required for the regulatory action (see paragraph (c) of this section).

(2) If the proposed rule is not eligible for one of the categorical exclusions listed in 10 CFR 51.22(c), the NRC shall prepare an environmental assessment on the proposed rule. If the NRC completes an environmental assessment and finds that the proposed rule is not a major action significantly affecting the quality of the human environment, an environmental impact statement need not be prepared. The NRC shall prepare and publish a finding of no significant impact (see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119). This finding 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 (see paragraph (g) of this section).

(3) If the proposed rule is not eligible for one of the categorical exclusions listed in 10 CFR 51.22(c) and the NRC finds through its environmental assessment that the proposed rule is a

major action significantly affecting the quality of the human environment, the NRC shall prepare an environmental impact statement on the proposed rule (see 10 CFR 51.20(a)(1)).

(4) The NRC shall also prepare an environmental impact statement if the proposed 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)).

(c) An environmental impact statement or an environmental assessment is not required for a licensing or regulatory action, including a proposed regulation, that is eligible for a categorical exclusion. A proposed rule is eligible for a categorical exclusion if the action belongs to a category of actions that the Commission has declared by rule to be a categorical exclusion after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment.

(1) The following types of rulemaking actions have been determined to be categorical exclusions:

(i) Amendments to Parts 1, 2, 4, 7, 8, 9, 10, 11, 14, 19, 21, 25, 55, 75, 95, 110, 140, 150, 170, or 171 of this chapter (10 CFR 51.22(c)(1)).

(ii) Amendments to the regulations in this chapter that are corrective or of a minor or nonpolicy nature and do not substantially modify existing regulations (10 CFR 51.22(c)(2)).

(iii) Amendments to Parts 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 51, 60, 61, 70, 71, 72, 73, 74, 81, or 100 of this chapter that are related to --

(A) Procedures for filing and reviewing applications for licenses or construction permits or other forms of permission, or for amendments to or renewals of licenses or construction permits or other forms of permission;

(B) Recordkeeping requirements; or

(C) Reporting requirements (10 CFR 51.22(c)(3)).

(iv) Actions on petitions for rulemaking relating to the amendments specified in this paragraph.

(2) If the NRC determines that a proposed regulation falls within a category of actions determined to be a categorical exclusion (10 CFR 51.22(c)), the NRC shall include the following statement in the Supplementary Information section of the preamble to the proposed rule.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation 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 regulation.

(d) In order to fulfill a commitment made to the Council on Environmental Quality, the NRC shall consult with the States on environmental issues before issuing a final environmental assessment and shall document the consultation in the environmental assessment. The EDO has approved an NRC procedure for consultation with the States during the preparation of an environmental assessment for a rulemaking action (see the memorandum from David L. Morrison to multiple addressees dated May 18, 1995). These procedures are presented in Appendix E to this handbook.

(e) In a letter dated March 31, 1994, from the Chairman to the President, the NRC voluntarily agreed to carry out the measures set forth in Executive Order 12898 mandating that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, or activities on minority populations and low-income populations. The NRC stated that these requirements applied primarily to its efforts to comply with NEPA and that it would address environmental justice aspects as part of its considerations under NEPA. The environmental justice procedures for the Office of Nuclear Reactor Regulation (NRR) and the

Office of Nuclear Material Safety and Safeguards (NMSS) were signed into effect on September 21, 1999, and September 7, 1999, respectively. (See NRR Office Letter No. 906, Revision 2, and NMSS Policy and Procedures Letter 1-50).

(f) If the environmental impact of a proposed licensing and regulatory action has been evaluated and an environmental impact statement has been prepared, the NRC shall include the following statement in the Supplementary Information section of the preamble to the proposed rule.

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 environmental impact statement on this proposed rule.

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.

(g) Unless the action is eligible for one of the categorical exclusions listed in 10 CFR 51.22(c) (see paragraph (c) of this section), the NRC shall prepare an environmental assessment on each licensing and regulatory action, including a proposed regulation, for which an

environmental impact statement has not been prepared (see 10 CFR 51.21, 51.30, and 51.31). If after completing an environmental assessment for a proposed regulation the NRC determines that an environmental impact statement need not be prepared, the NRC shall prepare and publish a finding of no significant impact (see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119). This finding 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. The NRC may either include the text of the environmental assessment in the Supplementary Information section of the preamble to the proposed rule or summarize the environmental assessment and indicate how interested persons may obtain a copy of it.

(1) If the NRC determines that a finding of no significant impact is appropriate for a proposed rule and is including the environmental assessment in the Supplementary Information section of the preamble to the proposed rule, the NRC shall include the following statement.

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.

(2) If the NRC determines that a finding of no significant impact is appropriate for a proposed rule and is presenting the environmental assessment in a separate document, the NRC shall include the following statement indicating this finding and summarizing the environmental assessment in the Supplementary Information section of the preamble to the proposed rule.

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.

(3) In most cases, the NRC need not conduct an environmental justice review for an environmental assessment that results in a finding of no significant impact. However, in certain cases, as described in the environmental justice procedures of the NRR or NMSS, the NRC may conduct an environmental justice review for an environmental assessment for a proposed rule and determine that a finding of no significant impact is appropriate. For these special cases, the NRC shall include the following statement in the Supplementary Information section of the preamble to the proposed rule.

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 or 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. The NRC has also 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. The NRC evaluated environmental justice for this environmental assessment 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. E.O. 12898 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." Comments on any aspect of the environmental assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

5.17 Paperwork Reduction Act.

(a) **General.** The Paperwork Reduction Act (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 act 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 act 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 Section 5.19 of this handbook). The NRC complies with the act 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 Management Branch, Office of the Chief Information Officer (OCIO), is responsible for coordinating NRC activities necessary to comply with the Paperwork Reduction Act.

(b) **Coverage.** The act 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. OMB clearance must be obtained for both voluntary and mandatory information collection requirements.

(1) 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.

(2) OMB clearance is not required for a request for public comment in connection with a rulemaking proceeding.

(c) **Preparation of an OMB clearance package.** If a proposed rule contains a new or amended information collection requirement, including any amendment that reduces the burden

imposed by an information collection requirement, or deletes an information collection requirement, the clearance package necessary to obtain OMB approval must be developed at the same time the proposed rule is being developed. 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. The NRC 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 transmitted to OMB.

(d) **Standard statements.** One of the following statements must be included in the Supplementary Information section of the preamble to each proposed rule concerning information collection requirements. Information collection requirements include any reporting, recordkeeping, third-party disclosure, or application requirement. The specific identification number in the following statements, 3150-XXXX, is the OMB approval number for information collection requirements that are contained in the affected parts. In addition to "3150," which identifies NRC as the issuing agency, "xxxx" represents the specific four-digit number that is assigned to represent a specific part within 10 CFR Chapter I. The Records Management Branch, OCIO, will identify the appropriate identification number for a proposed rule.

(1) **OMB clearance for a new information collection.** If OMB approval is required for a new information collection requirement, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for this information collection is estimated to average ___ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-XXXX), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the *Federal Register*). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(2) OMB clearance for a proposed reduction in regulatory burden. If OMB approval is required for an action reducing existing information collection requirements, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by ___ hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for further reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-XXXX), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the *Federal Register*). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(3) **OMB clearance for existing requirements not affected.** The NRC shall insert this statement in the Supplementary Information section of the preamble to the proposed rule if --

(i) The text of the proposed rule includes information collection requirements that were previously approved by OMB; and

(ii) These information collection requirements would not be amended if the proposed rule were adopted in final form without change.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or an amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-XXXX.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(4) **Insignificant changes to existing information collection requirements.** If the proposed rule would make insignificant changes to existing regulatory requirements, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Paperwork Reduction Act Statement

This proposed rule increases (or decreases) the burden on licensees to (state the requirement, including the regulatory citation). The public burden (or burden reduction) for this information collection is estimated to average ____ hour(s) per request. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-XXXX.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(5) **No information collection requirement.** If the proposed rule and the current 10 CFR part do not contain an information collection requirement, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Paperwork Reduction Act Statement

This proposed rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C 3501 et seq.).

(6) **Exempt information collection requirements.** If a proposed rule contains an information collection requirement that is exempt from the requirements of the Paperwork Reduction Act under 44 U.S.C. 3518(c)(1), the NRC shall insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Paperwork Reduction Act Statement

The information collections contained in this proposed rule are exempt from the Paperwork Reduction Act of 1995 (44 U.S.C 3518(c)(1)) because the information is being gathered in support of [insert one of the following four options to complete the statement: Option 1 - "a Federal criminal investigation or prosecution or the disposition of a particular criminal matter (44 U.S.C. 3518(c)(1)(A))"; Option 2 - "a civil action to which the United States or an agency or an official of the United States is a party (i.e., a court action) or an administrative action or investigation involving an agency against a specific individual or entity (e.g., an agency hearing) (44 U.S.C. 3518(c)(1)(B))"; Option 3 - "an antitrust suit (44 U.S.C. 3518(c)(1)(C))"; Option 4 - "intelligence and security cryptologic activities (44 U.S.C. 3518(c)(1)(D))"].

(7) **Information collection requirements of limited applicability.** If a proposed rule of limited applicability contains an information collection requirement that affects fewer than 10 respondents, the NRC shall insert the following statement in the Supplementary Information

section of the preamble to the proposed rule. Note that rules of general applicability having a universe of fewer than 10 respondents require OMB clearance.

Paperwork Reduction Act Statement

The information collection requirements contained in this proposed rule of limited applicability affect fewer than 10 respondents. Therefore, Office of Management and Budget clearance is not required pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

(e) **Guidance.** The OCIO is responsible for coordinating the activities necessary to comply with the Paperwork Reduction Act. Written OCIO 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 Paperwork Reduction Act requirements. Specific questions concerning the procedures and requirements of the Paperwork Reduction Act may be directed to Brenda Jo. Shelton, Chief, Records Management Branch (415-7233).

5.19 Regulatory analysis.

(a) **Introduction.** The Commission approved the issuance of NRC's revised Regulatory Analysis Guidelines on June 30, 1995 (SECY-95-028). The Regulatory Analysis Guidelines are printed in NUREG/BR-0058, Revision 3, July 2000. These guidelines establish a framework for --

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

(b) **Purpose.** (1) 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.

(2) Each regulatory analysis should address the following impacts:

- (i) Direct costs or savings to licensees, the NRC, and State and local government agencies;
- (ii) Nonradiation risk-related costs or savings to the general public;
- (iii) Averted onsite impacts; and
- (iv) Changes in regulatory efficiency or scientific knowledge needed for regulatory purposes.

(c) **Contents.** Each regulatory analysis must include the following standard elements:

- (1) A statement of the problem and the NRC's objectives for the proposed regulatory action.

(2) An identification and preliminary analysis of alternative approaches to resolving the problem.

(3) An estimate and evaluation of the values and impacts for the selected alternatives, including the uncertainties that affect these estimates.

(4) The conclusion reached concerning the evaluation of values and impacts and a safety goal evaluation, where appropriate.

(5) The decision rationale for selecting the proposed regulatory action.

(6) A tentative implementation schedule and implementation instrument for the proposed regulatory action.

(d) **Coverage.** (1) 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.

(2) 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.

(3) 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 proposed action.

(e) **Relationship 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.

(1) If an environmental impact statement has been prepared and forms the basis for the proposed rule, a summary of the environmental impact statement is an appropriate substitute for the information and analysis requirements identified in NUREG/BR-0058, Revision 3, Sections 4.1-4.3.

(2) If the proposed rule would impose collection requirements that require obtaining OMB approval under the Paperwork Reduction Act (see Section 5.17 of this handbook), the draft OMB clearance package must be included as a stand-alone appendix to the regulatory analysis.

(3) The regulatory analysis must contain information sufficient to address requirements mandated by the Regulatory Flexibility Act (see Section 5.21 of this handbook).

(i) If the proposed rule is likely to have a significant economic impact on a substantial number of small entities, a draft regulatory flexibility analysis must be prepared. The regulatory flexibility analysis is included as an appendix to the regulatory analysis and as part of the proposed rule. The regulatory flexibility analysis may reference information discussed in the body of the regulatory analysis.

(ii) If the NRC certifies that the proposed rule would 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 proposed rule on small entities to support this certification.

(4) If a backfit analysis is required for a proposed rule, the regulatory analysis must contain the information required by the Commission's backfit rule (see Section 5.23 of this handbook). 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.

(f) **Required statement.** A statement must be inserted in the Supplementary Information section of the preamble to the proposed rule concerning the regulatory analysis.

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

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

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.

(3) 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.

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.]

5.21 Regulatory Flexibility Act.

(a) **Purpose.** The Regulatory Flexibility Act (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act, 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 act requires that each agency analyze the impact of the proposed rule on different size entities, estimate the effectiveness of the regulatory proposal in addressing the source of the problem, and consider alternatives that would minimize compliance costs. For NRC regulatory actions, the act primarily impacts regulations that would affect byproduct, source, and special nuclear material licensees.

(b) **Applicability.** The act applies to each rule subject to notice and comment rulemaking under the APA (5 U.S.C. 553 (b)). Therefore, the requirements of the act apply to each proposed rule developed by the NRC. The act exempts a final rule for which a proposed rule was not issued.

(c) **Requirements.** In order to comply with the act'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 proposed regulatory actions on small entities.

(1) If the NRC believes that the proposed rule will have a "significant economic impact on a substantial number of small entities," the act requires that the NRC prepare an initial regulatory flexibility analysis (See paragraph (d) of this section for NRC's definition of "small entities"). 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 act. The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, Revision 3) 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 (see Section 5.19 of this handbook).

(2) The act permits the NRC to dispense with the preparation of an initial regulatory flexibility analysis if --

(i) The NRC determines that the proposed rule will not have a significant economic impact on a substantial number of small entities;

(ii) The Commission certifies this to be the case;

(iii) The certification and the factual basis for the certification are published in the proposed rule.

(d) **Size standards.** The NRC established size standards that it uses to determine which NRC licensees qualify as small entities (April 11, 1995; 60 FR 18344). The NRC size standards are codified in 10 CFR 2.810. The NRC shall use these size standards to identify regulations subject to the regulatory flexibility analysis requirements of the act. The size standards for NRC licensees are as follows:

§ 2.810 NRC Size Standards.

The NRC shall use the size standards contained in this section to determine whether a licensee qualifies as a small entity in its regulatory programs.

(a) A small business is a for-profit concern and is a --

(1) 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

(2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

(b) 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.

(c) 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.

(d) A small educational institution is one that is --

(1) Supported by a qualifying small governmental jurisdiction; or

(2) Not state or publicly supported and has 500 or fewer employees.

(e) For the purposes of this section, the NRC shall use 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.

(e) **Standard statements.** A statement concerning the Regulatory Flexibility Act must appear in the Supplementary Information section of the preamble for each proposed rule.

(1) If an initial regulatory flexibility analysis has been prepared, the NRC shall include one of the following statements.

(i) The standard statement that is used to seek public comment and announce availability reads as follows.

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.

(ii) The NRC must make a good faith effort to prepare a thorough analysis of the impact of a proposed regulation on small entities. However, if after preparing an initial regulatory flexibility analysis or conducting a preliminary examination of the anticipated impacts of the proposed rule on small entities the NRC needs 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, the NRC may use the following statement.

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 result in a significant economic burden upon 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.

(2) If an initial regulatory flexibility analysis is not required, the NRC shall 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.

(i) If a 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 upon 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 result in a significant economic burden upon 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.

(ii) If a 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).

(f) **Initial Regulatory Flexibility Analysis.** The act 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 a summary is published, 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. An initial regulatory flexibility analysis must contain the following information:

(1) 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.

(2) 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.

(3) 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 --

- (i) Provide a profile of the affected entities that is divided into size segments;
- (ii) Cite the NRC's size standard rule to identify the steps taken to develop a definition of a small entity that is different from the act's definition; and
- (iii) Identify the small entities expected to experience more significant impacts as a result of the rule.

(4) 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.

(i) 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.

(ii) 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.

(iii) 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.

(iv) The considerations in paragraphs (f)(4)(i) through (iii) of this section should be applied to each regulatory alternative under consideration.

(5) 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.

(6) 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 --

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

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

(iii) The use of performance rather than design standards; and

(iv) An exemption from coverage of the rule, or any part of the rule, for small entities.

(7) 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.

(g) **Guidance.** Questions concerning the Regulatory Flexibility Act may be directed to Michael T. Lesar (415-7163).

5.23 Backfit analysis.

(a) The NRC has established standards for the management of backfitting requirements imposed on power reactors (10 CFR 50.109). Essentially identical provisions were established to manage backfitting requirements imposed on gaseous diffusion plants (10 CFR 76.76). Provisions were established to manage backfitting requirements imposed on an independent spent fuel storage installation or a monitored retrievable storage installation (10 CFR 72.62). In addition, provisions were established to manage backfitting requirements imposed on special nuclear material licensees (10 CFR 70.76).

(b) 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.

- (1) The first component is the modification of or addition to --
 - (i) Systems, structures, components, or design of a facility;
 - (ii) The design approval or manufacturing license for a facility; or
 - (iii) The procedures or organization required to design, construct, or operate a facility.
- (2) The second component is that the modification or addition is the result of either --
 - (i) A new or amended provision of the Commission's regulations; or
 - (ii) A regulatory NRC staff position interpreting these regulations that is either new or different from a previously applicable NRC staff position.
- (3) The third component is that the modification or addition is considered a backfit only if it results from a new or amended regulation or NRC staff position issued after --
 - (i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;
 - (ii) Six months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses; or

(iv) The date of issuance of the design approval under Appendix M, N, or O to 10 CFR Part 52.

(4) The fourth component is that the modification or addition must be imposed as a mandatory requirement.

(c) Except as indicated in paragraph (d) of this section, the NRC shall prepare 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 --

(1) 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

(2) The direct and indirect costs that would result from the implementation of the backfit are justified.

(d)(1) The backfit analysis described in paragraph (e) of this section is not required and the "substantial increase" and "cost justification" standards of paragraph (c) of this section do not apply if --

(i) A backfit is necessary to ensure adequate protection of public health and safety;

(ii) 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; or

(iii) The backfit involves defining or redefining adequate protection.

(2) If the provisions of paragraph (e)(1) of this section apply, the NRC shall prepare a documented evaluation that includes a statement of the objectives of and the reasons for the

proposed backfit, and the basis for treating it as an exception to the requirements of paragraphs (c) and (d) of this section.

(e) A backfit analysis prepared in support of a potential backfit contained in a proposed rule must contain available information concerning any of the following factors, as well as any other material and relevant information. The backfit analysis must contain --

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

(f) A statement concerning the applicability of the backfitting requirements set out in 10 CFR Chapter I must appear in the Supplementary Information section of the preamble to each proposed rule.

(1) If a proposed rule contains a backfit requirement that would substantially increase safety beyond adequate protection and would do so at a justifiable cost, the NRC shall insert the following statement.

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 rule. The Commission has determined, on the basis of this analysis, that backfitting to comply with the requirements of this proposed 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).

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

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 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, and therefore,"; 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, and therefore,"; 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 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.)

(3) If the backfit requirements of 10 CFR Chapter I do not apply to a proposed rule, the NRC shall insert the following statement or an appropriate variation of this statement.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed 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.]

