NUREG/BR-0053

United States
Nuclear Regulatory Commission

# Regulations Handbook

Division of Rules and Records
Office of Administration

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# INTRODUCTION

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, knowledge of which is essential in developing rulemaking items for the NRC. Additional historical and relevant information pertaining to the NRC rulemaking process is included as well.

The handbook is intended to serve as a guidance tool for the professional staff who prepare, review, and coordinate rulemaking items. Appendix A to the handbook provides guidance for staff who prepare packages containing a Federal Register rulemaking document for transmission to the Office of the Federal Register. (Other appendices to this handbook are described in the section to which their use is most closely related.) The handbook should also be helpful to administrative, program support, and clerical staffs who may type or track rulemaking items.

The handbook provides all information relevant to each step in the rulemaking procedure in the particular section concerning that step. Since some of the information is very similar at successive rulemaking steps, there will be some repetition of information. However, our experience has shown this format to be most helpful to regulation writers and reviewers because it enables them to find all the information they need at one place concerning a particular step in the procedure rather than having to follow an elaborate system of cross references. Use of the handbook at each stage will help eliminate structural problems with the documents that may arise from improper formating or omitted requirements. It should also expedite the rulemaking process.

Because the rulemaking process is one that continuously changes, the handbook has been designed to incorporate future revisions. Specific instructions on how to update the handbook will accompany any revised material in the future, thus enabling the user to keep the handbook current and accurate.

This handbook represents the efforts of the entire Rules and Procedures Branch, and each member of the Branch contributed significantly to its preparation and development. A special note of commendation should go to Mr. Michael Lesar who served as the task leader and principal author. Mr. Lesar was also responsible for designing the contents and coverage of the handbook, and for seeing that the many production details were implemented. Before joining the NRC in 1981, Mr. Lesar was employed by the Office of the Federal Register where he was responsible for, among other things, producing OFR's classic Document Drafting Handbook which has become the principal authority for regulation writers in the Federal government. A special note of thanks should also go to Ms. Betty Golden, our Branch Secretary, who typed many drafts of this handbook.

Questions concerning the use of the handbook or any rulemaking process, suggestions for improving the content or format of the handbook, or corrections of any errors or inconsistencies in the handbook should be directed to the Rules and Procedures Branch (301-492-7086).

John D. Philips, Chief
Rules and Procedures Branch
Division of Rules and Records

PART 1 - THE RULEMAKING PROCESS

## 1.1 The Administrative Procedure Act.

The Administrative Procedure Act of 1946, as amended, (APA) sets out the minimum procedural requirements that Federal agencies are required to follow when they promulgate rules and conduct adjudicatory proceedings. The APA also establishes the standard for judicial review of administrative actions.

The APA was passed in response to the increased number of regulatory agencies created during the New Deal era. Its primary goal was, and 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).

In establishing minimum procedural requirements, the APA permits agency flexibility in developing additional procedures. These procedures can be found for each agency in the Code of Federal Regulations (CFR). The additional rulemaking procedures for the Nuclear Regulatory Commission (NRC) are discussed in more detail in section 1.7 of this handbook. In addition, 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.

The APA applies to both Executive Branch agencies and independent regulatory agencies such as the NRC.

## 1.3 The Code of Federal Regulations.

The Code of Federal Regulations (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.

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 (entitled "Energy"), Chapter I (entitled "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 the parts between 0 and 199. Those unused parts are reserved for future use by the NRC, as needed.

1.5 The Federal Register.

The Federal Register is published daily by the Office of the Federal Register, National Archives and Records Service, General Services Administration. It provides a uniform system for publishing Presidential documents, final rules, proposed rules, advance notices of proposed rulemaking, petitions for rulemaking, notices, policy statements, semiannual agenda of regulations, announcement of meetings, and other public documents for the conduct of agency business. These documents are discussed in detail in subsequent sections of the handbook.

The publication requirements of the Office of the Federal Register (OFR) are covered in this handbook. However, the OFR occasionally modifies these requirements. Questions regarding the most current OFR requirements or special publication requests should be directed to the Rules and Procedures Branch, Division of Rules and Records, ADM (extension 27086). The NRC staff is requested not to call the OFR directly. This will permit the NRC to maintain consistent and uniform guidelines and coordination in the publishing of NRC documents.

1.7 The NRC rulemaking process.

The need for a new NRC regulation normally arises from --

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

(b) Commission or staff initiative indicating a need for further regulation to resolve a safety, safeguards, or environmental problem; or

(c) Commission receipt of a petition for rulemaking.

Action on a regulation is normally assigned to a member of the technical or legal staff most familiar with the subject area. In the case of a technical regulation, the staff person responsible will review the problem and develop a preliminary range of alternatives designed to resolve the problem. As necessary, discussions are held with the staff of other offices and the Advisory Committee on Reactor Safeguards (ACRS) to obtain additional information and to refine the list of alternatives. If the proposed regulation will have an impact on Agreement State licensees, the views of Agreement States are also solicited early in the development process.

At this point, the staff prepares a draft of the regulation and, in accordance with guidelines adopted by the Commission in January 1978 (SECY 77-388A), a value/impact statement (regulatory analysis). If the proposed regulation is likely to have a significant economic impact on a substantial number of small entities, the staff prepares a regulatory flexibility analysis as required by the Regulatory Flexibility Act. If

the proposed regulation is likely to have a significant impact upon the quality of the environment, the staff prepares an environmental impact statement under the National Environmental Policy Act (NEPA). If an environmental impact statement is required for a proposed regulation, the regulatory analysis and the regulatory flexibility analysis are presented as part of the environmental impact statement.

The draft regulation, along with a Commission paper which explains the reasons for the proposed regulation and the regulatory analysis, is then circulated for review and comment at the Division Director level. The package is also submitted to the ACRS and other NRC offices which have knowledge concerning the subject of the regulation or which may be affected by, or otherwise interested in, the regulation. A copy is also sent to the Division of Rules and Records, ADM, and the Office of the Executive Legal Director (OELD) for review.

The responsible staff person then incorporates the comments received into the regulation and, if necessary, meets with the staff of the other offices to resolve any problems or differences. If it is not possible to resolve differing views between the offices, a meeting may also be held at this point with the Executive Director for Operations (EDO) to resolve the issue. Depending upon the complexity of the issues, there may be several rounds of staff comments. If applicable, comments on the proposed regulation may be requested from the Agreement States.

After all comments have been received, a revised package consisting of the Commission paper, the proposed regulation, and the regulatory analysis is sent to the offices for formal concurrence. After the offices have had an opportunity to review the final package, it is sent to the Division of Rules and Records, ADM and then to the EDO for review and, if the EDO agrees, for signature and transmittal to the Commission. If disagreement remains between the offices, the EDO may try to resolve the matter, or the issue will be sent to the Commission as a dissenting view. (For regulations which do not involve significant questions of policy or those not amending 10 CFR Parts 0, 2, 7, 8, 9, Subpart C, and 110, the EDO has been delegated the authority to issue the regulation).

If the regulation contains a reporting, application, or recordkeeping requirement affecting 10 or more persons, the regulation with an accompanying supporting statement is sent to the Office of Management and Budget for clearance under the Paperwork Reduction Act.

When the regulation is received at the Commission, it is scheduled by the Office of the Secretary for Commission consideration, with or without oral presentations. Usually, the Commission meetings on these matters are open under the Government in the Sunshine Act; in some cases, such as those involving classified or safeguards matters, the meetings may be closed to the public. Copies of the 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,

approve the regulation subject to specified changes, disapprove the regulation entirely, or direct that the regulation be revised and resubmitted to the Commission for reconsideration. The Commission's decision on a regulation is reflected in a Staff Requirements Memorandum issued by the Secretary. If the Commission orders changes to be made in the regulation, the Staff Requirements Memorandum sets forth the nature of these changes and the deadline for resubmission, usually fourteen days from the date of the memorandum.

If approved, the regulation is sent to the OFR for filing and publication. The appropriate Congressional Committees with oversight responsibility for the NRC are notified and a public announcement may be issued. If subject to the Regulatory Flexibility Act, the regulation is sent to the Chief Counsel for Advocacy of the Small Business Administration. If subject to NEPA, the draft environmental impact statement is published for public comment. After publication in the Federal Register, copies of the regulation are sent to all affected licensees and to other interested persons who have requested to be placed on a mailing list for NRC notices.

After the close of the comment period on the proposed regulation, the responsible staff person analyzes the comments received and makes any change to the regulation that may be appropriate. This process is essentially repeated for the final rule.