5.25 List of subject index terms.

The OFR requires that each agency include a list of subject index terms for each part affected in a proposed rule document (1 CFR 18.20). The list of terms is intended to identify the major topics of the proposed rule and the categories of persons affected by it in a standard fashion. These terms appear 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*.

(a) The NRC shall place the list of subject index terms for each CFR part affected as the last item in the Supplementary Information section of the preamble to each proposed rule document. The list of subject index terms must appear in each proposed rule document submitted for publication in the *Federal Register*. The NRC shall present the list of subject index terms in alphabetical order as follows:

Example: Format used in 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: Format used in 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.

(b) The NRC shall use the subject index terms developed by RDB and approved by the OFR in the 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 appears in Appendix C to this handbook. If an originating office wishes to use additional terms, it shall consult with RDB (415-7163).

(c) A list of subject index terms is not required for a proposed rule that --

- (1) Does not contain regulatory text;
- (2) Only presents nomenclature changes; or
- (3) Corrects a previously published document.

5.27 Words of issuance.

The words of issuance ("pursuant to" clause) 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 proposes to amend or add. Use the following words of issuance, with a listing of each 10 CFR part affected, in each proposed rule.

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. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 30, 50, and 73.

5.29 Amendatory language.

(a) A proposed rule document suggests changes or additions to the CFR. Each amendatory instruction must describe how the existing text of 10 CFR Chapter 1 would be changed so that the regulatory text of the proposed rule would become the (new) text in 10 CFR Chapter I. In preparing its amendatory language, the NRC shall use the standard terms presented in paragraph (c) of this section to instruct the OFR on how to change the CFR.

(b) Amendatory language must be exact. The amendatory language for each change must --

(1) Identify the specific CFR unit being amended by its complete numerical and alphabetical designation;

(2) Use one of the standard terms to describe how the CFR unit is being changed; and

(3) Address all the regulatory text set out in the document.

(c) 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.

(1) **Added.**

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

Examples:

1. Part 53 is added to read as follows: (An entire new CFR part is added).

2. Section 50.47 is added to read as follows: (An entire new CFR section is added to a CFR part).

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

(ii) 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 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]

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

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

Examples:

1. Part 73 is amended by revising §§73.17 and 73.50 to read as follows:
2. 10 CFR Chapter I is amended by adding Part 103 to read as follows:
3. Section 73.97 is amended by removing paragraph (e).

(3) **Corrected.** "Corrected" means that a clerical or typographical error in a published document is fixed. The error must be corrected before the next annual revision of 10 CFR Chapter I. Once the error is codified, a formal 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.

Examples:

1. In the issue of March 15, 1996 (61 FR 12345), 10 CFR 42.10 is corrected by changing the reference in the second line from "§44.10" to "§44.20."

2. In the issue of May 3, 1996 (61 FR 98765), the delegation of authority is corrected in the first paragraph of the second column by changing "Director" to read "Administrator."

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

Examples:

1. In §30.15, paragraphs (e) and (f) are redesignated as paragraphs (d) and (e).
2. Part 33 is redesignated as Part 75.
3. Section 73.11 is transferred to Part 100 and redesignated as §100.71.
4. In §54.12, paragraph (d) is redesignated as paragraph (e) and revised to read as follows:

(5) **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.

Examples:

1. Part 110 is amended by removing §110.70.
2. In §20.25, paragraphs (d)(2) and (f) are removed.

(6) **Republished.** "Republished" means that an unchanged unit of CFR text is set out for the convenience of the reader, often 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 proposed rule document may be used to update the CFR, the NRC shall present any republished text it chooses to use accurately.

Example:

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

(7) **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.

Examples:

1. In §20.25, paragraph (f) is revised to read as follows:
2. Section 9.9 is revised to read as follows:
3. Part 19 is revised to read as follows:

(8) **Nomenclature change.** "Nomenclature change" means that a term or phrase is changed throughout a CFR unit. It is mostly used to change an official designation or the title of an agency office. 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 shall determine, in consultation with the OFR, when marked pages must accompany a nomenclature change.

Example:

1. 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."

(9) **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. The NRC should avoid an open-ended suspension by stating the duration of the suspension in the document announcing the action. During the suspension, the suspended provision is not in

effect or enforceable. 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 followup document necessary to remove the suspended provision or to lift the suspension.

Example:

1. In §2.712, the provisions of paragraph (f) are suspended until further action by the Commission.
2. Section 95.49 is suspended from July 1, 1995, to October 1, 1996.

(10) **Withdrawn.** "Withdrawn" has a different connotation in a proposed rule document than in a final rule document.

(i) In a proposed rule, "withdrawn" is used to indicate that a previously published proposed rule will not be issued as a final regulation.

(ii) In a final rule, "withdrawn" is used to indicate that a final rule with a pending effective date will not go into effect.

(d) 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.

Examples:

1. 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).
2. 10 CFR 50.20 is amended by revising paragraphs (a)(5)(iii), (c)(3), (c)(5)(iv), and (d) to read as follows:

(e) If a document amends several nonconsecutive CFR sections within a part, the changes to each section must be completely described by a separate amendatory instruction.

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

(2) The authority citation for the part must appear directly after the part heading. (See Section 5.31 concerning authority citations.)

Example: The purpose of this example is to show a series of amendments within a part and the proper sequence and placement of the required elements.

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 Part 33.

**PART 33 - SPECIFIC DOMESTIC LICENSES OF
BROAD SCOPE FOR BYPRODUCT MATERIAL**

1. The authority citation for Part 33 is revised 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. (Note: The use of asterisks in amending CFR text is discussed in Section 5.37 of this handbook.)

5.31 Authority citations.

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

(1) 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 proposes to amend.

(2) 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).

(b) **Content.** RDB maintains a list of currently effective authority citations for each part in 10 CFR Chapter 1. The drafter may contact RDB to obtain the current authority citation for insertion into his or her document (415-6864). OGC is responsible for determining whether a change to the currently effective authority citation is required by the proposed amendment.

(c) **Placing authority citations: When amending an entire CFR part.** If a document sets out a whole 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.
- 19.12 Instructions 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: 42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 5841.

(d) Placing authority citations: When amending a portion of a CFR part. If a document amends only certain sections within a CFR part, a complete citation of authority must be presented.

(1) 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 as 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: 42 U.S.C. 2201, 2278a, 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.

(2) 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 the 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: *A part authority that is amended by adding 42 U.S.C. 2093 as an additional authority.*

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

AUTHORITY: 42 U.S.C. 2073, 2093, 2111, 2201, 2232, 2233, 5842, 5846.

2. Section 71.2 is revised to read as follows:

§71.2 Scope.

The regulations in the 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.

(3) If a section is issued under a specific authority that differs from the overall part authority, 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: *A part authority that includes section-specific citations. The second paragraph sets out the section-specific authorities.*

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

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

AUTHORITY: 42 U.S.C. 2092, 2093, 2094, 2095, 2201, 2232, 2233, 5842, 5846.

Section 40.31(g) also issued under 42 U.S.C. 2152. Section 40.46 also issued under 42 U.S.C. 2234.

5.33 Regulatory text: CFR codification.

(a) **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 proposed rule document must be presented as an amendment to 10 CFR Chapter 1. Regulatory text must --

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

(b) **CFR structure.** (1) 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

(2) 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.

(3) 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. The first section in Part 25 is expressed as "§25.1." Sections in a new or revised part need not be numbered consecutively. Using all odd or even sequential numbers in designating sections within a new or revised part leaves room for future expansion.

(4) 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), etc.
For further subdividing of a paragraph	(1), (2), (3), etc. (i), (ii), (iii), etc. (A), (B), (C), etc.
Note: Underlined symbols are printed in italics.	(<u>1</u>), (<u>2</u>), (<u>3</u>), etc. (<u>i</u>), (<u>ii</u>), (<u>iii</u>), etc.

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

Paragraph symbol	(a) (1) (i) (A) (<u>1</u>) (i)
Level of Designation	1 2 3 4 5 6

(i) 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

(ii) When a paragraph is subdivided, the alphanumeric designators should highlight the organization of the paragraph. Like 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.

(iii) The NRC shall 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 the drafter is attempting to include too much material within the section. As a result, a user will have more difficulty locating needed material within the 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. (See Section 17.7 of this handbook, Arranging material for ease of use.)

- (iv) The OFR no longer permits the use of an undesignated concluding paragraph.

Example: *This type of construction is forbidden.*

(a) 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.

- (v) 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.

- (6) The OFR does not permit 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.

(i) The NRC 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. However, any new material must be designated in standard fashion.

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

(iii) 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.

(c) **Plan for the future.** The NRC 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 after it has been in effect and changes are necessary.

(d) **Full text amendment.** The NRC shall present each amendment in a proposed 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.

(e) **Footnotes.** The NRC 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, care must be taken in the manner and form in which it is designated and presented. Incorrectly designated footnotes cause errors when a document is printed in the *Federal Register*, and again when regulatory text is codified in the CFR. The NRC shall follow these guidelines when presenting footnotes in the text of a regulatory document.

(1) 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. Asterisks or other symbols may not be used to designate footnotes within regulatory text.

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

(i) 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.

(ii) If both the preamble and the regulatory text of a document contain footnotes, a separate numbering sequence must be used in each. The preamble is not retained in the CFR.

(iii) 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).

(3) 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 must be set out as part of the amendment.

5.35 Regulatory text: Headings.

(a) **General.** 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.

(b) **Part headings.** The part heading is a concise statement that describes the content or effect of the regulatory program contained in the part. The NRC 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.

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

(1) 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.

* * * * *

(2) 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.

(d) **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....

* * * * *

5.37 Form of amendment: Section level.

(a)(1) Each amendment made at the section level requires three elements. These elements must appear in the following order--

- (i) Proper amendatory language;
- (ii) The section heading of the section being changed; and
- (iii) The regulatory text of the section being changed.

(2) 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.

(b) 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 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 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.

Regulatory 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.

(c) 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.

(1) Five asterisks in a row indicate that one or more entire paragraphs are not being amended.

(2) 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. (See Sections 5.33(b)(4) and (5) of this handbook concerning paragraph designation.)

(d) 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 elements must be included:

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

(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.

Example:

This example serves two purposes. It illustrates --

- (1) The proper method of presenting a series of section-level amendments within a document; and
- (2) The correct use of asterisks to indicate unchanged text within a section.

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

§20.1101 Radiation protection programs.

Indicates that paragraph
(a) is unchanged

* * * * *

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

Revised text of paragraph
(c)(1)

Indicates that the rest of
the section is unchanged

Amendatory language

Section heading

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 within
paragraph (b)(1)

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

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

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

Indicates that the rest of
the section is unchanged

Part heading

(c) * * *

(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

* * * * *

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

§20.2201 Reports of theft or loss of licensed material.

* * * * *

(b) * * *

(1) * * *

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

* * * * *

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

* * * * *

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

5.39 Form of amendment: Part and subpart level.

(a) Each amendment made at the part level requires the following elements. The elements must appear in the following order--

- (1) Proper amendatory language;
- (2) The part heading;
- (3) A table of contents for the part;
- (4) The authority citation; and
- (5) Regulatory text.

Example:

Amendatory language

1. 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 Applicability of 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.

Note: 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.

(b) Amendments may also 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.

(c) 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 --

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

5.41 Proper cross-referencing techniques.

(a) A "cross-reference" is a reference from one unit of the CFR to another unit. A cross-reference only may 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* (see Section 5.43 of this handbook, Incorporation by reference).

(b) 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 agency if the OFR finds that --

- (1) The reference is required by court order, statute, Executive order, or reorganization plan;
- (2) 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;
- (3) The reference is informational or improves clarity and does not impose a requirement;
- (4) 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
- (5) The reference is to the department level from a subagency.

(c) Identify the CFR unit being cited by the proper CFR unit designation in each cross-reference. A nonspecific reference, such as "herein," "above," or "below," requires interpretation by the user and may result in ambiguity.

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

HOW TO WRITE A CROSS-REFERENCE IN CFR TEXT

References to a different TITLE

<u>When referencing</u>	<u>Write</u>
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

<u>When referencing</u>	<u>Write</u>
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

<u>When referencing</u>	<u>Write</u>
A section	§20.15
A paragraph	§20.15(a)

References within the same SECTION

<u>When referencing</u>	<u>Write</u>
A paragraph	Paragraph (b) of this section
A subdivision within a paragraph	Paragraph (b)(1)(i) of this section

5.43 Incorporation by reference.

(a) 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.

(b) For an incorporation by reference to be valid, it must be approved by the Director of the Federal Register. OFR requirements for approval of an incorporation by reference appear at 1 CFR Part 51.

(1) Material is eligible for incorporation by reference if it meets the following criteria:

(i) It is published data, criteria, standards, specifications, techniques, illustrations, or similar material.

(ii) It does not detract from the legal or practical attributes of the Federal Register publishing system established by the Federal Register Act, the APA, 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 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.

(iii) 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.

(iv) 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 --

(A) Inspect the material at the OFR, the agency's central and regional offices, or in depository libraries; and

(B) Purchase the material from the publisher or the agency at reasonable cost.

(2) Statements of incorporation by reference contained in regulatory text must meet specific drafting standards. Each statement of incorporation by reference must --

(i) Include the words "incorporation by reference";

(ii) Identify the standard and/or material to be incorporated by title, date, edition, author, publisher, and identification number;

(iii) Contain a brief subject description;

(iv) Contain a statement of availability; and

(v) 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: A statement of incorporation by reference that meets OFR requirements.

(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 also is available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20852-2738, and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC 20408.

(1) As used in this section, references to Section 111 of the ASME Boiler and Pressure Vessel Code refer to Section III, Division I, 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:

(c) 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.

(d)(1) The OFR requires that a written request for each incorporation approval be submitted to the Director of the Federal Register. The request must be submitted at least 20 working days before the final rule is submitted for publication. Each request for incorporation by reference approval must contain --

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

(2) RDB usually requests a preliminary review of an anticipated incorporation by reference when the proposed rule containing the intended incorporation is published in the *Federal Register*. Although this preliminary review does not a guarantee OFR approval of the request, it provides the NRC and the OFR with an opportunity to resolve potential problems before the final rule is prepared and submitted for publication.

5.45 Signature block.

(a) Each proposed rule 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 _____, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

(b) Proposed rules that are approved and issued by the Commission are prepared for the signature of the Secretary of the Commission. Proposed rules that are issued under the rulemaking authority delegated to the EDO are prepared for the EDO's signature (see Section 1.7 of this handbook). Proposed rules that are issued under the rulemaking authority delegated to the CFO are prepared for the CFO's signature (see Section 1.9 of this handbook).

PART 7 - FINAL RULES

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7.1 Final rule documents: Description.

(a) Each document the NRC prepares that is published in the Rules and Regulations section of the *Federal Register* must meet the format requirements specified in 1 CFR Chapter I. The requirements applicable to a final rule are discussed in this part. 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. 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. The OFR classifies the following types of documents for publication in the Rules and Regulations section of the *Federal Register*.

(1) **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, the NRC shall publish each change to 10 CFR Chapter I in full and state 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.

(2) **Direct final rules.** A direct final rule is a regulatory document that is used for noncontroversial 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. For additional information concerning direct final rules, please see Part 9 of this handbook.

(3) **Interim or temporary rules.** An interim or temporary rule is a regulatory document that is effective for a definable 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 may request public comment 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.

(4) **Documents that relate 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 --

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

(5) **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 policy statement prepared by the NRC should comply with the format requirements specified in Section 7.7 of this handbook. The Rules and Directives Branch (RDB) should review each

policy statement to determine whether it meets all procedural and format requirements for publication and can be properly integrated into the *NRC Rules and Regulations* after it is published in the *Federal Register*.

(b) NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Rules and Regulations section of the *Federal Register*. Within NRC, the originating office has the primary responsibility for identifying and correcting errors that appear in a published final rule document. See Section 13.5 of this handbook for information on preparing a correction document. The originating office shall coordinate the preparation of a correction document with RDB.

(c) The following document format requirements are applicable to each final rule submitted for publication in the *Federal Register*.

(1) The NRC billing code, [7590-01-P], must appear in the upper right-hand corner on the first page of the document.

(2) Document text must be double-spaced.

(3) Document text may appear on only one side of the page.

7.3 Final rule documents: Anatomy.

This section examines a typical final rule document. Each essential element of a final rule is identified to help a writer meet the required elements of a final rule document and create a complete and correct document. The number of the section in this handbook that discusses each required element in detail is indicated in parentheses. The format used in this and other examples to present document text generally reflects the format used in printing the *Federal Register*. However, the format used in the sample final rule document (see Section 19.4 of this handbook) reflects the format used in typing a document for publication in the *Federal Register*.

SAMPLE: FINAL RULE

	Agency Heading	NUCLEAR REGULATORY COMMISSION
HEADINGS	CFR Citation Heading	10 CFR Part 50
(7.5)	RIN Heading	RIN 3150-AA11
	Subject Heading	Reporting Changes to the Quality Assurance Program
PREAMBLE	Captioned Headings	AGENCY: Nuclear Regulatory Commission.
(7.7)		ACTION: Final rule.
		SUMMARY: The Nuclear Regulatory Commission is amending its regulations to permit power reactor licensees to make certain quality assurance changes without obtaining NRC review and approval of these changes in advance. The final rule allows licensees to make routine or administrative changes that should not have an adverse impact on the effectiveness of their QA programs. This action reduces the financial and administrative burden on power reactor licenses without adversely impacting public health and safety.
		EFFECTIVE DATE: (Insert date 30 days after the date of publication).
		FOR FURTHER INFORMATION CONTACT: (Name of contact person) Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC

20555-0001; telephone 301-415-0011; e-mail
xxx@nrc.gov.

Statement of
Considerations
(7.9)

SUPPLEMENTARY INFORMATION:

The Nuclear Regulatory Commission (NRC) is amending its regulations to permit power reactor licensees to make certain changes to their QA programs without obtaining NRC approval in advance.

Note: If a final rule contains an extensive Supplementary Information discussion, the Supplementary Information section must begin with a table of contents for the Supplementary Information section (see Section 7.9 (b) of this handbook).

The Supplementary Information section must include a section-by-section analysis of the substantive provisions of the final regulatory text.

The Supplementary Information section must discuss the views, concerns, and comments raised by Agreement States in the development of a final rule that would amend 10 CFR Parts 30, 34, 35, 40, 61, or 70, or their State equivalent.

PROCEDURAL National
REGULATORY Technology
REQUIREMENTS Transfer and
 Advancement
 Act (7.13)

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that agencies use technical standards that are developed or adopted by voluntary consensus bodies unless the use of such a voluntary standard is inconsistent with applicable law or is otherwise impractical. In this final rule, the NRC is allowing its power reactor licensees to make certain types of changes to their quality assurance program without obtaining NRC approval in advance. This action relaxes existing regulatory requirements and does not constitute the establishment of a standard that contains generally applicable requirements.

National
Environmental
Policy Act
(7.15)

**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. (Briefly present the reasons why the action does not have any significant environmental impact, summarize the environmental assessment, and note any other related environmental documents.)

The NRC provided every State Liaison Officer a copy of the environmental assessment and the proposed

rule for this action and requested their comments on the environmental assessment. (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
(7.17)

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, OMB approval number 3150-0011.