PART 3 - PROPOSED RULES

3.1 Proposed rule documents: Description.

(a) Each document prepared by the Nuclear Regulatory Commission (NRC) that is published in the Proposed Rules section of the Federal Register must meet the format requirements of this part. The Office of the Federal Register (OFR) classifies documents for publication in one of four sections of the Federal Register. These sections are: Presidential Documents, Rules and Regulations, Proposed Rules, and Notices. Documents published in the Proposed Rule 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 Rule section are subject to greater public scrutiny and included in the numerical finding aids compiled by the OFR. The OFR classifies the following types of NRC documents for publication in the Proposed Rule 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 (5 U.S.C. 553) and any other applicable statutory authority. Proposed rule documents 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. The advance notice of proposed rulemaking seeks public comment on the need for regulating in the problem area, and often on the merits of NRC's anticipated regulatory response to the problem. 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 petitions for rulemaking filed with the Commission under its rulemaking procedures (10 CFR 2.802). Because these petitions propose to amend, add to, revise, or remove existing regulations in 10 CFR Chapter I, they are classified as proposed rules for publication in the Federal Register.

(iii) Meetings or hearings. The OFR classifies a document that announces a meeting or hearing that may be the first step in a rulemaking proceeding as a proposed rule for publication in the Federal Register.

(4) Regulatory agendas. The NRC publishes an agenda of regulations under development in the Federal Register each April and October to comply with the requirements of the Regulatory Flexibility Act (Pub. L. 96-354), Executive Order 12291, and Task IV.G.2 of the TMI Action Plan (NUREG 0669, May, 1980). The NRC also includes its summary of petitions for rulemaking pending before the Commission (10 CFR 2.802(g)) in its agenda of regulations. 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 under development each January and July. The NRC announces the availability of the updated agenda in a document published in the Proposed Rule section of the Federal Register and places a copy of the updated agenda in the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

(5) Policy statements. The Administrative Procedure Act (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. The Administrative Conference of the United States recommends the preservation of policy statements and interpretations in the Code of Federal Regulations (CFR) when they are of continuing interest to the public (1 CFR 305.76-2). When the staff considers developing a policy statement, it should contact the

Division of Rules and Records (DRR). DRR will contact the Office of the Executive Legal Director and the Office of the General Counsel to determine whether the policy statement under consideration is to be incorporated into 10 CFR Part 8, "Interpretations."

(b) NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Proposed Rule 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 9.3 of this handbook for information on preparing a correction document.

## 3.3 Proposed rule documents: Anatomy.

This section presents a dissection of a typical proposed rule document. Each essential element of a proposed rule is identified. This section is designed to help a writer identify the required elements of a proposed rule document and create a complete and correct document. The section of 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 proposed rule document (see 15.2 of this handbook) reflects the format used in typing a document for publication in the Federal Register.

SAMPLE: PROPOSED RULE

| | | |
|---|---|---|
| HEADINGS: (3.5) | Agency Heading | NUCLEAR REGULATORY COMMISSION |
| | CFR Part Heading | 10 CFR Part 50 |
| | Subject Heading | Reporting Changes to the Quality Assurance Program |
| PREAMBLE: | Captioned Headings (3.7) | AGENCY: Nuclear Regulatory Commission. |
| | | ACTION: Proposed rule. |
| | | SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to require holders of nuclear power plant construction permits and holders of operating licenses to implement the approved quality assurance program and to inform the Commission in writing of certain quality assurance program changes that affect the description of the quality assurance program included in their Safety Analysis Report and accepted by the Commission, within 30 days of making any change. The amendments will provide |

greater assurance that quality assurance programs approved by the Commission do not have their effectiveness reduced by subsequent changes.

DATES: Submit comments by September 8, 1981. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: Room 1121 1717 H St. NW., Washington, D.C. between 8:15 a.m. and 5:00 p.m.

Examine comments received, the environmental impact appraisal, and regulatory analysis at: The NRC Public Document Room, 1717 H St. NW., Washington, D.C.

Obtain regulatory analysis (single copy) from: (name, address, and telephone number of staff contact).

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301)443-0123.

Statement of Considerations (3.9)

SUPPLEMENTARY INFORMATION: The quality assurance (QA) requirements of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," are one of the cornerstones of the Commission's "defense-in-depth" concept for ensuring safe operation of nuclear power plants.

* * * * *

The proposed amendments would require that construction permit holders and licensees implement the approved quality assurance program, provide a current description of the program, evaluate all changes to the approved program, and, for certain changes that meet the criteria in the rule, submit the evaluation to the NRC for review.