The burden to the public for this information collection is estimated to average _____ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-xxxx), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory
Analysis
(7.19)

Regulatory Analysis

The Commission has prepared a regulatory analysis for this regulation that examines the costs and benefits of the alternatives considered by the Commission.

Regulatory
Flexibility Act
(7.21)

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. This 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 2.801).

Backfit Analysis
(7.23)

Backfit Analysis

As required by 10 CFR 50.109, the Commission has completed a backfit analysis for this final rule. The Commission has determined on the basis of this analysis that backfitting to comply with the requirements of this final rule provides 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: (Here insert the text of the backfit analysis.)

Small Business
Regulatory
Enforcement
Fairness Act
(7.25)

**Small Business Regulatory
Enforcement Fairness Act**

In accordance with the Small Business Regulatory Enforcement Fairness Act 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.

SUBJECT INDEX TERMS
(7.27)

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire prevention, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

WORDS OF ISSUANCE
(7.29)

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 50.

PART HEADING

**PART 50 - DOMESTIC LICENSING OF PRODUCTION
AND UTILIZATION OF FACILITIES**

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY CITATION

AUTHORITY: 42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2239, 5841, 5842, 5846.

AMENDATORY LANGUAGE
(7.33)

2. In §50.54, paragraph (a)(3) is revised to read as follows:

§50.54 Conditions of licenses.

(a) * * *

REGULATORY TEXT
(3.35-3.41)

(3) Each licensee described in paragraph (a)(1) of this section may make a change to a previously accepted quality assurance program (QA) description included or

referenced in the Safety Analysis Report without prior NRC approval, if the change does not reduce commitments in the program description as accepted by the NRC. Changes to the QA program that do not reduce the commitments made must be submitted to the NRC in accordance with the requirements of §50.71(e). In addition to QA program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

(i) The use of a QA standard approved by the NRC that is more recent than the QA standard in the licensee's current QA program at the time of the change;

(ii) The use of a QA alternative or exception approved by an NRC safety evaluation, if the bases of the NRC approval are applicable to the licensee's facility;

(iii) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(iv) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternately, the use of descriptive text;

(v) The elimination of QA program information that duplicates language in regulatory guides and QA standards to which the licensee is committed; and

(vi) Organizational revisions that ensure that persons and organizations performing QA functions continue to have requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

* * * * *

SIGNATURE BLOCK
(7.47)

Dated at Rockville, Maryland, this __ day
of _____, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

7.5 Document headings.

(a) Each final rule document the NRC submits for publication in the *Federal Register* begins with a series of headings that -

- (1) Identify NRC as the agency issuing the document;
- (2) Indicate the parts within 10 CFR Chapter I that the document amends, adds, or affects;
- (3) Provide the unique regulation identifier number (RIN) of the final rule; and
- (4) Indicate the subject matter of the document.

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-BB22

Testing Radioisotope Generators

(b) The "CFR Citation" heading must contain the number of each part the document amends or adds. Even if the document affects only 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 final rule for *Federal Register* publication, this heading must present the number of the CFR part that the subject matter of the document most closely matches. If no CFR part is appropriate, the CFR chapter designation may be used (10 CFR Chapter 1).

(c) 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. For assistance in identifying the RIN that has been assigned to a final rule, contact RDB (415-6863).

(d) The "Subject" heading is a brief statement that describes the content of the document. The CFR part heading may be sufficient for this purpose. However, more specific information may be needed if the part heading is too general or to differentiate between multiple documents amending the same part or parts.

(e) Occasionally, a document that appears in the Rules and Regulations section of the *Federal Register* concerns the identical subject matter of a document published previously. This situation usually occurs when followup documents are necessary in a rulemaking proceeding. To emphasize the relationship between the two documents, the OFR requires that the later document repeat the headings of the earlier document. In addition, a word or phrase identifying the action or type of the second document must be added to the subject heading.

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-BB22

Testing Radioisotope Generators; Confirmation of Effective Date

7.7 Preambles: Format requirements.

Each final rule the NRC prepares for publication in the *Federal Register* must begin with a preamble. Within 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, which are discussed below, arrange basic information concerning the regulation in a uniform format to allow a user to scan the beginning of the document for essential information. The OFR will not print a final rule document that does not meet the format requirements described in this section.

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

Example:

AGENCY: Nuclear Regulatory Commission.

(b) **ACTION.** This caption identifies the type of document being published more precisely than the publication categories of the *Federal Register* allow. This caption may not be used to summarize the content or amendatory action of the document. Permissible entries under this caption for a final rule document are as follows:

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: Final rule: Interpretation.

ACTION: Direct final rule.

ACTION: Interim rule.

ACTION: Interim rule with request for comment.

ACTION: Policy statement.

(c) **SUMMARY.** The Summary is a brief description, written in language that a nonexpert will understand, that allows the reader to determine the subject and intended effect of 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.

(1) The Summary must answer these questions:

(i) What does this document do?

(ii) Why is this action necessary?

(iii) What is the intended effect of this action?

(iv) Who is affected by the regulation? (For example, what class of licensee?)

(2) The answers to these questions must be presented in paragraph form and 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 NRC for required revisions.

(3) The Summary must --

(i) Avoid legal citations (e.g., 10 CFR 35.15(c)(2) or 42 U.S.C. 2201);

(ii) Refer to an act of Congress by popular name (e.g., Atomic Energy Act of 1954);

(iii) Avoid qualifications, exceptions, extensive background, or specific details; and

(iv) 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: 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.

(d) **DATES.** This caption identifies each date within the document that is vital to the rulemaking proceeding.

(1) 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.

(2) The date caption contains only the date. Additional information concerning compliance schedules, application procedures, and other matters should be presented in the Supplementary Information portion of the preamble, not under the "Dates" caption.

Example:

EFFECTIVE DATE: September 24, 2001.

(3) 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.

(4) 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.

(e) **ADDRESSES.** This caption identifies any address that the participant in a proceeding needs to know. This caption is optional in a final rule because comments are not requested and no other address may be necessary. Information that may be presented in a rule document includes the addresses for --

- (1) Mailing or hand delivering comments on an interim rule;
- (2) Attending a public hearing or meeting;
- (3) Examining any material available for public inspection; or
- (4) Obtaining other documents referred to in the final rule.

Example:

ADDRESSES: To inspect or obtain documents related to this rulemaking, see the Availability of Documents heading in the Supplementary Information section.

A hearing concerning licensee requirements under this regulation will be held at the NRC Auditorium, 11545 Rockville Pike, Rockville, Maryland.

(f) **FOR FURTHER INFORMATION CONTACT.** This caption identifies a person who can answer questions or provide additional information concerning the document. The name and telephone number of the designated individual must be presented. The NRC may include 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.

FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-1111; e-mail 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) 415-1111; e-mail xxx@nrc.gov, or (Name of contact person), Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-2222; e-mail xxx@nrc.gov.

7.9 Preambles: Supplementary Information.

(a) The Supplementary Information section of the preamble serves as the published history of the document. The Supplementary Information section in a final rule contains the background information and specific details necessary to explain the basis and purpose of the regulation. The Supplementary Information for a final rule is based upon the Supplementary Information for the preceding proposed rule. In most respects, the Supplementary Information discussion for the substantive aspects of the final rule will be exactly the same as the Supplementary Information discussion for the proposed rule except for --

- (1) The comment analysis;
- (2) Where the final rule differs from the proposed rule's recommendation; and
- (3) Where necessary to reflect the differing status between a proposed rule and a final rule.

(b) In Supplementary Information, the NRC shall, at a minimum, explain its reasoning in support of the adopted regulation in sufficient detail to provide the courts with a factual and reasoned explanation to serve as the basis for judicial review. The items presented in this paragraph serve as an overview of the topics that must be considered to present an adequate explanation of the regulation. 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 should include a discussion of --

- (1) The purpose of the regulation;
- (2) The need for the regulation;
- (3) The laws or directives that authorize the regulatory action;
- (4) The relationship of the regulation to existing regulations;

(5) The rulemaking history of the proceeding that specifically identifies, by complete *Federal Register* citation, the proposed rule and any other published document that is relevant to this rulemaking action;

(6) The alternatives considered in developing the regulation;

(7) The economic impact of the selected alternative on those likely to be affected by the regulation;

(8) The public comments received;

(9) The views, concerns, and comments raised by Agreement States during development of the final rule;

(10) How, if at all, the regulation was modified in response to public comment, Agreement State participation, or any other factors;

(11) A section-by-section analysis of the substantive provisions of the final regulation on a provision-by-provision basis;

(12) Any noncompliance or penalty provisions;

(13) Whether the final rule has an effect on family well-being; and

(14) Whether the final rule uses a voluntary consensus standard or a Government-unique standard.

(c) The drafter shall use descriptive center headings to divide and describe material in the Supplementary Information section. Center headings help break up long stretches of text and aid the user in finding particular items of interest. By providing a table of contents that consists of the headings used in the Supplementary Information portion of the preamble, the drafter also can provide the user with a quick overview of the information presented. A table of contents should be provided for all but the briefest rules.

Example: This example illustrates the use of descriptive headings and a table of contents in the Supplementary Information section of the preamble.

SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Rulemaking Initiation.
- III. Action Taken.
- IV. Basis for Technetium.
- V. Basis for Uranium Limit.
- VI. Specific Licensing Conditions.
- VII. Analysis of Public Comment.
- VIII. Section-by-Section Analysis of Substantive Changes.
- IX. Agreement State Compatibility.
- X. Availability of Documents.
- XI. Voluntary Consensus Standards.
- XII. Finding of No Significant Environmental Impact: Availability.
- XIII. Paperwork Reduction Act Statement.
- XIV. Regulatory Analysis.
- XV. Regulatory Flexibility Certification.
- XVI. Backfit Analysis.
- XVII. Small Business Regulatory Enforcement Fairness Act.

(d) If the NRC published the regulation as a proposed rule, the NRC shall discuss the substantive comments received in response to the proposed rule in the Supplementary Information section of the preamble to the final rule. A substantive comment is any comment that is a serious attempt to address an issue that was raised in the proposed rule. Comments presenting substantive changes or suggestions must be discussed in detail. Nonsubstantive, editorial, corrective comments, as well as those that request clarification or present exhortations, may simply be acknowledged.

(1) In presenting its analysis of public comments the NRC shall --

(i) Indicate any substantive change made in the final rule as a result of public comment and the reasons for accepting the suggestion;

(ii) Indicate any new material or information relevant to the rulemaking received as a result of public comment; and

(iii) Discuss any substantive comments that were not accepted and the reasons for rejecting them.

(2) If substantive changes are made in a final rule as a result of public comment on a proposed rule, the 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 --

(i) The NRC's explanation for selecting the final version of the rule from the alternatives considered;

(ii) The breadth of alternatives first mentioned in the proposed rule;

(iii) The magnitude of the changes; and

(iv) The factual reasons for the change.

(3) 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 NRC's response and its reasons for accepting or rejecting the comment.

(i) Comment analysis is not a vote count. Logic and reasoning are more important than numbers.

(ii) Fairness is essential in responding to comments, both in characterizing the comment and in explaining why the comment was accepted or rejected.

(iii) Each individual comment need not be addressed separately. If several comments raise the same issue, they may be treated in the aggregate and addressed in a single response.

(iv) Comments of a minor or clarifying nature should be discussed in the aggregate in the comment analysis.

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

(4) 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, the NRC may summarize the analysis in the comment response section of the Supplementary Information portion of the preamble. In this discussion, the NRC should indicate that a detailed analysis has been prepared and is available for public inspection in the NRC Public Document Room.

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 and copying for a fee at the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland.

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 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 deleted 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 the 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 the 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 or for any reimbursement to an employer. On the basis of a review of the accusations to DOL, it appears that, at an early stage, DOL accomplishes termination of the proceedings when the accusation appears to be unwarranted.

(e) The Supplementary Information section must contain a section-by-section analysis of the substantive provisions of the final regulatory text. This analysis provides a substantive description of the changes made in the regulation sufficient to provide the NRC staff, the affected licensees, and the public with the information necessary to determine what is specifically required by each provision. This description should present a concise description of what the provision does and provide any necessary clarification concerning the nature of the

imposed requirement. The section-by-section analysis should focus on implementation issues, such as how specific terms of art are interpreted and what the NRC's expectations are in specific situations. The section-by-section analysis should also discuss any substantive differences between the proposed rule and the final rule. The section-by-section analysis should not explain the reasons (basis) why the NRC is adopting the provision or change in question.

Example:

Section-by-Section Analysis

Section 170.11 Exemptions.

This section is amended to add a new paragraph indicating that amendments to materials portable gauge licenses issued in accordance with NUREG-1556 that change only the name of the Radiation Safety Officer (RSO) are exempt from amendment fees. This change is consistent with the recent Business Process Redesign (BPR) initiative and NUREG-1556, Volume 1, issued for public comment on October 3, 1996 (61 FR 51729). Amendment fees will not be assessed for the amendments issued in accordance with NUREG-1556 to portable gauge licenses because the regulatory program would include licensee commitments concerning RSO qualifications and if those commitments are included in the amendment application, the NRC would not conduct a technical review.

Section 170.20 Average cost per professional staff-hour.

This section is amended to establish two professional staff-hour rates based on FY 1997 budgeted costs--one for the reactor program and one for the nuclear material and nuclear waste program. Accordingly, the NRC reactor direct staff-hour rate for FY 1997 for all activities the fees for which are based on full cost under §170.21 is \$131 per hour, or \$233,055 per direct FTE. The NRC nuclear material and nuclear waste direct staff-hour rate for all materials activities the fees for which are based on full cost under §170.31 is \$125 per hour, or \$222,517 per direct FTE. The rates are based on the FY 1997 direct FTEs and NRC budgeted costs that are not recovered through the appropriation from the NWF or the General Fund. The NRC has continued the use of cost center concepts established in FY 1995 in allocating certain costs to the reactor and materials programs in order to more closely align budgeted costs with specific classes of licensees. The method used to determine the two professional hourly rates is as follows:

* * * * *

(f) The Supplementary Information section of the preamble to each final rule that affects facilities licensed under 10 CFR Parts 30, 34, 35, 40, 61, and 70, or their State equivalent, must contain a discussion of the opportunities afforded to the public and Agreement States for their early and substantive participation in the rulemaking process. This discussion must present the views, concerns, and comments raised by the public and Agreement States during the development of the final rule. This discussion should contain sufficient detail to provide the public and Agreement States with an additional opportunity to review NRC's rationale in response to their comments during the public comment period. The discussion should be presented as a readily identifiable portion of the general discussion concerning any substantive comments received in the Supplementary Information section of the preamble to the final rule (See paragraph (d) of this section).

(g) If a final rule affects Indian tribes or receives comments from Indian tribes or Tribal organizations, the Supplementary Information section of the preamble to the final rule must contain a readily identifiable discussion of any substantive comments received. (See paragraph (d) of this section.)

(h) The NRC shall include a statement in the Supplementary Information section of the preamble to the final rule 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.

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 Public Electronic Reading Room (PERR). The NRC's public electronic reading room is located at www.nrc.gov/NRC/ADAMS/index.html. (Provide accession number for each document.)

The NRC staff contact (NRC Staff). (Provide the name, address, and telephone number of the NRC staff contact.)

Document	PDR	Web	PERR	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		
RGx.xx	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 the Chief Information Officer, 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 posted at NRC's technical document Website www.nrc.gov/NRC/NUREGS/indexnum.html.

(i) The Administrative Procedure Act (APA) generally requires that an agency publish a notice of proposed rulemaking to provide an interested person with notice of the proceeding and afford him or her 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 become effective 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.

(1) If the NRC has not published a notice of proposed rulemaking, the NRC shall indicate the APA exemption under which it waives notice and comment procedures.

(i) The NRC may determine that the publication of a proposed rule is unnecessary if --

(A) The rule is an interpretive rule that is not, of itself, substantive or binding;

(B) The rule is a general statement of policy that does not establish a binding norm imposing substantive rights or obligations;

(C) The rule is a rule of agency organization, procedure, or practice; or

(D) The NRC can show good cause that notice and comment are impracticable, unnecessary, or contrary to the public interest.

(ii) The NRC shall allow a 30-day post-promulgation comment period for --

(A) 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; and

(B) 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.

(iii) If the NRC determines that a proposed rule is not required, the NRC shall 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).

(2) If the NRC determines that a final rule should become effective when it is published in the *Federal Register*, the NRC shall indicate the APA exception under which it waives the deferred effective date requirement.

(i) The NRC may waive the deferred effective date requirement --

(A) For a substantive rule granting or recognizing an exception or relieving a restriction;

(B) For an interpretative rule;

(C) For a statement of policy; or

(D) When the NRC can show good cause for making the rule effective immediately.

(ii) If the NRC determines that the deferred effective date requirement may be waived for a final rule, the NRC shall 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*.

(3) 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.

(j) Assessment of Federal regulations and policies on families.

(1) Section 654 of the Treasury and General Government Appropriations Act, 1999 (act) (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 must also provide an adequate rationale for implementing those policies and regulations that may negatively affect family well-being.

(2) The act does not impose any restrictions on the effective date of any rule or policy.

(3) The following statement must be inserted in the Supplementary Information section of the preamble, directly above the Voluntary Consensus Standards heading, to any final rule for those actions that may have a negative effect on family well-being.

Assessment of Federal Regulations and Policies on Families

In accordance with Section 654 of the Treasury and General Government Appropriation 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.]

(4) The following statement must be inserted in the Supplementary Information section of the preamble, directly above the Voluntary Consensus Standards heading, to any final rule for those actions that may affect family well-being but the impact of which will not be negative .

Assessment of Federal Regulations and Policies on Families

In accordance with Section 654 of the Treasury and General Government Appropriation 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.

(5) 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.

(6) A simple process for assuring compliance with the requirements of the act is contained in Appendix G to this handbook. Questions concerning this act may be directed to Michael T. Lesar (415-7163).

7.11 Procedural requirements for rulemaking.

(a) Sections 7.13 through 7.25 of this handbook discuss the portion of the Supplementary Information section of the preamble relating to the procedural requirements the NRC follows in developing and issuing a final rule. The requirements are intended to ensure that the NRC considers the impact of each regulatory alternative in the process of developing a final rule. The regulatory procedures the NRC follows in developing a final rule include --

(1) 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 (see Section 7.13 of this handbook).

(2) An assessment of the environmental impact of the final rule under the National Environmental Policy Act and 10 CFR Part 51 (see Section 7.15 of this handbook);

(3) OMB approval for each new or amended information collection requirement under the Paperwork Reduction Act (see Section 7.17 of this handbook);

(4) A regulatory analysis prepared in accordance with the Regulatory Analysis Guidelines approved by the Commission and issued as NUREG/BR-0058, Revision 3. A regulatory analysis examines the economic impact, in terms of costs and benefits, of alternatives considered in developing the final rule (see Section 7.19 of this handbook);

(5) An analysis of the economic impact of the final rule on small entities under the Regulatory Flexibility Act (see Section 7.21 of this handbook);

(6) A backfit analysis prepared in accordance with 10 CFR 50.109, 70.76, 72.62, or 76.76 (see Section 7.23 of this handbook);

(7) Compliance with the congressional review procedures established by the Small Business Regulatory Enforcement Fairness Act (see Section 7.25 of this handbook); and

(b) The environmental assessment and regulatory analysis should precede, or be prepared concurrently with, the development of the proposed rule. These documents should not be developed after the proposed rule is drafted. These analyses are invaluable tools in determining the necessity, extent, and direction of the rulemaking proceeding. As more information becomes available through the rulemaking process, the analyses may be adjusted or developed in greater detail. The regulatory action is reevaluated in terms of the more extensive analyses and adjusted as necessary before it is issued as a final action. However, after the draft analyses are made available for comment, if any changes are made to the analyses that are not the result of the public comment process, the analyses should be issued in draft form for comment.

(c) If the final rule adds or amends an information collection requirement affecting 10 or more persons, the NRC must obtain OMB approval of the information collection requirements. OMB must approve the information collection requirements before the final rule may be submitted for signature and publication. Section 5.1 of the Regulatory Analysis Guidelines requires that factors needed to obtain OMB approval be addressed in the regulatory analysis.

(d) The content of the analyses required under the Commission's Regulatory Analysis Guidelines and the Regulatory Flexibility Act is similar. The act permits a regulatory flexibility analysis to be combined with any other analysis as long as it meets the requirements of the act (see Section 7.21 of this handbook). 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 (see Section 7.19 of this handbook).

(e) The NRC's Regulatory Analysis Guidelines have been developed so that a regulatory analysis that conforms to the guidelines will meet the requirements of the backfit rule.

7.13 National Technology Transfer and Advancement Act.

(a) 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. These bodies have agreed 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).

(b) The preamble of each final rule must repeat the statement concerning the use of voluntary standards that appeared in the proposed rule or the interim final rule; acknowledge, summarize, and respond to any comments received; and explain the NRC's final decision.

(1) If a voluntary consensus standard is being used, the preamble must identify the standard and indicate any alternative consensus standards that were identified.

(2) If a Government-unique standard is being used instead of an existing voluntary consensus standard, the preamble must identify the standard and explain why using the voluntary consensus standard would be inconsistent with applicable law or is otherwise impractical.

(3) If a Government-unique standard is being used and no voluntary consensus standard has been identified, the preamble must contain a statement to that effect.

(4) If the rule does not constitute the establishment of a standard containing generally applicable requirements, it must contain a statement to that effect.

(c) The NRC shall include the following statement addressing the use of voluntary standards in the Supplementary Information section of the preamble to each 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 final rule, (insert one of the following options):

Option 1. "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. "The NRC is using the following Government-unique standard: (identify the standard by name, developing organization, and date issued). NRC is using this standard instead of the following voluntary consensus standard: (identify the standard by name, developing organization, and date adopted). 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. "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. "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."

(d) If the final rule concerns the NRC's approval of a standard design certification, the NRC shall include the following statement addressing the use of voluntary standards in the Supplementary Information section of the preamble.

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 final rule, the NRC 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 final rule.

(e) 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, the 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.

(f) Written 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 additional information, see the standards Website:
www.nrc.gov/NRC/REFERENCE/Standards/index.html.

7.15 National Environmental Policy Act (NEPA).

(a) 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 decisionmaking process of the agency.

(b) The NRC shall assess the environmental impact of each final regulatory action and include a statement concerning the environmental impact in the Supplementary Information section of the preamble to each final rule. If a proposed rule was developed for the action, the NRC has made its preliminary determination as to the environmental impact of the action (see Section 5.15 of this handbook). Absent significant public comment received 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, the NRC should complete all consultation requirements before the final environmental action is issued.

(1) If a final rule 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 or an environmental assessment is not required for the regulatory action (See paragraph (c) of this section).

(2) If the final rule is not eligible for one of the categorical exclusions listed in 10 CFR 51.22(c), the NRC shall prepare an environmental assessment on the final rule. The draft environmental assessment prepared for the proposed rule must be updated to reflect any changes resulting from public comment or new information received from any other source. If the NRC completes an environmental assessment and finds that the final rule is not a major action significantly affecting the quality of the human environment, an environmental impact

statement need not be prepared. The NRC shall prepare and publish a finding of no significant impact (see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119.) This finding 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 (See paragraph (f) of this section).

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

(4) The NRC shall also prepare an environmental impact statement if the final 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)).

(c) An environmental impact statement or an environmental assessment is not required for a licensing or regulatory action, including a final rule, which is eligible for a categorical exclusion. A final rule is eligible for a categorical exclusion if the action belongs to a category of actions that the Commission has declared by rule to be a categorical exclusion after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment.

(1) The following types of rulemaking actions have been determined to be categorical exclusions:

(i) Amendments to Parts 1, 2, 4, 7, 8, 9, 10, 11, 14, 19, 21, 25, 55, 75, 95, 110, 140, 150, 170, or 171 of this chapter (10 CFR 51.22(c)(1)).

(ii) Amendments to the regulations in this chapter that are corrective or of a minor or nonpolicy nature and do not substantially modify existing regulations (10 CFR 51.22(c)(2)).

(iii) Amendments to Parts 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 50, 51, 60, 61, 70, 71, 72, 73, 74, 81, or 100 of this chapter that are related to --

(A) Procedures for filing and reviewing applications for licenses or construction permits or other forms of permission, or for amendments to or renewals of licenses or construction permits or other forms of permission;

(B) Recordkeeping requirements; or

(C) Reporting requirements (10 CFR 51.22(c)(3)).

(iv) Actions on petitions for rulemaking relating to the amendments specified in this paragraph.

(2) If the NRC determines that a final rule falls within a category of actions determined to be a categorical exclusion (10 CFR 51.22(c)), the NRC shall include the following statement in the Supplementary Information section of the preamble to the final rule.

Environmental Impact: Categorical Exclusion

The NRC has determined that this 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 final rule.

(d) In order to fulfill a commitment made to the Council on Environmental Quality, the NRC shall consult with the States on environmental issues before issuing an environmental assessment and shall document the consultation in the environmental assessment. The Executive Director for Operations (EDO) has approved an NRC procedure for consultation with the States during the preparation of an environmental assessment for a rulemaking action (see

the memorandum from David L. Morrison to multiple addressees dated May 18, 1995). These procedures are presented in Appendix E to this handbook.

(e) In a letter dated March 31, 1994, from the Chairman to the President, the NRC voluntarily agreed to carry out the measures set forth in Executive Order 12898 mandating that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, or activities on minority or low-income populations. The NRC stated that these requirements applied primarily to its efforts to comply with NEPA and that it would address environmental justice aspects as part of its considerations under NEPA. The environmental justice procedures for the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Materials Safety and Safeguards (NMSS) were signed into effect on September 21, 1999, and September 7, 1999, respectively. (See NRR Office Letter No. 906, Revision 2 and NMSS Policy and Procedures Letter 1-50).

(f) If the environmental impact of a final licensing and regulatory action has been evaluated and an environmental impact statement has been prepared, the NRC shall include the following statement in the Supplementary Information section of the preamble to the final rule.

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 final environmental impact statement for this regulation.

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 have 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.]

(g) Unless the action is eligible for one of the categorical exclusions listed in 10 CFR 51.22(c) (see paragraph (c) of this section), the NRC shall prepare an environmental assessment on each licensing and regulatory action, including a final rule, for which an environmental impact statement has not been prepared (see 10 CFR 51.21, 51.30, and 51.31). If after completing an environmental assessment for a final rule the NRC determines that an environmental impact statement need not be prepared, the NRC shall prepare and publish a finding of no significant impact (see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119). This finding 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. The NRC may either include the text of the environmental assessment in the Supplementary Information section of the preamble to the final rule or summarize the environmental assessment and indicate how interested persons may obtain a copy of it.

(1) If the NRC determines that a finding of no significant impact is appropriate for a final rule and is including the environmental assessment in the Supplementary Information section of the preamble to the final rule, the NRC shall include the following statement.

**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.)

(2) If the NRC determines that a finding of no significant impact is appropriate for a final rule, the NRC shall include the following statement indicating this finding and summarizing the environmental assessment in the Supplementary Information section of the preamble to the final rule.

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.)

(3) The NRC guidance on environmental justice does not automatically require an environmental justice review for an environmental assessment that results in a finding of no significant impact. However, in certain cases, as described in the environmental justice procedures of NRR or NMSS, the NRC may conduct an environmental justice review for an environmental assessment for a proposed rule and determine that a finding of no significant impact is appropriate. For these special cases, the NRC shall include the following statement in the Supplementary Information section of the preamble to the final rule.

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.)

7.17 Paperwork Reduction Act.

(a) **General.** The Paperwork Reduction Act (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 act 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 act 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 Section 7.19 of this handbook). The NRC complies with the act 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 Management Branch, Office of the Chief Information Officer (OCIO), is responsible for coordinating NRC activities necessary to comply with the Paperwork Reduction Act.

(b) **Coverage.** The act applies to any document that imposes an information collection requirement, such as a recordkeeping, application, reporting, or third-party disclosure requirement, on 10 or more persons. OMB clearance must be obtained for both voluntary and mandatory information collection requirements.

(1) 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.

(2) OMB clearance is not required for a request for public comment in connection with a rulemaking proceeding.

(c) **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 existing information collection requirement, including recordkeeping, application, reporting, and third-party disclosure requirements, that appears in 10 CFR Chapter I must be reapproved by OMB when the current OMB clearance expires. An information collection requirement appearing in NRC regulations is invalid and unenforceable unless --

- (1) It is approved by OMB; or
- (2) The Commission overrides an OMB denial.

(d) Submittal of an OMB clearance package for a final rule.

(1) A clearance package necessary to obtain OMB approval must be developed and submitted to OMB for a final rule that--

(i) Was not first issued as a proposed rule and contains an information collection requirement;

(ii) Was submitted to OMB as a proposed rule but the information collection requirement was not approved by OMB; or

(iii) 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.

(2) 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, including any amendment that reduces the burden imposed by an information collection requirement, since the clearance package for the proposed rule was submitted for OMB approval.

(3) The NRC may not submit a final rule that contains a new or an 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.

(e) **Standard statements.** One of the following statements must be included in the Supplementary Information section of the preamble to each final rule concerning information collection requirements. Information collection requirements include any reporting, recordkeeping, third-party disclosure, or application requirement. The specific identification number in the following statements, 3150-XXXX, is the OMB approval number for information collection requirements that are contained in the affected parts. The Records Management Branch, OCIO, will identify the appropriate identification number for a final rule.

(1) **OMB clearance for a new information collection.** If OMB approval is required for a new information collection requirement, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-____.

The burden to the public for this information collection is estimated to average _____ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs NEOB-10202 (3150-XXXX), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(2) **OMB clearance for a reduction in regulatory burden.** If OMB approval is required for a final rule reducing existing information collection requirements, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-_____.

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by _____ hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for further reducing the burden, to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-XXXX), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(3) **OMB clearance for existing requirements not affected.** The NRC shall insert this statement in the Supplementary Information section of the preamble to the final rule if --

- (i) The text of the final rule includes information collection requirements that were previously approved by OMB; and
- (ii) These information collection requirements are not amended in the final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-XXXX.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(4) Insignificant changes to existing information collection requirements. If the final rule makes insignificant changes to existing regulatory requirements, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Paperwork Reduction Act Statement

This final rule increases (or decreases) the burden on licensees to (state the requirement, including the regulatory citation). The public burden (or burden reduction) for this information collection is estimated to average ____ hour(s) per request. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-XXXX.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

(5) No information collection requirements. If the final rule and the current CFR part do not contain an information collection requirement, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

(6) **Exempt information collection requirements.** If a final rule contains an information collection requirement that is exempt from the requirements of the Paperwork Reduction Act under 44 U.S.C. 3518(c)(1), the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Paperwork Reduction Act Statement

The information collections contained in this final rule are exempt from the Paperwork Reduction Act of 1995 (44 U.S.C. 3518 (c)(1)) because the information is being gathered in support of [insert one of the following four options to complete the statement: Option 1 - "a Federal criminal investigation or prosecution or the disposition of a particular criminal matter (44 U.S.C. 3518(c)(1)(A))"; Option 2 - "a civil action to which the United States or an agency or an official of the United States is a party (i.e., a court action) or an administrative action or investigation involving an agency against a specific individual or entity (e.g., an agency hearing) (44 U.S.C. 3518(c)(1)(B))"; Option 3 - "an antitrust suit (44 U.S.C. 3518(c)(1)(C))"; or Option 4 - "intelligence and security cryptologic activities (44 U.S.C. 3518(c)(1)(D))"].

(7) **Information collection requirements of limited applicability.** If a final rule of limited applicability contains an information collection requirement that affects fewer than 10 respondents, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule. Note that rules of general applicability having a universe of fewer than 10 respondents require OMB clearance.

Paperwork Reduction Act Statement

The information collection requirements contained in this final rule of limited applicability affect fewer than 10 respondents. Therefore, Office of Management and Budget clearance is not required pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

(f) **Guidance.** The OCIO is responsible for coordinating the activities necessary to comply with the Paperwork Reduction Act. Written OCIO guidance appears in MD 3.54,

"Collections of Information and Reports Management." In addition, each office has appointed an Information Management Coordinator who provides advice, direction, and assistance in meeting Paperwork Reduction Act requirements. Specific questions concerning the procedures and requirements of the Paperwork Reduction Act may be directed to Brenda Jo. Shelton, Chief of the Records Management Branch (415-7233).

7.19 Regulatory analysis.

(a) **Introduction.** The regulatory analysis for the final rule is based upon the draft regulatory analysis that was 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.

(b) **Guidance.** The Commission approved the issuance of NRC's revised Regulatory Analysis Guidelines on June 30, 1995 (SECY-95-028). The Regulatory Analysis Guidelines are printed in NUREG/BR-0058, Revision 3, July 2000. These guidelines establish a framework for --

- (1) Analyzing the need for and consequences of a regulatory action;
- (2) Selecting a preferred alternative from potential courses of action;
- (3) Documenting the analysis in an organized and understandable format.

(c) **Purpose.** (1) 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.

- (2) Each regulatory analysis must assess the following impacts:
 - (i) Direct costs or savings to licensees, the NRC, and State and local government agencies;
 - (ii) Nonradiation risk-related costs or savings to the general public;
 - (iii) Averted onsite impacts; and

(iv) Changes in regulatory efficiency or scientific knowledge needed for regulatory purposes.

(d) **Contents.** Each regulatory analysis must include the following standard elements:

- (1) A statement of the problem and the NRC's objectives for the regulatory action.
- (2) An identification and analysis of alternative approaches to resolving the problem.
- (3) An estimate and evaluation of the values and impacts for the selected alternatives, including the uncertainties that affect these estimates.
- (4) The conclusion reached concerning the evaluation of values and impacts and a safety goal evaluation, where appropriate.
- (5) The decision rationale for selecting the regulatory action.
- (6) A tentative implementation schedule and implementation instrument for the regulatory action.

(e) **Coverage.** (1) 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 place a burden on licensees.

(2) 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.

(3) 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.

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

(1) If the final rule imposes collection requirements that require obtaining OMB approval under the Paperwork Reduction Act (see Section 7.17 of this handbook), the OMB clearance package must be included as a stand-alone appendix to the regulatory analysis.

(2) The regulatory analysis must contain information sufficient to address requirements mandated by the Regulatory Flexibility Act (see Section 7.21 of this handbook).

(i) If the final rule is likely to have a significant economic impact on a substantial number of small entities, a final regulatory flexibility analysis must be prepared. The regulatory flexibility analysis is included as an appendix to the regulatory analysis and as part of the final rule. The regulatory flexibility analysis may reference information discussed in the body of the regulatory analysis.

(ii) If the NRC certifies that the final 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 final rule on small entities to support this certification.

(3) If a backfit analysis is required for a final rule, the regulatory analysis must contain the information required by the Commission's backfit rule (see Section 7.23 of this handbook). The NRC's Regulatory Analysis Guidelines have been developed so that a regulatory analysis is prepared that conforms to the guidelines to meet the requirements of the backfit rule.

(4) If an environmental impact statement has been prepared and forms the basis for the 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 3, Sections 4.1-4.3.

(g) **Required statement.** A statement must be inserted in the Supplementary Information section of the preamble to the final rule concerning the regulatory analysis.

(1) 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.

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.

(2) 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:

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.]

(3) 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.

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.]

7.21 Regulatory Flexibility Act.

(a) **Purpose.** The Regulatory Flexibility Act (5 U.S.C. 601 et seq.), as amended by the Small Business Regulatory Enforcement Fairness Act, 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 act requires that each agency analyze the impact of the final rule 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 act primarily impacts regulations that would affect byproduct, source, and special nuclear material licensees.

(b) **Applicability.** The act applies to each rule subject to notice and comment rulemaking under the APA (5 U.S.C. 553 (b)). The act does not apply to 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.

(c) **Requirements.** In order to comply with the act'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.

(1) If the NRC believes that a final rule will have a "significant economic impact on a substantial number of small entities," the act requires that the NRC prepare a regulatory flexibility analysis (See paragraph (d) of this section for NRC's definition of "small entities"). 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 act. The NRC's Regulatory Analysis

Guidelines (NUREG/BR-0058, Revision 3) 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 (see Section 7.19 of this handbook).

(2) The act permits the NRC to dispense with the preparation of a regulatory flexibility analysis if --

(i) The NRC determines that the final rule does not have a significant economic impact on a substantial number of small entities;

(ii) The Commission certifies this to be the case; and

(iii) The certification and the factual basis for it are published in the final rule.

(d) **Size standards.** The NRC established size standards that it uses to determine which NRC licensees qualify as small entities (April 11, 1995; 60 FR 18344). The NRC size standards are codified in 10 CFR 2.810. The NRC shall use these size standards to identify regulations subject to the regulatory flexibility analysis requirements of the act. The size standards for NRC licensees are as follows:

§ 2.810 NRC Size Standards.

The NRC shall use the size standards contained in this section to determine whether a licensee qualifies as a small entity in its regulatory programs.

(a) A small business is a for-profit concern and is a --

(1) 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

(2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

(b) 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.

(c) 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.

(d) A small educational institution is one that is --

(1) Supported by a qualifying small governmental jurisdiction; or

(2) Not state or publicly supported and has 500 or fewer employees.

(e) For the purposes of this section, the NRC shall use 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.

(e) **Standard statements.** A statement concerning the Regulatory Flexibility Act must appear in the Supplementary Information section of the preamble for each final rule.

(1) If a final regulatory flexibility analysis has been prepared, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the 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.

(2) If a final regulatory flexibility analysis is not required, the NRC shall 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.

(i) If a final rule affects 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 (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.

(ii) If a final rule affects 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 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).

(f) **Final Regulatory Flexibility Analysis: Content.** The final regulatory flexibility analysis is an updated version of the initial analysis. The final analysis must be revised to reflect new information received through public comment or any other source. The act requires that the final regulatory flexibility analysis contain --

- (1) A succinct statement of the need for, and the objectives of, the rule;
- (2) 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;

(3) 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;

(4) 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;

(5) 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.

(g) **Emergency provisions.** The act 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.

(1) 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.

(2) 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.

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

(h) **Guidance.** Questions concerning the Regulatory Flexibility Act may be directed to Michael T. Lesar (415-7163).