PROCEDURAL REGULATORY REQUIREMENTS

National Environmental Policy Act (3.13)

ENVIRONMENTAL IMPACT: NEGATIVE DECLARATION

The proposed amendment, if adopted, would not result in any activity that affects the environment. The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations, 10 CFR Part 51 that an environmental impact statement is not required for this proposed regulation. The environmental impact appraisal forming the basis for this determination is available for inspection at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

Paperwork Reduction Act (3.15)

PAPERWORK REDUCTION REVIEW

The proposed rule will be submitted to the Office of Management and Budget for clearance of the information collection requirements that may be appropriate under the Paperwork Reduction Act (Pub. L. 96-511). The SF-83 "Request for Clearance," Supporting Statement, and related documentation submitted to OMB will be placed in the NRC Public Document Room at 1717 H St. NW., Washington, D.C. 20555. The material will be available for inspection and copying for a fee.

Regulatory Analysis (3.17)

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 draft analysis is available for inspection in the NRC Public Document Room, 1717 H St. NW., Washington, D.C. Single copies of the analysis may be obtained from (name, address, and telephone number of staff contact).

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

Regulatory Flexibility Act (3.19)

REGULATORY FLEXIBILITY ACT CERTIFICATION

In accordance with the Regulatory Flexibility Act of 1980, (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 Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

SUBJECT INDEX TERMS (3.21)

LIST OF SUBJECTS IN 10 CFR PART 50

Antitrust, Classified information, Fire prevention, Intergovernmntal relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting requirements.

WORDS OF ISSUANCE (3.23)

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

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

AUTHORITY CITATION (3.27)

AUTHORITY: Secs. 103, 104, 161, 182, 183, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 958, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2239); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246 (42 U.S.C. 5841, 5842, 5846) unless otherwise noted.

Sec. 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Secs. 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended; (42 U.S.C. 2234). Secs. 50.100-50.102 issued under Sec. 186, 68 Stat. 955; (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958 as amended; (42 U.S.C. 2273), §§50.10(a), (b), and c(c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§50.10(b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§50.35(e), 50.59(b), 50.70, 50.71, 50.72, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

AMENDATORY LANGUAGE
(3.25)

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

§50.54 Condition of licenses.

(a)(1) Each licensee shall implement the quality assurance program described or referenced in the Safety Analysis Report and modified by changes to the Safety Analysis Report.

(2) Each licensee shall submit to the appropriate NRC Regional Office within 90 days of the effective date of this regulation the current description of the quality assurance program unless the description previously approved has not been changed.

(3) After the effective date of this rule, the licensee may make changes to a previously submitted quality assurance program description provided the change does not decrease the effectiveness of the program so that the revised program no longer meets the criteria of Appendix B to 10 CFR Part 50. Prior to making any change to a previously submitted QA program description, the licensee shall prepare a written evaluation identifying the change, the reason for the change, and the basis for concluding that the change satisfies the criteria of Appendix B to 10 CFR Part 50. A copy of this evaluation must be maintained at the facility for three years.

REGULATORY TEXT
(3.29 - 3.35)

(4) For changes made to the quality assurance program affecting the program description included in the Safety Analysis Report which (i) change or affect the

authority, independence or management reporting levels previously established for organizations or persons performing quality assurance functions; or (ii) change or affect the controls previously established over activities affecting the quality of the nuclear power plant structures, systems, and components, the evaluation described in paragraph (a)(3) of this section must be submitted within 30 days of making any such change to the appropriate NRC Regional Office shown in Appendix D to Part 20 of this chapter, with one copy sent to the Resident Inspector and one copy sent to the Chief of the Document Management Branch, TIDC, ADM, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

* * * * *

SIGNATURE BLOCK

Dated at Washington, D.C., this ___ day of _____, 1982.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

3.5 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, establish, or affect; and

(3) Indicate the subject matter of the document.

Example:
NUCLEAR REGULATORY COMMISSION
10 CFR Parts 30 and 35
Testing Radioisotope Generators

(b) The "CFR Part" heading must contain the number of each part the document proposes to amend or establish. Even if the document proposes to affect 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 I).

(c) Occasionally, a document appearing in the Proposed Rule section of the Federal Register concerns the identical subject matter of a document published previously. This situation usually occurs when follow-up documents are necessary in a rulemaking proceeding. To emphasize

the relationship between the two documents, the 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

Testing Radioisotope Generators; Extension of Comment Period

3.7 Preambles: Format requirements.

Each proposed rule the NRC prepares for publication in the Federal Register must begin with a preamble. Previously, the preamble was also known as the Statement of Considerations. Although the preamble itself 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 the OFR set out in 1 CFR 18.12. These requirements, which are discussed below, arrange basic information in a uniform format to allow a user to scan 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 simply identifies NRC as the agency that is issuing the document. Do not write the initals "U.S." as part of the agency name. The initials are not required as part of the agency entry. However, the initials "U.S." are used in the official mailing address of the Commission. End this and all other required entries with a period.