7.23 Backfit analysis.

(a) The NRC has established standards for the management of backfitting requirements imposed on power reactors (10 CFR 50.109). Essentially identical provisions were established to manage backfitting requirements imposed on gaseous diffusion plants (10 CFR 76.76). Provisions were established to manage backfitting requirements imposed on an independent spent fuel storage installation or a monitored retrievable storage installation (10 CFR 72.62). In addition, provisions were established to manage backfitting requirements imposed on special nuclear material licensees (10 CFR 70.76).

(b) 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.

(1) The first component is the modification of or addition to --

(i) Systems, structures, components, or design of a facility;

(ii) The design approval or manufacturing license for a facility; or

(iii) The procedures or organization required to design, construct, or operate a facility.

(2) The second component is that the modification or addition is the result of either --

(i) A new or amended provision of the Commission's regulations; or

(ii) A regulatory NRC staff position interpreting these regulations that is either new or different from a previously applicable NRC staff position.

(3) The third component is that the modification or addition is considered a backfit only if it results from a new or amended regulation or staff position issued after --

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;

(ii) Six months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses; or

(iv) The date of issuance of the design approval under Appendix M, N, or O to 10 CFR Part 52.

(4) The fourth component is that the modification or addition must be imposed as a mandatory requirement.

(c) Except as indicated in paragraph (d) of this section, the NRC shall prepare 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 --

(1) 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

(2) The direct and indirect costs that would result from the implementation of the backfit are justified.

(d)(1) The backfit analysis described in this paragraph (d) is not required and the "substantial increase" and "cost justification" standards of paragraph (c) of this section do not apply if --

(i) A backfit is necessary to ensure adequate protection of public health and safety;

(ii) 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; or

(iii) The backfit involves defining or redefining adequate protection.

(2) If the provisions of paragraph (e)(1) of this section apply, the NRC shall prepare 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 requirements of paragraphs (c) and (d) of this section.

(e) A backfit analysis prepared in support of a backfit contained in a final rule must contain available information concerning any of the following factors, as well as any other material and relevant information. The backfit analysis must contain --

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

(f) A statement concerning the applicability of the backfitting requirements set out in 10 CFR Chapter I must appear in the Supplementary Information section of the preamble for each final rule.

(1) If a final rule contains a backfit requirement that would substantially increase safety beyond adequate protection and would do so at a justifiable cost, the NRC shall insert the following statement.

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 final rule. The Commission has determined, on the basis of this analysis, that backfitting to comply with the requirements of this final rule provides 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 the backfit analysis).

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

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 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, and therefore"; 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;" or 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, that 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 are required by the final rule and sets forth the basis for the Commission's conclusions 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.)

(3) If the backfit requirements of 10 CFR Chapter I do not apply to the final rule, the NRC shall insert the following statement or an appropriate variation of this statement.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this 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"; or 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.]

7.25 Small Business Regulatory Enforcement Fairness Act.

(a) Among other requirements, the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires Federal agencies to provide Congress with an opportunity to review agency rules. For each final rule, an agency is required to 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. The report, a standard form developed for this purpose by the General Accounting Office (GAO) and OMB, 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. This relevant information would include any cost-benefit analyses, regulatory flexibility analyses, Paperwork Reduction Act statements, and any environmental assessments or impact statements. The report must be made using the standard form developed by OMB and GAO for this purpose. Additional information concerning the form and instructions for completing it appear in Appendix F to this handbook.

(b) The effective date for all "major" rules may be no earlier than 60 days after the date Congress receives the required material or 60 days after publication of the final rule in the *Federal Register*, whichever is later. The legislation also establishes special congressional procedures for the disapproval of agency 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--

- (1) An annual effect on the economy of \$100,000,000 or more;
- (2) A major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or

(3) 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.

(c) Under the act, the OMB is responsible for determining whether a rule is "major." Therefore, the NRC must submit a description of its final rules to OMB and OMB must verify the NRC's determination as to whether the final rule is considered a major rule under this act before the final rule may be submitted for signature and publication.

(d) The following statement must be inserted in the Supplementary Information section of the preamble to the final rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act 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.

(e) On June 25, 1996, the EDO issued a memorandum to office directors that established a simple process for assuring compliance with SBREFA. These procedures are presented in Appendix F to this handbook. Questions concerning SBREFA may be directed to Michael T. Lesar (415-7163).

7.27 List of subject index terms.

The OFR requires each agency to include a list of subject index terms for each part affected in a final rule document (1 CFR 18.20). The list of terms is intended to identify the major topics of the final 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*.

(a) The NRC shall 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 final rule document. The list of subject index terms must appear in each final rule document submitted for publication in the *Federal Register*. The NRC shall present the list of subject index terms in alphabetical order as follows:

Example: Format for 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: Format of 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.

(b) The NRC shall use the list of subject index terms developed by RDB and approved by the OFR in the 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 appears in Appendix C to this handbook. If an originating office wishes to use additional terms, it shall consult with RDB (415-7163).

(c) A list of subject index terms is not required for a final rule that--

- (1) Does not contain regulatory text;
- (2) Only presents nomenclature changes; or
- (3) Corrects a previous document.

7.29 Words of issuance.

The words of issuance ("pursuant to" clause) 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. Use the following words of issuance, with a listing of each 10 CFR part affected, in each final rule.

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 Parts 30, 50, and 73.

7.31 Amendatory language.

(a) A final rule document makes changes or additions to the CFR. The regulatory text of each final rule 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.

(b) Amendatory language must be exact. The amendatory language for each change must --

(1) Identify the specific CFR unit being amended by its complete numerical and alphabetical designation;

(2) Use one of the standard terms to describe how the CFR unit is being changed; and

(3) Address all the regulatory text set out in the document.

(c) 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.

(1) **Added.**

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

Examples:

1. Part 53 is added to read as follows: (An entire new CFR part is added).
2. Section 50.47 is added to read as follows: (An entire new CFR section is added to a CFR part).
3. In §50.54, paragraph (f) is added to read as follows: (A paragraph is added to a CFR section).

(ii) 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 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]

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

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

Examples:

1. Part 73 is amended by revising §§73.17 and 73.50 to read as follows:
2. 10 CFR Chapter I is amended by revising Part 100 to read as follows:
3. Section 73.97 is amended by removing paragraph (e).

(3) **Corrected.** "Corrected" means that a clerical or typographical error in a published document is fixed. The error must be corrected before the next annual revision of 10 CFR Chapter I. Once the error is codified, a formal 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.

Examples:

1. 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."
2. 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."

(4) **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.

Examples:

1. In §30.15, paragraphs (e) and (f) are redesignated as paragraphs (d) and (e).
2. Part 33 is redesignated as Part 75.
3. Section 73.11 is transferred to Part 100 and redesignated as §100.71.
4. In §54.12, paragraph (d) is redesignated as paragraph (e) and revised to read as follows:

(5) **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.

Examples:

1. Part 110 is amended by removing §110.70.
2. In §20.25, paragraphs (d)(2) and (f) are removed.

(6) **Republished.** "Republished" means that an unchanged unit of CFR text is set out for the convenience of the reader, often 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 final rule document is used to update the CFR, the NRC shall present any republished text it chooses to use accurately.

Example:

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

(7) **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.

Examples:

1. In §20.25, paragraph (f) is revised to read as follows:
2. Section 9.9 is revised to read as follows:
3. Part 19 is revised to read as follows:

(8) **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 shall determine, in consultation with the OFR, when marked pages must accompany a nomenclature change.

Example:

1. 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."

(9) **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. The NRC 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 followup document necessary to remove the suspended provision or to lift the suspension.

Examples:

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

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

(10) **Withdrawn.** "Withdrawn" has a different connotation in a final rule document than in a proposed rule document.

(i) In a final rule, "withdrawn" is used to indicate that a final rule with a pending effective date will not go into effect.

(ii) In a proposed rule, "withdrawn" is used to indicate that a previously published proposed rule will not be issued as a final regulation.

(d) 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.

Examples:

1. 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).

2. 10 CFR 50.20 is amended by revising paragraphs (a)(5)(iii), (c), (c)(3)(iv), and (d) to read as follows:

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

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

(2) The authority citation for the part must appear directly after the part heading. (See Section 7.33 of this handbook concerning authority citations.)

Example: The purpose of this example is to show a series of amendments within a part and the proper placement and sequence of the required elements.

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:

§33.13 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.

(Note: The use of asterisks in amending CFR text is discussed in Section 7.39 of this handbook).

7.33 Authority citations.

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

(1) 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.

(2) 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.

(b) **Content.** RDB maintains a complete list of the currently effective authority citations for each part in 10 CFR Chapter I. The drafter may contact RDB to obtain the current authority citation for insertion into his or her document (415-6864). OGC is responsible for determining whether a change to the currently effective authority citation is required by the amendment.

(c) **Placing authority citations: When amending an entire CFR part.** If a document sets out a whole 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: 42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 5841.

(d) **Placing authority citations: When amending a portion of a CFR part.** If a document amends only certain sections within a CFR part, a complete citation of authority must be presented.

(1) 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: 42 U.S.C. 2201, 2278a, 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.

(2) 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: *A part authority that is amended by adding 42 U.S.C. 2093 as an additional authority.*

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

AUTHORITY: 42 U.S.C. 2073, 2093, 2111, 2201, 2232, 2233, 5842, 5846.

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.

(3) 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: *A part authority that includes section-specific citations. The second paragraph sets out the section-specific authorities.*

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

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

AUTHORITY: 42 U.S.C. 2092, 2093, 2094, 2095, 2201, 2232, 2233, 5842, 5846.

Section 40.31(g) also issued under 42 U.S.C. 2152. Section 40.46 also issued under 42 U.S.C. 2234.

7.35 Regulatory text: CFR codification.

(a) **Amending the CFR.** The regulatory text of a final rule document is codified in the CFR. NRC regulations are codified in 10 CFR Chapter I. The regulatory text of each NRC final rule document must be presented as an amendment to 10 CFR Chapter 1. Regulatory text must --

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

(b) **CFR structure.** (1) 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

(2) 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.

(3) 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. Using all odd or even sequential numbers in designating sections within a new or revised part leaves room for future expansion.

(4) 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), etc.
For further subdividing of a paragraph	(1), (2), (3), etc. (i), (ii), (iii), etc.
	(A), (B), (C), etc.
Note: Underlined symbols are printed in italics.	(<u>1</u>), (<u>2</u>), (<u>3</u>), etc. (<i>i</i>), (<i>ii</i>), (<i>iii</i>), etc.

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

Paragraph symbol	(a)	(1)	(i)	(A)	(<u>1</u>)	(i)
Level of Designation	1	2	3	4	5	6

(i) 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.

(ii) 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.

(iii) The NRC shall 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. (See Section 17.7 of this handbook, Arranging material for ease of use.)

- (iv) The OFR no longer permits the use of an undesignated concluding paragraph.

Example: *This type of construction is forbidden.*

(a) 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.

- (v) 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.

(6) The OFR does not permit 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.

(i) The NRC 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.

(ii) 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.

(iii) 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.

(c) **Plan for the future.** The NRC 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 after it has been in effect and changes are necessary.

(d) **Full text amendment.** The NRC shall 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.

(e) **Footnotes.** The NRC shall 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, care must be taken in the manner and form in which it is designated and presented in regulatory text. Incorrectly designated footnotes cause errors when a document is printed in the *Federal Register* and again when regulatory text is codified in the CFR. The NRC shall follow these guidelines when presenting footnotes in the text of a regulatory document.

(1) 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. Asterisks or other symbols may not be used to designate footnotes within regulatory text.

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

(i) 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.

(ii) If both the preamble and the regulatory text of a document contain footnotes, a separate numbering sequence must be used in each. The preamble is not retained in the CFR.

(iii) 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).

(3) 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.

7.37 Regulatory text: Headings.

(a) **General.** 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.

(b) **Part headings.** The part heading is a concise statement that describes the content or effect of the regulatory program contained in the part. The NRC 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.

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

(1) 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.

(2) 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.

(d) **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....

* * * * *

7.39 Form of amendment: Section level.

(a)(1) Each amendment made at the section level requires three elements. These elements must appear in the following order--

- (i) Proper amendatory language;
- (ii) The section heading of the section being changed; and
- (iii) The regulatory text of the section being changed.

(2) 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.

(b) 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.

Regulatory 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.

(c) 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.

(1) Five asterisks in a row indicate that one or more entire paragraphs are not being amended.

(2) 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. (See Sections 7.35(b)(4) and (5) of this handbook concerning paragraph designation.)

(d) 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 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.

Example:

This example serves two purposes. It illustrates --

- (1) The proper method of presenting a series of section-level amendments within a document; and
- (2) The correct use of asterisks to indicate unchanged text within a section.

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	<u>§20.1101 Radiation protection programs.</u>
Indicates that paragraph (a) is unchanged	* * * * *
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.

(b) * * *

The paragraph designation and three asterisks are necessary to place this amendment within paragraph (b)(1)

(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

Amendatory language

Revised authority citation

Amendatory language

Section heading

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

Revised text of paragraph (c)

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

* * * * *

PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

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

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

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

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

* * * * *

(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.

7.41 Form of amendment: Part and subpart level.

(a) Each amendment made at the part level requires the following elements. The elements must appear in the following order--

- (1) Proper amendatory language;
- (2) The part heading;
- (3) A table of contents for the part;
- (4) The authority citation; and
- (5) Regulatory text.

Example:

Amendatory language

1. 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.

Note: 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.

(b) 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.

(c) 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 --

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

7.43 Proper cross-referencing techniques.

(a) A "cross-reference" is a reference from one unit of the CFR to another unit. A cross-reference only may 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* (see Section 7.45 of this handbook, Incorporation by reference).

(b) 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 --

(1) The reference is required by court order, statute, Executive order, or reorganization plan;

(2) 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;

(3) The reference is informational or improves clarity and does not impose a requirement;

(4) 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

(5) The reference is to the department level from a subagency.

(c) Identify the CFR unit being cited by the proper CFR unit designation in each cross-reference. A nonspecific reference, such as "herein," "above," or "below," requires interpretation by the user and may result in ambiguity.

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

HOW TO WRITE A CROSS-REFERENCE IN CFR TEXT

References to a different TITLE

<u>When referencing</u>	<u>Write</u>
A chapter	1 CFR Chapter 1
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

<u>When referencing</u>	<u>Write</u>
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

<u>When referencing</u>	<u>Write</u>
A section	§20.15
A paragraph	§20.15(a)

References within the same SECTION

<u>When referencing</u>	<u>Write</u>
A paragraph	Paragraph (b) of this section
A subdivision within a paragraph	Paragraph (b)(1)(i) of this section

7.45 Incorporation by reference.

(a) 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.

(b) For an incorporation by reference to be valid, it must be approved by the Director of the Federal Register. OFR requirements for approval of an incorporation by reference appear at 1 CFR Part 51.

(1) Material is eligible for incorporation by reference if it meets the following criteria:

(i) It is published data, criteria, standards, specifications, techniques, illustrations, or similar material.

(ii) 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 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.

(iii) 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.

(iv) 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 --

(A) Inspect the material at the OFR, the agency's central and regional offices, or in depository libraries; and

(B) Purchase the material from the publisher or the agency at reasonable cost.

(2) Statements of incorporation by reference contained in regulatory text must meet specific drafting standards. Each statement of incorporation by reference must --

(i) Include the words "incorporation by reference";

(ii) Identify the standard and/or material to be incorporated by title, date, edition, author, publisher, and identification number;

(iii) Contain a brief subject description;

(iv) Contain a statement of availability; and

(v) Refer to 5 U.S.C. 552(a) and 1CFR Part 51 and include a statement indicating that the Director of the Federal Register approves the incorporation by reference.

Example: A statement of incorporation by reference that meets OFR requirements.

(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, 800 North Capitol Street, NW., Suite 700, Washington, DC. 20001

(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:

(c) 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.

(d) 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, the NRC shall include the--

(1) Term "incorporation by reference" in the list of subject index terms for the part that contains the incorporation by reference; and

(2) Following language under the DATES caption of the preamble to the final rule:

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).

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

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

7.47 Signature block.

(a) Each final rule 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 _____, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

(b) Final rules that are approved and issued by the Commission are prepared for the signature of the Secretary of the Commission. Final rules that are issued under the rulemaking authority delegated to the EDO are prepared for the EDO's signature (see Section 1.7 of this Handbook). Final rules that are issued under the rulemaking authority delegated to the CFO are prepared for the CFO's signature (see Section 1.9 of this handbook).

PART 9 - DIRECT FINAL RULES

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9.1 Description.

(a) The direct final rule process was developed by the Environmental Protection Agency to speed the approval, through rulemaking, of revisions to State implementation plans under the Clean Air Act. The direct final rule process was endorsed in a report of the National Performance Review, "Improving Regulatory Systems," and recommended for agency use by the Administrative Conference of the United States (ACUS) as a means of avoiding delay and duplicative publication of noncontroversial rules (see ACUS Recommendation 95-4, Procedures for Noncontroversial and Expedited Rulemaking (60 FR 43110; August 18, 1995)). ACUS urged that an agency use the direct final rule process when it believes that the rulemaking action would not generate any significant adverse comment. This type of noncontroversial rule would be eligible for issuance as a direct final rule under two rationales:

(1) The rule could be issued under the provision of the Administrative Procedure Act (APA) that exempts the notice and comment requirements when the agency finds for good cause that notice and public procedure are unnecessary; and

(2) The procedure for issuing a direct final rule is in accordance with the notice and comment procedures of the APA (5 U.S.C. 553).

(b) NRC has adopted the direct final rule process and uses the following procedures. 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 as discussed in paragraph (b)(3) of this section. 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, absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a separate comment period for the action.

(1) If no public comments are received, the direct final rule becomes effective on the specified effective date. The NRC shall publish a subsequent document that confirms the effective date (see Section 19.8 of this handbook).

(2) If public comments are received but they are not significant adverse comments, the direct final rule becomes effective on the specified effective date. The NRC shall publish a subsequent document that confirms the effective date. In this document, the NRC may respond to the public comments received and explain why the comments were not considered to be significant adverse comments, if necessary.

(3) If significant adverse comments are received, the NRC publishes a document in the *Federal Register* that withdraws the direct final rule 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.

(4) 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.

9.3 Guidance for determining when to use a direct final rule.

The NRC should consider using the direct final rule process for a *noncontroversial* action on which it *does not expect to receive significant adverse comment*.

(a) The NRC Direct Final Rule Working Group suggests that the NRC can determine that significant adverse comments are unlikely and, therefore, that the direct final rule process may be considered for use if --

(1) The amendments being made by the rule--

(i) Are of a minor nature;

(ii) Formalize an existing practice;

(iii) Reflect an update to include a new, accepted technology;

(iv) Adopt or update a generally accepted standard; or

(v) Do not constitute a relaxation of current requirements.

(2) Generally reflect stakeholder consensus in that the amendments being made by the rule --

(i) Are not expected to engender stakeholder opposition;

(ii) Do not have a significant economic impact on any stakeholder; or

(iii) Do not result in a significant burden on any stakeholder.

(b) The NRC Direct Final Rule Working Group also suggests that the direct final rule process be used for an amendment to a Certificate of Compliance listing in 10 CFR 72.214 if the conditions in paragraph (a) of this section are met, unless one of the amendments being made by the rule --

(1) Involves a new accident scenario;

(2) Significantly alters a method of evaluation or analysis or implements a new method of evaluation or analysis;

- (3) Causes offsite dose consequences to increase by 50 percent of the margin;
- (4) Results in an increase in the frequency and likelihood of a previously evaluated accident by more than 50 percent; or
- (5) Significantly alters a design basis limit for a fission product barrier.

9.5 Direct final rule document.

A direct final rule must meet the all of the procedural and format requirements outlined for final rules in Part 7 of this handbook.

(a) The NRC shall comply with all Office of the Federal Register (OFR) requirements applicable to publication of a final rule. These requirements are outlined in Part 7 of this handbook.

- (1) Document headings (Section 7.5).
- (2) Preamble format requirements (Section 7.7).
- (3) List of subject index terms (Section 7.27).
- (4) Words of issuance (Section 7.29).
- (5) Amendatory language (Section 7.31).
- (6) Authority citation (Section 7.33).
- (7) Regulatory text: CFR codification (Section 7.35).
- (8) Regulatory text: Headings (Section 7.37).
- (9) Form of amendment: Section level or Part level (Section 7.39 or Section 7.41).

(b) The NRC shall include a Supplementary Information section in a direct final rule that provides the background discussion and specific information necessary to explain the basis and purpose of the regulation. The information included in the Supplementary Information section must be sufficient to provide an adequate basis for the rulemaking on the record in the event of a court challenge to the final rule (see Section 7.9 of this handbook). The Supplementary Information section must also explain the basis for NRC's conclusion that public comment is unnecessary under the APA. In addition, the Supplementary Information section must contain the following paragraph describing the direct final rule process.

Example:

Because NRC considers this action noncontroversial, 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*), the NRC will publish a document that withdraws this action and will address the comments received in response to these amendments. These comments will be addressed in a subsequent final rule based on a 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.

(c) In developing and issuing a direct final rule, the NRC shall comply with all the legal and procedural requirements applicable to a final rule. These issues would typically be addressed in a direct final rule document as indicated in the following paragraphs.

(1) **National Technology Transfer and Advancement Act (Section 7.13).** A direct final rule may adopt a new, generally accepted consensus standard or update a previously accepted general consensus standard. The NRC shall include an appropriate version of the standard statement presented in Section 7.13 (c) of this handbook in the direct final rule.

(2) **National Environmental Policy Act (NEPA) (Section 7.15).** A direct final rule must either qualify as a categorical exclusion under 10 CFR 51.22(c) or the NRC 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).

(i) If the direct final rule is the type of action that qualifies as a categorical exclusion, include a statement as indicated in Section 7.15 (c)(2) of this handbook.

(ii) If the direct final rule is the type of action for which an environmental assessment was prepared and a finding of no significant impact was made, include a statement as indicated in Section 7.15 (g) of this handbook.

(3) **Paperwork Reduction Act (Section 7.17).** A direct final rule does not impose a new information collection requirement or make a significant change to an existing information collection requirement.

(i) If the direct final rule does not affect Office of Management and Budget (OMB) clearance for an existing information collection requirement, the NRC shall insert the statement presented in Section 7.17(e)(3) of this handbook.

(ii) If the direct final rule makes an insignificant change to existing information collection requirements, the NRC shall insert the statement presented in Section 7.17(e)(4) of this handbook.

(iii) If the direct final rule and the current CFR Part do not contain an information collection requirement, the NRC shall insert the statement presented in Section 7.17(e)(5) of this handbook.

(4) **Regulatory analysis (Section 7.19).** 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. The NRC shall 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 a statement concerning the regulatory analysis as indicated in Section 7.19(g) of this section.

(5) **Regulatory Flexibility Act (Section 7.21).** 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. The NRC shall include a regulatory flexibility certification statement as indicated in Section 7.21 (e)(2) of this handbook.

(6) **Backfit analysis (Section 7.23).** 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. The NRC shall include a statement to this effect as indicated in Section 7.23 (f)(3) of this handbook.

(7) **Small Business Regulatory Enforcement Fairness Act (Section 7.25).** The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act apply to a direct final rule. Therefore, a report concerning the action must be submitted to each House of Congress and the Comptroller General as indicated in Section 7.25 of this handbook. The NRC shall also request OMB verification of its determination that the action is not a major rule as required by the act and include a statement to this effect as indicated in Section 7.25(d) of this handbook.

(d) For a sample direct final rule, see Section 19.6 of this handbook.

9.7 Companion proposed rule to a direct final rule document.

A companion proposed rule is published concurrently with each 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. The companion proposed rule must meet all of the procedural and format requirements outlined for proposed rules in Part 5 of this handbook.

(a) The NRC shall comply with all OFR requirements applicable to publication of a proposed rule. These requirements are outlined in Part 5 of this handbook.

- (1) Document headings (Section 5.5).
- (2) Preamble format requirements (Section 5.7).
- (3) List of subject index terms (Section 5.25).
- (4) Words of issuance (Section 5.27).
- (5) Amendatory language (Section 5.29).
- (6) Authority citation (Section 5.31).
- (7) Regulatory text: CFR codification (Section 5.33).
- (8) Regulatory text: Headings (Section 5.35).
- (9) Form of amendment: Section level or Part level (Section 5.37 or Section 5.39).

(b) The Supplementary Information section in the companion proposed rule to a direct final rule contains a cross-reference to the direct final rule that is published concurrently for the information necessary to explain the basis and purpose of the regulation and the information concerning NRC's compliance with the legal and procedural requirements applicable to the rulemaking action. In addition, the Supplementary Information section to the companion

proposed rule must also contain the following paragraph describing the direct final rule process and the role of the companion proposed rule.

Example:

Because NRC considers this action noncontroversial, 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.

(c) For a sample companion proposed rule to a direct final rule see Section 19.7 of this handbook.

9.9 Criteria for determining a significant adverse comment.

The NRC Direct Final Rule Working Group suggests the following criteria for determining whether a comment on a direct final rule constitutes a significant adverse comment.

(a) 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.

(b) The NRC Direct Final Rule Working Group provided the following guidance concerning the disposition of an individual comment.

(1) A comment is not adverse if --

(i) The comment supports the rule; or

(ii) 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.

(2) A comment is adverse, but not significant, if --

(i) The comment opposes the rule but provides no reason;

(ii) 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 nonsubstantive); or

(iii) 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.

(3) Even if a comment is considered adverse but not significant under the criteria in paragraph (b)(2) of this section, the NRC may choose to treat comments that essentially protest or oppose an NRC action without providing a reason or issue that would warrant a substantive response as significant adverse comments under the NRC's "increase public confidence"

initiative.

(4) A comment is adverse and significant if --

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

(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.

(ii) 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.

9.11 Withdrawing a direct final rule.

(a) If the NRC receives significant adverse comment on a direct final rule, it must publish a document in the *Federal Register* that withdraws the direct final rule. If the NRC desires to continue with the rulemaking action, it must publish 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.

(1) The NRC shall publish a document in the *Federal Register* that withdraws the direct final rule before the specified effective date. See Section 19.10 of this handbook for a sample document that withdraws a direct final rule.

(2) If the NRC is unable to publish a document in the *Federal Register* that withdraws the direct final rule before the specified effective date, the NRC shall 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 Section 19.11 of this handbook for a sample document that withdraws a direct final rule after the effective date and revokes the regulatory text codified by that action.

(b) 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 Section 19.9 of this handbook for a sample document that delays the effective date of a direct final rule.

(c) The NRC 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 Section 19.12 of this handbook for a document that responds to public comments received on a direct final rule that were not considered to be significant adverse comments.

PART 11 - ADVANCE NOTICES OF PROPOSED RULEMAKING

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11.1 Enhanced public participation.

(a) The NRC may choose to begin a rulemaking proceeding by publishing an advance notice of proposed rulemaking (ANPR). The NRC may also designate certain significant rulemakings for enhanced public participation throughout their development and publish other less formal types of documents to invite public participation (see Section 3.7 of this handbook). The publication of an ANPR, or any other type of document announcing enhanced public participation, does not represent a commitment by the NRC to issue a proposed or final rule on the matter in question. This issue remains a matter of agency discretion unless Congress has mandated rulemaking concerning the contemplated action. Public response to the ANPR or to an enhanced public participation initiative is a factor in determining whether or not the rulemaking proceeding continues beyond this preliminary stage and, if continued, the direction taken in developing the proposed and final rule.

(b) The ANPR is the most formal mechanism for initiating an enhanced public participation rulemaking. In an ANPR, the NRC generally describes a problem or situation and may present an outline of the anticipated regulatory response to the problem. An ANPR is an appropriate beginning for a rulemaking proceeding when the NRC wishes information concerning --

- (1) The extent and seriousness of the problem under consideration;
- (2) Whether a regulation is an appropriate solution to the problem;
- (3) The merits of NRC's anticipated regulatory response to the problem;
- (4) Information concerning possible solutions to the problem that NRC may not have considered; and
- (5) The effects that the anticipated regulatory response or any other solution may have in related areas.

(c) The NRC may propose several alternative solutions in an ANPR and request public comment on each alternative. Although regulatory text is not essential in an ANPR, the NRC may choose to present its anticipated action as an amendment to the regulations in 10 CFR Chapter I to direct public attention to and encourage public comment on the changes under consideration. If regulatory text is not presented, NRC may describe its intended approach in narrative fashion and present a list of questions and issues for comment to direct public attention to the type and nature of the changes under consideration.

(d) Because an ANPR or the other types of actions that announce enhanced public participation in a specific regulatory initiative serve as the first public notice that a rulemaking proceeding is anticipated, the Office of the Federal Register (OFR) classifies these documents as proposed rules and publishes them in the Proposed Rules section of the *Federal Register*. As a result, each of these documents prepared by the NRC must meet certain format requirements for proposed rules set out in Part 5 of this handbook. If the ANPR or enhanced public participation initiative presents contemplated regulatory text, the document must meet requirements for a proposed rule concerning amendatory language and codification. This part discusses the particular requirements of Part 5 as they apply to an ANPR or other type of document concerning an enhanced public participation rulemaking.

11.3 Headings.

(a) Each ANPR or enhanced public participation document that the NRC submits for publication in the *Federal Register* must begin with a series of headings that--

- (1) Identify NRC as the agency issuing the document;
- (2) Indicate the parts within 10 CFR Chapter I that the document would affect;
- (3) Indicate the unique regulation identifier number (RIN) of the ANPR; and
- (4) Indicate the subject matter of the document.

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

RIN 3150-CC33

Certification of Industrial Radiographers

(b) The "CFR Part" heading must contain the number of each part that would be affected by the action considered in the ANPR. If the ANPR does not include regulatory text, this heading must present the number of the CFR part that the subject matter of the document most closely matches. If no CFR part is appropriate, the CFR chapter designation may be used (10 CFR Chapter I).

(c) The "RIN" heading indicates 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 has requested that this number be included in the heading of each rulemaking document published in the *Federal Register*. The Rules and Directives Branch assigns a RIN to each regulatory action. A RIN is assigned to an ANPR after the rulemaking plan has been approved.

(d) The "Subject" heading is a brief statement that describes the content of the document. The CFR part heading may be sufficient for this purpose. However, more specific information may be needed if the part heading is too general or to differentiate between multiple documents amending the same part or parts. Generally, the subject heading used for the ANPR is used as the subject heading in any subsequent rulemaking document concerning the matter.

(e) Occasionally, a followup document is necessary to supplement a previously published ANPR. To emphasize the relationship between the documents, the OFR requires that the later document repeat the headings of the earlier document. In addition, a word or phrase identifying the action or type of the second document must be added to the subject heading.

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

RIN 3150-CC33

Certification of Industrial Radiographers; Public Meeting

11.5 Preamble format requirements.

Because an ANPR or other type of document announcing an enhanced public participation initiative is classified for publication in the Proposed Rules section of the *Federal Register*, each of these types of documents prepared by the NRC must comply with the preamble format requirements of the OFR in 1 CFR 18.12. These requirements arrange basic information in a uniform format that allows a user to scan the document for essential information. The OFR will not print an ANPR or other type of enhanced public participation document that does not meet these format requirements. These format requirements are discussed, in detail, in Section 5.7 of this handbook. The following example illustrates how the format requirements are applied to an ANPR or an enhanced public participation document.

Example:

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In this advance notice of proposed rulemaking, the Commission is presenting an alternative to the present system of permitting a radiography licensee to train and designate individuals as radiographers. The suggested alternative would require that each individual who uses byproduct material in industrial radiography be certified by a third party approved by the NRC. This action is intended to ensure that all radiographers possess adequate training and experience to operate radiographic equipment safely. This action is taken in response to a petition for rulemaking and continuing Commission concern over the problem of radiography overexposures.

DATES: Comment period expires (insert date 75 days after publication in the *Federal Register*). Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments or suggestions to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking Website at <http://ruleforum.llnl.gov>. This site provides the capability of uploading comments as files (any format) if your Web browser supports that function. For information about the interactive rulemaking Website, contact Ms. Carol Gallagher, (301) 415-5905 (e-mail: CAG@nrc.gov).

To inspect or obtain documents related to this rulemaking, see the Availability of Documents heading in the Supplementary Information section.

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) 415-1357.

11.7 List of subject index terms.

(a) The OFR requires each agency to include a list of subject index terms for each part affected in an ANPR (1 CFR 18.20). The list of subject index terms is intended to identify the major topics of the ANPR and the categories of persons affected by it in a standard fashion. An enhanced public participation document may not require a list of subject index terms entry.

(b) The NRC shall place the list of subject index terms for each affected *Code of Federal Regulations* (CFR) part as the last item in the Supplementary Information section of each ANPR. A list of the approved subject index terms for each part in 10 CFR Chapter I appears in Appendix C to this handbook. The NRC shall use the existing subject index terms for each affected part unless the rulemaking would introduce a new topic that is not covered by the existing terms. The NRC shall present the list of subject index terms in alphabetical order as follows.

Example:

List of Subjects in 10 CFR Part 34

Criminal penalties, Packaging and containers, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

11.9 Authority citations.

(a) Each ANPR must contain a citation of the legal authority under which the NRC is issuing the document. Because of the explanatory and tentative nature of an ANPR, it is generally sufficient to cite NRC's basic rulemaking authority as the authority for issuing the ANPR. If the ANPR does not present regulatory text, the NRC shall present the authority citation in an ANPR directly after the "List of Subjects" entry in the document. The NRC shall present the authority citation in the following fashion.

Example:

The authority citation for this document is (42 U.S.C. 2201, 5841).

(b) If the ANPR presents contemplated regulatory text, the ANPR must present the authority citation for each affected part in the same manner as in a proposed rule. See Section 5.31 of this handbook for the content and placement requirements applicable to authority citations. The NRC shall use the existing authority citation for each affected part unless the contemplated regulatory action is the result of new or amended legislation.

11.11 Document text.

The principles of clarity and style discussed in Part 17, "Writing Techniques," of this handbook apply to an ANPR, or any other type of document concerning an enhanced public participation initiative, in the same manner as they would apply to a proposed rule or a final rule.

(a) The explanatory text of an ANPR is generally presented under the "Supplementary Information" heading. In the explanatory text of an ANPR, the NRC shall include a discussion of --

- (1) Any background or historical information relevant to the proceeding, including a complete *Federal Register* citation for any previously published document;
- (2) The issues under consideration;
- (3) The features that may be included in any proposed rule;
- (4) The alternative solutions that are under consideration;
- (5) Any potential alternative solutions that have already been considered and rejected and the reasons for the decision;
- (6) The specific areas in which the NRC needs further information or on which NRC is requesting public comment; and
- (7) Any opportunities afforded to the public and Agreement States for their early and substantive participation in the development of the ANPR.

(b) If the NRC is presenting alternative approaches or solutions in the ANPR, each alternative must be clearly identified as an alternative and so labeled. This step facilitates public comment on the ANPR as well as NRC analysis and response to public comment.

Example:

Alternative 1: Certification of industrial radiographers by a third party.

(c) The NRC may include a list of questions for public comment. This practice channels public response to an ANPR into areas most useful for evaluating the rulemaking action. The NRC shall address the responses to any questions presented in the ANPR in the Supplementary Information section of the resulting proposed rule, a separate document that accompanies the proposed rule, or in the document that withdraws the ANPR if the NRC decides not to proceed with rulemaking.

Example:

In light of the previous discussion, the NRC is particularly interested in receiving comments concerning the following issues:

1. Is the training provided to radiographers under the present system adequate?
2. Would a third-party certification program reduce the number of overexposures in the radiographic industry?
3. Would a third-party certification program motivate radiographers to work more safely?
4. What elements in the present system or in the suggested alternative are particularly desirable or undesirable? Why?
5. If a third-party certification is adopted, what items should be included in the standard for determining the competence of individuals to act as radiographers?
6. If a third-party certification program is adopted, should it apply to individuals presently working as radiographers or only to new radiographers?
7. If a third-party certification program is adopted, should certificates be issued to individuals for life or should there be periodic renewals of the certification?
8. Would a third-party certification program affect the ability of a licensee to respond to variable manpower needs?
9. A third-party certification program would likely be based on a cost recovery fee system. Would the cost to licensees of the program be warranted?
10. Which alternative of the two discussed (present system, third-party system) is preferable? Why? Are there other better alternatives? If so, please explain.
11. With respect to the two alternatives, what kind of enforcement action could and should be taken against radiographers who do not operate equipment safely or do not follow established procedures? What rights should radiographers have with respect to enforcement actions?

12. Would a small licensee bear a disproportionate economic impact because of its size under a third-party system?

13. For those organizations interested in a third-party certification program, what would be the estimated cost in implementing the program?

(d) If the NRC presents regulatory text in an ANPR, the NRC shall meet the requirements applicable to regulatory text in a proposed rule document. These requirements are outlined in Part 5 of this handbook.

- (1) Amendatory language (Section 5.29).
- (2) Regulatory text: CFR codification (Section 5.33).
- (3) Regulatory text: Headings (Section 5.35).
- (4) Form of amendment: Section level or Part level (Section 5.37 or Section 5.39).

PART 13 - NOTICES AND CORRECTIONS

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13.1 Writing a notice document.

(a) **General description.** Each document the NRC submits for publication in the *Federal Register* that does not contain regulatory text, impose requirements with general applicability and legal effect, affect a rulemaking proceeding, or announce an enhanced public participation initiative related to rulemaking is classified as a notice document and published in the Notices section of the *Federal Register*. NRC notice documents usually deal with a particular aspect of the agency's licensing activities. NRC documents frequently affect a named party, usually the licensee or a prospective licensee. Although many NRC notice documents are required by law to be published, others are published voluntarily by the NRC to provide the public with general information of interest to a wider audience than that usually served by the agency. The types of notice documents the NRC publishes in the *Federal Register* include --

- (1) Application for a new, renewed, or amended license;
- (2) The issuance of a new, renewed, or amended license;
- (3) Announcement of a license suspension or revocation;
- (4) The granting of an exemption to a particular licensing requirement;
- (5) Announcement of an enforcement action;
- (6) Announcement of environmental determinations and the availability of certain environmental statements;
- (7) Abnormal occurrence reports;
- (8) Committee meeting announcements;
- (9) Memoranda of understanding between the NRC and another organization;
- (10) Announcement of actions necessary to comply with the Paperwork Reduction Act concerning Office of Management and Budget review and requests for public comment;

(11) The issuance of a generic communication between the NRC and a particular segment of its licensees;

(12) Announcement of site reclamation and decommissioning actions;

(13) The issuance and availability of regulatory guides; and

(14) The availability of documents in the NUREG series or other technical reports.