Example:
AGENCY: Nuclear Regulatory Commission.

(b) ACTION. This caption is designed to identify 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.
ACTION: Advance notice of proposed rulemaking.
ACTION: Petition for rulemaking.
ACTION: Petition for rulemaking: Denial.
ACTION: Petition for rulemaking: Withdrawal.
ACTION: Policy statement.

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

(1) The Summary paragraph 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 must be contained in three or four brief sentences 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 NRC documents by the OFR, and may result in the OFR returning the 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, or specific details; and

(iv) Describe what the document does rather than how it affects the CFR (e.g., Write "upgrade certification criteria for licensed operators" not "adds new Appendix A to 10 CFR Part 50.")

Example:

SUMMARY: The Nuclear Regulatory Commission is proposing to add to its power reactor safety regulations 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 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 contains 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 dates; and

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

(2) Information concerning public hearing procedures 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, 1981. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received before this date. Public hearings will be held November 17 and 24, 1981.

(e) ADDRESSES. This caption contains addresses that an interested person needs in order to participate in the rulemaking proceeding. Information that may be presented includes the addresses for --

(1) Mailing public comments;

(2) Hand delivering public comments;

(3) Attending a public hearing or meeting;

(4) Examining any material available for public inspection; or

(5) Obtaining a NUREG series report or any other document referred to in the proposed rule.

Example:

ADDRESSES: Submit comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Copies of comments received may be examined at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

The public hearing will be held in the auditorium of the General Services Administration Building, 18th & F Sts. NW., Washington, D.C.

(f) FOR FURTHER INFORMATION CONTACT. This caption contains the name, address and telephone number of a person who can answer questions or provide additional information concerning the document. Two or more persons may be listed as contacts concerning different aspects of a document.

Example: A single contact person.
FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427-1234.

Example: Two contact persons.
FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-9876 or (Name of contact person), Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-0102.

3.9 Preambles: Supplementary Information.

The Supplementary Information section of the preamble serves as the regulatory history of the document. The Supplementary Information section in a proposed rule presents the background information and specific detail necessary to inform interested persons of the issues involved in the rulemaking proceeding.

(a) In Supplementary Information, the NRC shall, at a minimum, explain its reasoning for developing the proposed regulation in sufficient detail to assure interested persons of the opportunity to comment on the proposed rule in a meaningful way. The items listed in this paragraph provide a general overview of the topics that must be considered in order to present an adequate explanation of the proposed rule. In order 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 genesis of the proposed regulation;

(4) The alternatives considered in developing the proposed regulation;

(5) 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;

(6) The issues to be commented on in the proposed regulation;

(7) A history of the rulemaking proceeding to this point; and

(8) A response to public comment from the advance notice of proposed rulemaking.

(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. By providing a table of contents that consists of the headings used in the Supplementary Information portion of the preamble, the drafter can also provide the user with a quick overview of the information presented.

> Example: The purpose of this example is to illustrate 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. Environmental Impact: Negative Declaration.
> IX. Paperwork Reduction Review.
> X. Regulatory Analysis.
> XI. Regulatory Flexibility Act Certification.
> XII. List of Subjects.

BACKGROUND

Under current NRC regulations, no person may possess, use, or transfer technetium-99 or low-enriched uranium (defined in 10 CFR 70.51(a)(2) as that uranium whose isotope content is less than 20 percent uranium-235 by weight) as contaminants in metals except as authorized in a specific license issued by the NRC under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," as appropriate. The effect of the requirements for specific licenses has been to inhibit trade in metal scrap contaminated with small amounts of these two radioactive materials and prevent recycling by the secondary metals industry of smelted alloys containing these two radioactive materials as residual contamination.

RULEMAKING INITIATION

The Department of Energy has underway Cascade Improvement Programs and Cascade Upgrading Programs begun by the AEC at all three U.S. uranium enrichment plants -- Oak Ridge, TN, Portsmouth, OH, and Paducah, KY. In the early 1970s, a market survey showed that no scrap dealers or processors would purchase any of the metal scrap generated by the programs if their customers would be required to hold specific licenses to possess or use recycled contaminated scrap.

* * * * *

(c) The Supplementary Information section should not contain a list of the changes made in the regulation that simply restates amendatory language in the preamble. If a detailed breakdown of the changes made in a large regulation is necessary, the information may be presented

in tabular form. Where appropriate, a detailed description of the substantive changes made in the regulation may be included.

(d) If the NRC published an advance notice of proposed rulemaking, it must discuss the substantive comments received on the ANPRM in the Supplementary Information section of the preamble to the proposed rule. The discussion should indicate any new material or suggested alternatives presented in the comments and indicate any substantive changes made in the proposed rule as a result of public comments. In addition, the discussion should indicate the substantive comments received that were not adopted and NRC's reasons for rejecting those comments.

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

(2) Fairness is essential in responding to public comments. This is true in both characterizing the comment and in explaining why the comment was accepted or rejected.

(3) Each individual comment need not be addressed separately. If several comments raise the same substantive issue, they may be treated generically in the comment analysis. Comments of a minor or clarifying nature should be lumped together for discussion in comment analysis.

(4) 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).

3.11 Procedural requirements for rulemaking.

(a) Sections 3.13 through 3.19 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 regulatory procedures the NRC follows in developing a proposed rule include --

(1) An assessment of the environmental impact of the proposed rule under the National Environmental Policy Act and 10 CFR Part 51 (see 3.13 of this handbook);

(2) Obtaining approval of the Office of Management and Budget (OMB) for each new or changed information collection requirement under the Paperwork Reduction Act (see 3.15 of this handbook);

(3) An analysis of the economic impact, in terms of costs and benefits, of the proposed rule as required by the Commission's Value/Impact guidelines in SECY-77-388A (see 3.17 of this handbook). This analysis will be referred to as the regulatory analysis; and

(4) An analysis of the economic impact of the proposed rule on small entities under the Regulatory Flexibility Act (see 3.19 of this handbook).

(b) It is important that the environmental assessment and economic analyses precede, or are prepared concurrently with, the development of the proposed rule. The 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 intended regulatory action would then be reevaluated in terms of the more extensive analyses and adjusted as necessary.

(c) 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 3.19 of this handbook). The regulatory flexibility analysis may be performed as a part of the regulatory analysis.

(d) After the proposed rule has been developed, the NRC determines whether it imposes or changes any information collection requirement. If the proposed rule adds or changes an information collection requirement affecting 10 or more persons, the NRC submits it to OMB for approval. OMB must approve the information collection requirements before they may become effective. (See NRC Manual Chapter 0230.)

3.13 National Environmental Policy Act (NEPA).

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.,) requires each Federal agency to prepare environmental impact statements 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.

(a) The NRC shall prepare an environmental impact statement on each licensing and regulatory action if the proposed action --

(1) Is a major Federal action significantly affecting the quality of the human environment (See 10 CFR 51.5(a)); or

(2) Involves a matter which the Commission has determined should be covered by an environmental impact statement (See 10 CFR 51.5(a)(12) and (b)).

(b) A statement concerning environmental impact must appear in the Supplementary Information section of the preamble to each proposed regulation that has potential environmental impact.

(1) 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 10 CFR Part 51, the NRC has prepared a draft environmental impact statement on this proposed rule.

The draft environmental impact statement is available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, D.C. Single copies of the draft environmental impact statement may be obtained from (Name, address and telephone number of contact person).

Note: Availability of the draft environmental impact statement must also be indicated under the ADDRESS caption of the preamble.

(2) If the environmental impact of a proposed licensing and regulatory action has been evaluated and it is determined that an environmental impact statement need not be prepared, the NRC shall prepare a negative declaration; that is, a statement that the NRC has determined not to prepare an environmental impact statement for the action, and an environmental impact appraisal setting forth the basis for that determination (10 CFR 51.7). In addition, the NRC shall include the following statement in the Supplementary Information section of the preamble to the proposed rule presenting the negative declaration required by 10 CFR 51.5(c) and 51.7.

ENVIRONMENTAL IMPACT: NEGATIVE DECLARATION

The proposed amendment, if adopted, would not result in any activity that significantly affects the quality of the human environment. The Commission has determined that under the National Environmental Policy Act, and the criteria in

10 CFR Part 51, that an environmental impact statement is not required for this proposed regulation.

The environmental impact appraisal forming the basis for this determination is available for inspection at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

3.15 Paperwork Reduction Act.

(a) General. The Paperwork Reduction Act of 1980 (Pub. L. 96-511, 44 U.S.C. Chapter 15) is intended to reduce the time, effort, and financial resources that the private sector expends in providing information to the Federal government. The Act is also intended to reduce the cost to the Federal government of collecting, using, and disseminating information and to ensure that the information collected by the Federal government is useful. The Act requires each Federal agency to obtain approval from the Office of Management and Budget (OMB) for each information collection activity that affects ten or more persons. 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 and, where appropriate, the expiration date. (See NRC Manual Chapter 0230).