(b) **Headings.** The headings of a notice document must identify the NRC as the agency issuing the document and indicate the subject matter of the document.

(1) If the document involves a licensing matter that relates to a named party, the named party must be included as part of the subject heading.

(2) The NRC may include an "Agency number" heading on a notice document. This heading, usually the NRC Docket Number, identifies the document within NRC's internal filing and reference system. The "Agency number" may be keyed to a specific licensing proceeding. If the "Agency number" is used, the NRC shall insert the "Agency number" heading above the subject heading.

Example:

NUCLEAR REGULATORY COMMISSION	Agency
[Docket Nos. 50-324 and 50-325]	Agency Number (optional)
Carolina Power & Light Co.;	Subject
Consideration of Amendments To	
Facility Operating Licenses, No	
Significant Hazards Considerations	

(c) **Document text.** The principles of clarity and style discussed in Part 17, "Writing Techniques," of this handbook apply to notice documents as well as rulemaking documents.

(1) The format requirements for preambles (1 CFR 18.12) do not apply to notice documents. However, because this format presents information in a concise manner, the

drafter should use this format in constructing a notice document. If the NRC uses this format in a notice document, it may omit captions of the format that are not applicable. However, the remaining captions must be presented in the proper sequence. The NRC may not create new captions for the format or vary the standard order in which the captions are presented. Material not identified by the prescribed captions must be placed under the Supplementary Information caption.

Example:

[7590-01-P]

NUCLEAR REGULATORY COMMISSION
NRC Requirements Regarding the Environmental Qualification
of Safety-Related Electrical Equipment; Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The NRC staff will discuss the content of safety evaluations, which are being issued to power reactor licensees, regarding the qualifications requirements for their safety-related electrical equipment.

DATES: July 7, 8, 9, and 10, 2001.

ADDRESS: Holiday Inn of Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20014.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-1357.

SUPPLEMENTARY INFORMATION:

The purpose of this meeting is to further the licensee's understanding of the NRC requirements regarding the Qualification of Safety-Related Electrical Equipment. The meeting will serve as a mechanism to address industry concerns and answer questions on the subject.

The meeting will be divided into sessions for the NRC presentations and sessions for licensee questions. In order to allow more efficient use of question sessions, those who attend will be grouped by NSSS affiliation. The tentative agenda is as follows:

July 7, 2001

- Identification of Systems

- (Remainder of agenda included)

Persons other than NRC staff and licensee representatives may observe the meeting but will be permitted to participate in the discussions only as time allows.

Registration will be conducted before the meeting.

Dated at Rockville, Maryland, this 3rd day of June, 2001.

For the Nuclear Regulatory Commission.

Samuel J. Collins, Director,
Office of Nuclear Reactor Regulation.

(2) If a notice is issued under statutory authority, the NRC may cite this authority in narrative form in the text of the document.

Example:

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards will hold a meeting on June 4-6 2001, in room T-3 B4, 11545 Rockville Pike, Rockville, Maryland.

(3) If a notice document requires an effective date, the NRC shall include a statement of the effective date in the text of the document.

Example:

This license modification is effective October 31, 2001.

(4) If a notice document relates to or references a previously published *Federal Register* document, it must contain a precise reference to the earlier document.

(i) A reference to a document published in the *Federal Register* should identify the volume number, page number, and the date of the issue in which the document appears.

Example:

The NRC has made a determination, on the basis of criteria published in the *Federal Register* (66 FR 10905; February 24, 2001) that events involving an actual loss or significant reduction in the degree of protection against radioactive properties of source, special nuclear, and byproduct materials are abnormal occurrences.

(ii) A reference to material contained in the *Code of Federal Regulations* (CFR) should identify the CFR title and the part or section number in which the referenced provision appears.

Examples:

1. Accordingly, under Section 161 of the Atomic Energy Act, as amended, and the Commission's regulations in 10 CFR Parts 2 and 50, it is ordered that, effective immediately, Facility Operating License No. DPR-23 is modified by the addition of the following requirements....

2. If a hearing is requested by a person other than the licensee, that person shall describe, in accordance with 10 CFR 2.714(a)(2), the manner in which his or her interest is affected by this order.

13.3 Submitting a notice document for publication.

(a) The Rules and Directives Branch (RDB) is responsible for certifying and transmitting the NRC's general notice documents for publication in the *Federal Register*. The staff office that originates the notice document is responsible for preparing a complete publication package and submitting the package to RDB. The complete publication package must be submitted to RDB by 8:30 am to ensure that final processing may be completed before the 9:00 am courier pickup for delivery to the Office of the Federal Register (OFR).

(b) The publication package for each general notice document must meet the following requirements:

(1) The package should be transmitted under cover of a memorandum or form that identifies a contact person for the document and specifies any special handling desired, such as a request for emergency publication, the confirmation of a publication or comment closing date, or the computation and insertion of a specific date. If the computation and insertion of a specific date is desired, the memorandum or form must indicate the number of days after publication in the *Federal Register* for that date.

(2) The package must include the signed document, and the signature must be handwritten in ink. The name and title of the person signing the document must be typed directly beneath the handwritten signature.

(i) The OFR does not accept a document in which the signature and the typed name are not identical, such as a document in which one official signs "for" another. In such an instance, the name of the person who signs the document must be typed in the signature block and the person's title must be described as "Acting xxx."

(ii) The NRC recommends that the signer use blue ink. It is difficult to distinguish an original signature from a photocopy if black ink is used.

(3) The package must include five copies of the signed document.

(4) The package must include a 3.5-inch diskette that contains a copy of the document in WordPerfect. The diskette must have a label that identifies NRC as the issuing agency, the file name of the document, and WordPerfect as the software used to create the document. RDB will forward the diskette to the OFR and the Government Printing Office for their use in typesetting the document. The diskette must contain only the document to be published and reflect only the text that is to appear in the *Federal Register*. Transmittal memoranda, letters to licensees, and concurrence pages may not be included on the diskette.

(c) The following document format requirements are applicable to each general notice submitted for publication in the *Federal Register*.

(1) The NRC billing code, [7590-01-P], must appear in the upper right-hand corner on the first page of the document.

(2) Document text must be double-spaced.

(3) Document text may appear on only one side of the page.

13.5 Writing a correction document.

(a) The NRC is responsible for verifying the completeness and accuracy of each document it publishes in the *Federal Register*. The office that originates the document has the primary responsibility for proofreading the published document and identifying and correcting any errors that may have occurred during the printing process.

(b) The NRC may not use a correction document as a vehicle for writing in second thoughts or to "fine-tune" a published document. Changes of this nature are amendments, not corrections, and may not be presented in the guise of a correction document.

(c) If the error occurred in the publication process, the OFR is responsible for making any correction necessary to accurately reflect the content of the original document. The originating office may correct printing errors by contacting RDB (415-7163) and identifying the *Federal Register* issue in which the document was published and the errors to be corrected.

(1) If the error is significant or substantive, the OFR will prepare a correction and publish it in a future issue of the *Federal Register*.

(2) If a typographical or punctuation error does not affect the substance of the document, the OFR will correct the regulatory text when it is printed in the *Code of Federal Regulations*.

(d) If the error appeared in the original document submitted to the OFR for printing, the NRC is responsible for correcting the error. Unless prior arrangements have been made with RDB, the originating office shall prepare the correction document. Each correction document must be prepared, signed, and submitted to the OFR as a document for publication. The correction document must refer to the document containing the error and clearly identify each error that is being corrected.

(1) The headings of a correction document must repeat the headings of the document containing the error. The word "correction" is added to the subject heading. The CFR heading identifies only the parts affected by the correction. If the preamble to a rulemaking document is being corrected, list all CFR parts affected by the original document.

(2) If a correction is to a proposed or final rule document, the correction document must comply with the preamble requirements of 1 CFR 18.12 (see Sections 5.7 or 7.7 of this handbook).

(3) The complete *Federal Register* citation of the document being corrected, including page and date of publication, must be presented.

(4) The location of the error being corrected must be identified as clearly as possible.

(i) In codified text, cite the CFR unit that contains the error.

(ii) In noncodified text or tabular material, specify the *Federal Register* page number and column containing the error.

(5) The actual change must be described as briefly and accurately as possible. If necessary, present the incorrect material first; then present the corrected text.

(e) Sample correction documents appear at Section 19.18 of this handbook.

PART 15 - PETITIONS FOR RULEMAKING

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15.1 Legal and procedural background.

(a) The Administrative Procedure Act provides any interested person with the right to petition an agency for the issuance, amendment, or repeal of a rule (5 U.S.C. 553(e)). This statute expands on the "right to petition" provided by the First Amendment to the Constitution and imposes on Federal agencies the obligation to receive, consider, and act upon petitions that are submitted to them.

(b) The NRC implements this statute in regulations that establish the procedures by which any interested person may file a petition for rulemaking with the Commission (10 CFR 2.802). Section 2.802 presents basic information concerning how an interested person submits a petition to the NRC, the minimum information a petition must contain to be acceptable for processing, and the procedures the NRC uses in processing petitions.

(c) In addition to 10 CFR 2.802, the NRC developed and issued Regulatory Guide (RG) 10.12, "Preparation of Petitions for Rulemaking Under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents."

(1) RG 10.12 provides an alternative within the petition process that encourages the petitioner to submit more detailed supporting information in the petition than is minimally required for acceptance. This practice could facilitate NRC's decision on the merits of the petition. The provisions of RG 10.12 do not change any previously existing procedure, right, or obligation. For additional information, see Section 15.5 of this handbook.

(2) RG 10.12 also clarifies procedures by which an interested person may submit proposals to change existing guidance documents. These guidance documents include regulatory guides, bulletins, generic letters, and portions of standard review plans that do not have the force and effect of a regulation but serve to identify or clarify methods or positions acceptable to the NRC staff for compliance with NRC regulations.

15.3 Minimum content requirements.

(a) Paragraph (c) of 10 CFR 2.802 presents the minimum content requirements that a petition for rulemaking must meet for the NRC to find it acceptable for processing. The type of information required is considered the minimum threshold necessary for the NRC to understand the petitioner's concerns and suggested solution and respond to the request in a meaningful way.

(b) A petition for rulemaking must --

(1) Set forth a general solution to the problem or present the substance or text of any proposed regulation or amendment or specify the regulation that is to be revoked or amended;

(2) State clearly and concisely the petitioner's grounds for and interest in the action requested; and

(3) Include a statement in support of the petition that sets forth the specific issues involved; the petitioner's views or arguments with respect to those issues; relevant technical, scientific, or other data involved that are reasonably available to the petitioner; and any other pertinent information necessary to support the action sought. Where possible, the petitioner should note any specific cases in which the current requirements are unduly burdensome, deficient, or need to be strengthened. This information may prove to be extremely important when the NRC considers the merits of the petitioner's suggested amendments.

15.5 Providing additional information with a petition.

(a) RG 10.12 encourages the petitioner to provide more detailed supporting information than that required by 10 CFR 2.802(c). This practice would allow the NRC to treat petitions more expeditiously and facilitate NRC action on petitions with strong technical merit. In addition, the submittal of additional information may improve the priority for processing the petition by the NRC staff.

(b) RG 10.12 specifies the additional supporting information that a petitioner should submit in addition to the minimum threshold requirement. The additional supporting information should include --

(1) The suggested regulatory text necessary to accomplish the petitioner's desired amendment;

(2) The statement of considerations (preamble) for the suggested regulatory change;

(3) Material necessary to indicate compliance with applicable legal requirements such as the National Environmental Policy Act, the Paperwork Reduction Act, and the Regulatory Flexibility Act;

(4) A regulatory analysis;

(5) Material necessary to indicate compliance with the Commission's backfit regulations (10 CFR 50.109, 70.76, 72.62, or 76.76); and

(6) A guidance document, usually in the form of a regulatory guide, when applicable. A regulatory guide usually accompanies a performance-based regulation.

15.7 Contacts with the NRC before the petition is filed.

(a) A prospective petitioner may consult with the NRC before filing a petition for rulemaking by writing to the Director, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Chief, Rules and Directives Branch. A prospective petitioner may also telephone the Rules and Directives Branch (RDB) on (301) 415-7163 or on the toll-free number for inquiries concerning NRC regulations: (800) 368-5642.

(b) The extent to which a member of the NRC staff may assist a prospective petitioner is limited by 10 CFR 2.802(b). In any consultation before a petition for rulemaking is filed, the assistance that may be provided a prospective petitioner by a member of the NRC staff is limited to --

(1) Describing the procedure and process for filing and responding to a petition for rulemaking;

(2) Clarifying an existing NRC regulation and the basis for the regulation; and

(3) Assisting the prospective petitioner to clarify a potential petition so that the Commission is able to understand the nature of the issues of concern to the petitioner.

(c) The NRC staff may not --

(1) Write or assist in the writing of a petition for rulemaking to amend 10 CFR Chapter I for an external party;

(2) Negotiate wording for a specific revision to 10 CFR Chapter I with a petitioner or prospective petitioner; or

(3) Encourage a prospective petitioner to submit a petition for rulemaking in order to bypass normal agency procedures for the initiation and development of a rulemaking action.

(d) NRC employees may not discourage a prospective petitioner from submitting a petition for rulemaking or encourage a petitioner to withdraw a petition once it is submitted.

(e) Informing an individual of the option to petition the Commission or to contact the agency for assistance with the petition process is not considered prohibited assistance. Neither is the NRC staff prohibited from consulting with external parties to assemble necessary information to clarify regulatory deficiencies and evaluate their health and safety significance. A prospective petitioner who needs guidance regarding the submission and processing of petitions for rulemaking should be referred to RDB.

(f) If any improper NRC staff assistance is provided to a prospective petitioner regarding technical or substantive issues, that assistance must be disclosed to the Commission in the paper forwarding the rulemaking action for approval and in any public notice regarding the petition and in any rulemaking that may result from the petition that is published in the *Federal Register*.

15.9 Filing a petition with the NRC.

A prospective petitioner may file the petition with the NRC by addressing it to The Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff. If any other NRC employee receives a petition for rulemaking or a document that may qualify as a petition, the employee shall forward the document immediately to the Rulemakings and Adjudications Staff, Office of the Secretary (SECY).

15.11 Preliminary processing and threshold determination.

(a) When SECY receives a petition for rulemaking or a document that may qualify as a petition for rulemaking, it records the date of receipt of the document and sends a copy of the document to RDB.

(1) Within 1 day after receiving the prospective petition from SECY, RDB sends a letter to the petitioner that acknowledges receipt of the petition by the NRC. The letter also states that the NRC will update the petitioner on the status of the petition.

(2) RDB performs an initial review of the petition and makes a preliminary sufficiency determination within 2 days after receiving the petition. If RDB determines that the petition obviously meets the threshold requirements of 10 CFR 2.802 (c) (see Section 15.3 of this handbook), RDB begins preliminary processing as discussed in paragraphs (c) and (d) of this section. If RDB questions whether a petition meets the threshold requirements applicable to a petition, RDB requests a determination from the Office of the General Counsel (OGC) as to whether or not the document meets the threshold requirements for a petition for rulemaking. RDB requests that OGC respond to a determination request within 5 working days.

(b) If the document does not meet the requirements for a petition for rulemaking, processing continues as indicated in Section 15.13 of this handbook.

(c) If the document meets the requirements for a petition for rulemaking, RDB takes the following actions within 1 working day.

(1) RDB assigns a docket number to the petition and informs SECY of the assigned docket number. SECY establishes the official docket file for the petition.

(2) RDB forwards a copy of the petition to the Public Document Room.

(3) RDB forwards an advance copy of the petition to the Office of Nuclear Material Safety and Safeguards and the Office of Nuclear Reactor Regulation with a preliminary indication of

the NRC staff office to which the formal request for action on the petition will be submitted. RDB also forwards an advance copy of the petition to OGC.

(d) Within 10 working days, RDB forwards a formal request for a decision from the appropriate NRC staff office on whether the petition should be processed routinely or handled as a "fast-track" petition (see Section 15.15 of this handbook). A fast-track petition is initially published for comment in the *Federal Register* as a proposed rule in accordance with 10 CFR 2.802(e). RDB prepares a draft notice of receipt of the petition and forwards it with the fast-track request. If the NRC staff office determines that the petition for rulemaking is not suitable for fast-track processing, the NRC staff office is requested to comment and concur on the draft notice of receipt and return it to RDB for publication in the *Federal Register*. RDB requests that the NRC staff office provide its response within 10 working days.

(1) If the NRC staff office determines that fast-track processing is appropriate, processing continues as indicated in Section 15.17 of this handbook.

(2) If the NRC staff office determines that fast-track processing is not appropriate, processing continues as indicated in Section 15.19 of this handbook.

(e) After a petition has been submitted and the NRC staff has reviewed the merits of the petition, discussions between the NRC staff and the petitioner regarding the wording for specific provisions of the regulations must occur in an open, public forum. The NRC shall provide sufficient advance notice to the public in accordance with the guidelines contained in Management Directive (MD) 3.5, "Public Attendance at Certain Meetings Involving the NRC Staff."

15.13 Petitions that do not meet threshold requirements.

(a) If a petition does not include sufficient information to meet the threshold requirements for a petition for rulemaking (see Section 15.3 of this handbook), the Executive Director for Operations (EDO) will make a determination that a petition is deficient. The EDO's determination, which is based upon the recommendation of RDB and OGC, should be made within 30 days from the date of receipt of the petition by SECY. RDB prepares a memorandum to the EDO transmitting this recommendation and a draft letter to the petitioner pointing out the aspects in which the petition is deficient.

(b) The petitioner is informed as to how the petition is deficient and is given an opportunity to submit additional information. If a petitioner does not correct the deficiency within 90 days from the date of notification by the EDO that the petition is incomplete, the petition will be returned to the petitioner without prejudice to the petitioner's right to file a new petition. Correspondingly, RDB drafts the appropriate letter to the petitioner, obtains the necessary concurrences, and forwards the letter to the EDO for signature.

(c) The Commissioners are placed on distribution for any letter to a petitioner that states that a petition is deficient or that returns a petition because it is incomplete.

15.15 Petitions eligible for "fast-track" processing.

(a) Occasionally, the NRC receives a petition for rulemaking that requests an obviously meritorious amendment to the regulations. To expedite the rulemaking process, these petitions may be published initially for public comment as a proposed rule. This type of action constitutes fast-track processing and eliminates the usual step of publishing a notice of receipt of a petition that invites public comment when this additional procedural step is unnecessary. Fast-track petitions are processed by the staff according to the procedures specified in this section and in Section 15.17 of this handbook.

(b) Following a determination that a petition meets the threshold requirements of 10 CFR 2.802(c), RDB assigns the petition to the appropriate NRC staff office to determine whether the petition is eligible for fast-track processing. The NRC staff office assigns a contact person to handle the petition and makes the fast-track determination within 10 working days.