(b) Coverage. The Act applies to any document that imposes a recordkeeping, application, or reporting requirement on ten 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.

PAPERWORK REDUCTION REVIEW

This proposed rule contains no new or amended recordkeeping, reporting, or application requirement or any other type of information collection requirement subject to the Paperwork Reduction Act (Pub. L. 96-511).

(d) Guidance. Questions concerning the procedures and requirements of the Paperwork Reduction Act may be directed to Steve Scott, Chief, Document Management Branch, TIDC (ext. 28585).

(c) Standard statements. One of the following statements must be included in the Supplementary Information section of each proposed rule that contains an information collection requirement. Information collection requirements include any reporting, recordkeeping, or application requirement.

(1) OMB clearance required. If OMB approval is required for an information collection request, the NRC shall insert this statement.

PAPERWORK REDUCTION REVIEW

The proposed rule will be submitted to the Office of Management and Budget for clearance of the information collection requirements that may be appropriate under the Paperwork Reduction Act (Pub. L. 96-511). The SF-83 "Request for Clearance," Supporting Statement, and related documentation submitted to OMB will be placed in the NRC Public Document Room at 1717 H St. NW., Washington, D.C. 20555. The material will be available for inspection and copying.

(2) OMB Clearance Not Required. If OMB clearance is not required for an information collection request, the NRC shall insert the following statement.

PAPERWORK REDUCTION REVIEW

The information collection requirement contained in this proposed rule is required by law or to obtain a benefit and submitted to nine or fewer people. Therefore, OMB clearance under Pub. L. 96-511 is not required.

(3) No information collection requirement. If the proposed rule does not contain an information collection requirement, the NRC shall insert the following statement.

3.17 Regulatory analysis.

(a) The NRC requires the preparation of a regulatory analysis for each substantive regulatory action, including each proposed rule. A regulatory analysis is required for each proposed amendment or addition to NRC regulations in 10 CFR Chapter I that could impose a significant burden on the public.

(1) A regulatory action is an action taken in support of NRC's mission to protect the safety of the public, the national security, and the environment. These actions govern the issuance of licenses to produce, transport, store, dispose of, or utilize nuclear material. Regulatory actions include changes to conditions that a prospective licensee must meet and under which an existing licensee must operate. A substantive regulatory action generally includes any change or addition to NRC's regulations that imposes an obligation or confers a benefit.

(2) A regulatory analysis is generally equivalent to the value/impact analysis. The value/impact guidelines adopted by the Commission in January 1978 (SECY-77-388A) remain in effect.

(3) A regulatory analysis may also satisfy the requirements of the Regulatory Flexibility Act by considering the economic effect of the proposed rule on small entities (see 3.19 of this handbook).

(b) A regulatory analysis allows the NRC to compare the consequences of each identified alternative that satisfies a particular regulatory objective. The regulatory analysis must identify the costs and undesirable side effects as compared to the relative merit or benefit of each alternative solution considered in developing the proposed rule. A regulatory

analysis, as an objective attempt to estimate the relative or absolute differences in the effectiveness of alternative regulatory approaches, provides a formal statement of reasons for selecting the alternative presented in the proposed rule.

(c) The regulatory analysis explicitly documents each judgment and assumption that was made in developing a proposed regulation. This allows the Commission, the public, and the licensees to understand and evaluate the basis for the proposed action. In addition, the preparation of the regulatory analysis aids the staff in identifying each issue and the related problems associated with each contemplated alternative.

(d) The depth and extent of a regulatory analysis depends primarily on the anticipated magnitude of the costs and benefits associated with the regulation. Generally, a more extensive regulatory analysis is required when --

(1) The regulatory action will result in large costs and impacts or significant benefits and safety improvements; or

(2) It is likely that the public or the licensees will contest the characterization of the problem or the selected alternative.

(e) Each regulatory analysis must stand on its own. Although a regulatory analysis may list, and discuss, if appropriate, any related regulatory action, the regulatory analysis is self-contained for each regulation.

(f) Each regulatory analysis contains the following elements:

(1) Objective. A statement of what the regulation is intended to accomplish.

(i) How does it affect licensee practices?

(ii) How does it affect public health and safety?