(c) The NRC may consider a petition eligible for fast-track processing if it --

(1) Proposes action granting or recognizing an exemption from requirements in 10 CFR Chapter I or granting relief from restrictions while not imposing additional burdens upon or increasing the risks to the health and safety of any segment of industry or the public;

(2) Proposes action involving interpretive rules; rules of agency organization, procedure, or practice; and rules for the orderly conduct of Commission business;

(3) Proposes action involving an amendment to 10 CFR Chapter I that is corrective or of a minor or nonpolicy nature and that does not substantially modify existing regulations;

(4) Proposes action involving --

(i) A minor safety, safeguards, or environmental issue;

(ii) An increase in NRC efficiency; or

(iii) A reduction in the regulatory burden on licensees.

(5) Proposes action involving a request already under consideration in an ongoing rulemaking proceeding. However, NRC's consideration of a request already included in an ongoing rulemaking depends on the status of the rulemaking proceeding;

(6) Proposes other action that is clearly meritorious and will not adversely affect the rights of other licensees or persons; or

(7) Contains the type of additional supporting information described in RG 10.12 and Section 15.5 of this handbook.

(d) The NRC normally will not consider a petition eligible for fast-track processing if the proposed action will --

(1) Require the preparation of an environmental impact statement;

(2) Impose new or increased reporting, application, or recordkeeping requirements subject to clearance by the Office of Management and Budget;

(3) Have a significant economic impact on a substantial number of small entities (see discussion of Regulatory Flexibility Act requirements in Sections 5.21 and 7.21 of this handbook);

(4) Have a significant impact on NRC staff and resource commitments; or

(5) Result in denial of the petition for rulemaking.

15.17 "Fast-track" processing.

(a) If the assigned office determines that the fast-track process is appropriate for a petition for rulemaking, the assigned office shall inform RDB of this decision. The assigned office begins processing the petition under fast-track procedures by developing a rulemaking plan that will initiate rulemaking action addressing the issues raised in the petition.

(b) Under fast-track procedures, the rulemaking plan must be submitted for Commission or EDO approval within 90 days of informing RDB of the decision to proceed with a rulemaking action. The assigned office shall include a schedule in the rulemaking plan that indicates its intent to expedite the completion of the rulemaking at the both the proposed rule and the final rule stage.

(c) The assigned office is responsible for implementing Commission, EDO, or Chief Financial Officer action for the rulemaking through the issuance of the final rule (See Part 1 of this handbook and MD 6.3, "The NRC Rulemaking Process").

15.19 Routine processing.

(a) If the assigned office determines that the fast-track process is not appropriate for a petition for rulemaking, the assigned office shall inform RDB of this decision. The assigned office shall also concur or provide comment on the draft notice of receipt of petition for rulemaking prepared by RDB for publication in the *Federal Register*. The notice of receipt describes the contents of the petition and allows at least 75 days for public comment. The assigned office identifies the staff contact within the assigned office that will be responsible for further action on the petition.

(b) RDB amends the notice of receipt as necessary to reflect assigned office comments. RDB then forwards the notice of receipt for OGC review and approval. RDB requests that OGC respond to this request within 5 working days. After OGC approves the notice of receipt, RDB forwards the notice of receipt to SECY for signature and transmittal to the Office of the Federal Register for publication. At the same time, RDB forwards a letter to the petitioner that transmits a copy of the notice of receipt, informs the petitioner of the petition's docket number, and indicates that RDB will forward copies of any comments received to the petitioner.

(c) The assigned office shall establish a schedule with intermediate milestones, as appropriate, and a target date for resolution of the petition. The schedule and target date are intended to cover the period from the date the notice of receipt is published in the *Federal Register* to the date on which the response indicating resolution of the petition is transmitted to the EDO. The resolution determination may be forwarded to the EDO in the entry for the petition in the Status Report on Petitions for Rulemaking prepared by RDB or in a memorandum to the EDO.

(1) A petition is considered resolved when the assigned office has determined what regulatory decision will be made concerning the petition. A petition may be resolved by

deciding to grant the petition (all or in part) and to proceed with a rulemaking action or by deciding to deny the petition. However, the resolution of a petition does not complete action on the petition. The resolution of a petition consists of the decision on the course of action the NRC will follow to complete action on the petition by either granting or denying it.

(2) Action on a petition is completed and the petition is "closed" when the NRC formally grants the petition by completing and publishing the final rule necessary to grant the petitioner's request or when the NRC denies the petition by publishing a notice of this action in the *Federal Register* and by advising the petitioner of this action in writing. In addition, action on a petition may be completed if the petition is withdrawn by the petitioner. For additional information on the closure of a petition, see Section 15.27 of this handbook.

(d) The EDO has established procedures to ensure that the resolution of a petition for rulemaking is accomplished on a timely basis. (See the memoranda from the EDO to Office Directors dated August 13, 1986, and April 6, 1988.) These procedures require that the resolution of a petition occur within 12 months from the date the notice of receipt of the petition is published in the *Federal Register*.

(1) The assigned office shall report the status of each petition for which it is responsible. These status reports are to coincide with the updating of the NRC Regulatory Agenda (NUREG-0936). The schedule for the resolution of each petition will be included in the regulatory agenda.

(2) Any proposed extension of the resolution date of a petition must be approved by the EDO in advance. The EDO reviews proposed extensions of resolution concurrently with the review of completion of rulemaking dates. RDB forwards a report to the EDO that indicates the status of each petition. The status report includes the reason for any extension of the resolution date for a petition and the proposed new resolution date.

15.21 Processing after publication for public comment.

(a) **Fast-track petition (published as a proposed rule).** At the conclusion of the comment period specified in the proposed rule, the contact person in the assigned office sends a letter to the petitioner enclosing copies of any comments that were received in response to the publication of the proposed rule in the *Federal Register*. The letter also states the initial target date for completion of NRC staff review of the comments received and development of a final rule. The assigned office is responsible for notifying the petitioner of any subsequent changes in the target date or of the contact person to whom the petition is assigned.

(b) **Routine petition (notice of receipt published for comment).**

(1) Shortly after the comment period specified in the *Federal Register* notice of receipt of petition (normally 75 days) closes, RDB sends a letter to the petitioner enclosing copies of any comments that have been received concerning the petition. The letter also states the initial target date for completion of NRC staff review of the petition and the name and telephone number of the contact person in the assigned office who is responsible for future action on the petition.

(2) RDB sends a memorandum to the program office that transfers the petition file and responsibility for further action to that office. That office becomes the lead office responsible for resolving and completing action on the petition. The attachments to the memorandum include--

- (i) The petition for rulemaking;
- (ii) The notice of receipt as published in the *Federal Register*, and
- (iii) Any public comments that have been received.

(3) The lead office is responsible for notifying the petitioner of any subsequent changes in the target date for completion of NRC staff review and of the contact person to whom the petition is assigned. The contact person should make an initial contact with the petitioner and

periodic contact, at a minimum of every 6 months, until action is completed on the petition.

(i) These contacts may be made by telephone, e-mail, or letter and are intended to advise the petitioner, in general terms, of the status of NRC action on the petition and of the ultimate disposition of the petition. Routine correspondence to the petitioner may be signed by an appropriate official in the responsible office. The lead office shall send copies of correspondence sent to a petitioner to RDB and to the official docket file maintained by SECY. Telephone contacts should be described in a note to the file that summarizes the discussion.

(ii) The lead office shall forward a copy to the petitioner of each Federal Register document that addresses the petition or would be a step in completing action on the petition.

(4) Any meeting between the NRC staff and the petitioner to resolve issues raised by the petition or to negotiate wording for revisions to specific provisions of the regulations in question must be publicly noticed in accordance with NRC guidelines on staff meetings open to the public in MD 3.5. The lead office is responsible for the publication of the notice of the meeting in the *Federal Register*.

(5) If a lead office determines that action on the petition has been completed through administrative measures other than publication of a *Federal Register* document, it should consult with RDB and OGC for a final determination. After it reviews actions taken during the processing of the petition, RDB will notify the assigned office if all necessary action on the petition has been completed and describe how the proceeding is to be terminated.

(c) Assistance during processing.

(1) RDB will assist with the preparation and review of *Federal Register* documents required during the processing of petitions for rulemaking.

(2) OGC will provide legal advice to the staff during the processing of petitions for rulemaking.

(d) **NRC staff response to significant actions.** The lead office is responsible for notifying RDB and OGC of any significant action or change that occurs during the processing of the petition. The lead office should include RDB and OGC in any negotiations with a petitioner that could result in understandings that could materially affect the handling and disposition of a petition. Coordination of staff plans with RDB is necessary for actions such as the potential or actual withdrawal of a petition to enable RDB to keep the EDO informed of the status of petitions for rulemaking and to describe the status of petitions accurately in the regulatory agenda.

15.23 NRC staff priority for action on a petition.

(a) RG 10.12 presents guidelines that the NRC staff should use in establishing priorities to resolve and complete action on a petition for rulemaking. The NRC staff considers the merits of each petition in its evaluation and scheduling. The degree to which information submitted in support of a petition is complete, accurate, and thorough affects how rapidly the NRC staff is able to make a determination. A petition for rulemaking submitted under 10 CFR 2.802 is generally either --

(1) A petition related to safety significance pertaining to adequate protection of public health and safety, the environment, and the common defense and security; or

(2) A petition that would reduce the regulatory burden by eliminating requirements that are marginal to safety.

(b) The NRC staff should use the following guidelines in establishing priorities for action on a petition.

(1) The safety significance of a petition is the first criterion used in scheduling NRC staff action on a petition. Petitions concerning adequate protection of public health and safety, the environment, and the common defense and security would receive immediate NRC staff attention and be given the first priority for NRC staff action. In assessing the safety significance of a petition, the NRC staff considers the technical information submitted in support of the petition, other information available to the NRC staff, and whether the suggested amendments meet the backfit criteria of 10 CFR 50.109, 70.76, 72.62, or 76.76, if applicable.

(2) If a petition is safety-neutral, that is, its implementation would have an insignificant effect on the level of protection provided to public health and safety, and the petition is supported by the type of additional information described in RG 10.12 and Section 15.5 of this handbook, the petition would be given the second priority for NRC staff action.

(3) If a petition is safety-neutral and is not supported by the type of additional information described in RG 10.12 and Section 15.5 of this handbook but meets the threshold requirements of 10 CFR 2.802(c) as described in Section 15.3 of this handbook, the petition would be given the third priority for NRC staff action.

15.25 Typical process for resolving a petition.

After the comment period on the notice of receipt closes, RDB forwards the petition file to the lead office. The lead office assumes responsibility for resolving and completing action on the petition. A petition is considered resolved when the lead office makes its regulatory decision for the petition by deciding to grant the petition (all or in part) and proceeding with a rulemaking action or by deciding to deny the petition. Section 15.27 of this handbook discusses how and when action on a petition is completed.

(a) **Working group.** During or shortly after the close of the public comment period, the lead office establishes a working group for the petition. The working group reviews the petition and the comments received and develops a recommended resolution. The working group is composed of –

- (1) A task leader from the lead office;
- (2) A member from other units within the lead office that have program responsibilities related to the rulemaking;
- (3) A member from OGC to provide legal advice and support;
- (4) A member from RDB to address procedural issues; and
- (5) A member from other staff offices, as appropriate.

(b) **Evaluating the petition.** In considering the merits of the petition, the working group reviews the petition, any supporting information presented by the petitioner, and the public comments received. In doing so, the working group considers each regulatory issue raised by the petition, the rationale for each request, and whether the requested action is warranted to improve safety or provide regulatory relief or another tangible benefit.

(c) **Petition Review Board.** The lead office establishes a petition review board to provide management approval for the course of action to be taken in resolving a petition for rulemaking. The petition review board consists of –

(1) The appropriate level of management in the lead office for approving or disapproving the course of action recommended by the working group;

(2) The director or deputy director of the division within the lead office responsible for action on the petition;

(3) The director or deputy director of other affected divisions;

(4) Appropriate representatives from other affected offices;

(5) The Assistant General Counsel for Rulemaking and Fuel Cycle or his or her designee;
and

(6) The Chief of RDB or his or her designee.

(d) **Presentations to the Petition Review Board.** The task leader will schedule a meeting of the petition review board and present the working group's recommendation to obtain management approval for the resolution.

(e) **Petition Review Board decision.** The petition review board will attempt to reach a consensus on the resolution of the petition. The petition review board may –

(1) Approve the working group's recommended resolution;

(2) Specify a different resolution;

(3) Request additional information and a further briefing; or

(4) Refer the matter to the office director or deputy director to obtain a decision, if necessary.

(f) Implementation.

(1) If the resolution is to grant the petition, the working group prepares an appropriate rulemaking plan as described in Section 3.3 of this handbook.

(2) If the resolution is to deny the petition, the working group prepares a memorandum to the EDO or a Commission paper that recommends denial. See Section 15.27(c) of this handbook for the contents of a denial package.

15.27 Completing action on a petition.

Action on a petition for rulemaking is considered complete or "closed" when the petition, or each of its parts, has been withdrawn, denied, or granted.

(a) Withdrawal of petition for rulemaking.

(1) Only the petitioner may withdraw a petition or part of a petition. However, the NRC staff may contact a petitioner if events have occurred since the petition was docketed and a notice of receipt and request for comment was published that could make the petitioner consider withdrawal. If the withdrawal is made by telephone, the contact person should request that the petitioner submit an official letter of withdrawal to provide a record of the request. If the petitioner does not submit a written request for withdrawal, the contact person should make a record of the conversation noting the date, name, and position of the person claiming to represent the petitioner. The lead office shall send a followup letter to the petitioner that confirms the withdrawal.

(2) If the petition is withdrawn, RDB, after consultation with the contact person, prepares a *Federal Register* document that informs the public of the action. The *Federal Register* document is circulated to the assigned office and OGC for concurrence before it is submitted for signature.

(b) Granting a petition for rulemaking. A petition or part of a petition is granted through issuance of a final rule that responds to the petitioner's request or other Commission action acceptable to the petitioner. See Section 19.21 of this handbook for a sample final rule that grants a petition for rulemaking.

(1) If the lead office plans to grant a petition for rulemaking, it must prepare a rulemaking plan for the contemplated rule. The rulemaking plan should contain, as a minimum, the type of information that would routinely be submitted to the petition review board, such as a summary

of public comment received on the petition and the staff's recommended course of action. The lead office may include additional information in the rulemaking plan as necessary to reflect a substantial number of significant comments or the sensitive policy or political impacts of the requested change.

(2) A complete analysis of public comment received on the petition must be included in the proposed rule that is developed and published for the action.

(3) The lead office is responsible for preparing a letter to the petitioner to be sent to the petitioner before publication of the proposed rule or the final rule in the *Federal Register* (to be signed by either the EDO, the Chief Financial Officer (CFO), or the Secretary of the Commission). The proposed or final rule must be enclosed with the letter.

(c) Denial of petition for rulemaking.

(1) A petition or part of a petition is denied through the publication of a Federal Register document and official written notification to the petitioner. If part of a petition is denied, the assigned office is responsible for processing the remaining parts of the petition until each remaining part has been withdrawn, denied, or granted. A petition must be denied even if the NRC takes other actions to address a petitioner's concerns, such as the issuance of a regulatory guide, policy statement, or legal interpretation.

(2) The assigned office prepares the following documents in the case of a denial of a petition:

(i) A memorandum to the EDO or a Commission paper.

(ii) A *Federal Register* document that provides notice of denial (to be signed by either the EDO, the CFO, or the Secretary of the Commission). The EDO and the CFO have the authority to deny petitions for rulemaking concerning issues that are within the scope of the rulemaking authority delegated to the EDO or the CFO. Denials of petitions, in whole or in part, that address major or policy issues require action by the Commission.

(iii) A letter to the petitioner to be sent to the petitioner before publication of the notice of denial in the *Federal Register* (to be signed by either the EDO, the CFO, or the Secretary of the Commission).

(iv) Congressional letters to be signed by the Director of the Office of Congressional Affairs.

(v) A draft public announcement, if appropriate.

(3) In preparing the *Federal Register* notice of denial of a petition, the assigned office shall ensure that each of the issues raised by the petitioner has been addressed. The NRC's response to each of the issues raised and the reasoning presented for denying the petition must be presented in a manner and with sufficient detail to indicate that the NRC has adequately considered each of the petitioner's requests. Each *Federal Register* document that provides notice of denial of a petition must include --

- (i) A complete summary of each of the issues raised in the petition;
- (ii) A summary and analysis of any public comment received;
- (iii) NRC's response to each of the issues raised; and
- (iv) NRC's reasons for denying the petition.

(4) When preparing a *Federal Register* document that denies a petition, the following format items are omitted from the Commission paper and *Federal Register* document --

- (i) The standard statements concerning the regulatory analysis, the Paperwork Reduction Act, the Regulatory Flexibility Act, and the National Environmental Policy Act;
- (ii) The authority citation; and
- (iii) The list of subject index terms.

(5) See Section 19.22 of this handbook for a sample denial of a petition for rulemaking.

(d) **Incorporation of a petition for rulemaking.** When similar or related issues are involved, a petition or part of a petition may be incorporated into an ongoing rulemaking if certain factors are taken into consideration.

(1) If any of the three following factors exist, the petition or the part of a petition under review should be treated separately.

(i) Incorporation of the petition or part of the petition into an ongoing rulemaking may delay the completion of the rulemaking to an extent that is undesirable given the Commission's established priorities.

(ii) Incorporation of the petition or part of the petition into an ongoing rulemaking could delay the resolution of the petitioner's request to the point that the delay in reaching a final decision on the merits of the petition amounts to a denial of the petition.

(iii) The action to incorporate the petition occurs at a stage in the rulemaking that does not permit adequate consideration of the issue involved.

(2) If a petition is incorporated into an ongoing rulemaking, the assigned office prepares a letter to the petitioner when the decision to incorporate the petition is made. The letter should identify the rulemaking action, explain the current status of that rulemaking, and indicate that the petitioner will be informed of subsequent action concerning the proceeding.

(e) **Actions that do not complete action on a petition for rulemaking.** The administrative or procedural steps discussed in this paragraph do not grant, deny, or complete action on a petition for rulemaking or any of its parts. Action on a petition for rulemaking is completed only when the steps set out in paragraphs (a), (b), or (c) of this section have been accomplished for the petition or each of its parts.

(1) The resolution of a petition does not complete action on the petition. The resolution of a petition for rulemaking consists of a decision on the course of action the NRC will follow to complete action on the petition by either granting or denying it.

(2) Incorporation of a petition or part of a petition into an ongoing rulemaking does not cause the petition or its parts to lose the identity of a discrete agency action item that must eventually be withdrawn, denied, or granted. Incorporation, by itself, does not "grant" or "complete" action on a petition for rulemaking.

(3) The intermediate procedural or administrative steps and milestones used by NRC offices to control the processing of petitions for rulemaking (e.g., review, analysis, reports, studies, position papers, issuance of publications in the NUREG series) do not "grant," "deny," or "complete" action on a petition or its parts.

(f) Dockets and files.

(1) SECY maintains the official docket file on a petition for rulemaking. The assigned office should send a copy of all petition-related documents for inclusion in the official docket to SECY through the Agencywide Documents Access and Management System. The assigned office should also send a paper copy of petition-related documents to RDB so that RDB can monitor the current status of each ongoing action.

(2) RDB maintains a file of currently active petitions for rulemaking. Documents concerning current petitions and petitions that have been completed through action by the EDO or the Commission are published in the *NRC Rules and Regulations*. Questions concerning the status of any petition for rulemaking may be directed to RDB (415-7163).