(2) Background. A description of the problem and the analytical approaches to the problem.

(i) Identify the safety or health hazard.

(ii) Identify the various factors that must be weighed in reaching a decision.

(3) Alternatives. An identification of a set of reasonable approaches for dealing with the problem.

(i) What assumptions must be made to conclude that the alternatives would be effective?

(ii) What major uncertainties could affect conclusions about the desirability of each alternative?

(4) Benefit and cost estimates.

(i) What are the major benefits of each alternative? How would each reduce hazards or increase safety and by how much?

(ii) What are the estimated costs or other adverse impacts of each alternative? Who would incur the cost?

(iii) What are the potential undesirable side effects of each alternative?

(5) Specification of criteria. A description of the standards by which the alternatives are judged and on which the recommendation is based.

(6) Final decision. Describe the alternative selected and the justification for choosing that alternative over the others.

(g) If a regulatory analysis has been prepared for a proposed rule, a statement must be inserted in the Supplementary Information section of the preamble to the proposed rule that references the regulatory analysis and describes how an interested person may obtain a copy.

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 draft analysis is available for inspection in the NRC Public Document Room, 1717 H St. NW., Washington, D.C. Single copies of the analysis may be obtained from (insert name, address, and phone number of staff contact)

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.

3.19 Regulatory Flexibility Act.

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354; 5 U.S.C. 601 et seq.) requires that each Federal agency fit regulatory and informational requirements to the scale of the entity being regulated. The Act requires that agencies consider the economic effect of its regulations on small entities. In the case of the NRC, the Act is particularly applicable to byproduct, source, and special nuclear material licensees.

(a) Requirements. The Act applies to each proposed rule issued after January 1, 1981.

(1) The Act does not apply if --

(i) A rule is first issued in final form without notice of proposed rulemaking; or

(ii) If the notice of proposed rulemaking was published in the Federal Register before January 1, 1981.

(2) If 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. The Act also requires that this analysis, or a summary of the analysis, be published in the Federal Register for public comment. The Act provides that a regulatory flexibility analysis may be combined with other analyses as long as it meets the requirements of the Act. The NRC may prepare the regulatory flexibility analysis as a portion of the regulatory analysis that considers the costs and benefits of the proposed rule (see 3.17 of this handbook).

(3) The NRC need not prepare an initial regulatory flexibility analysis if --

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

(ii) The Commission certifies this to be the case in the proposed rule.

(b) 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 ACT

The NRC has prepared an initial regulatory analysis of the impact of this proposed rule on small entities. The analysis indicates that although the proposed rule will have an economic impact of $500-750 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. A copy of the analysis is available for inspection in the NRC Public Document Room, 1717 H Street, NW., Washington, D.C. Single copies of the analysis may be obtained from (name, address, and telephone number of staff contact).

The NRC requests written comments on the analysis. Send comments to the Secretary of the Commission, U.S. Nuclear

Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Branch.

(ii) The NRC is required to make a good faith effort to prepare a thorough analysis of the impact of a proposed regulation on small entities. However, if after the completion of the analysis the NRC still 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 ACT

The NRC is seeking public comment on the initial regulatory flexibility analysis. The NRC is particularly seeking 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 which offer comments on how the regulations could be modified to take into account the differing needs of small entities should specifically discuss the following items:

(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.

(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, D.C. 20555, Attn: Docketing and Service Branch.

(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 include a succinct statement explaining the reasons for this certification. The statement must contain sufficient information to support the conclusion. The statement must include 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.

REGULATORY FLEXIBILITY CERTIFICATION STATEMENT

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 affects about 2,000 specific licensees under 10 CFR 35.11 or 35.12. These licenses are issued principally to medical institutions. Small business entities, primarily physicians in private practice, comprise about 275 of the special medical licensees. Since 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 which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a larger licensee;

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

(c) Initial Regulatory Flexibility Analysis: Summary. 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. A summary must contain the following information:

(1) Reasons for issuing the proposed rule. Include a short paragraph explaining the statutory, policy, program, or practical reasons for the rule or amendment. Cite the preamble for more details.

(2) Objectives 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) Description and 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.

(4) Description of projected reporting, recordkeeping, and other compliance requirements for each type of small entity together with the type of professional skill required to complete report or record. These requirements should be described generally. Reference the more detailed statement of requirements in the preamble or codified text. Indicate the type of small entity subject to each requirement, i.e., field radiographers, private physicians, manufacturers of certain equipment, etc. Indicate the type of professional skill needed to prepare the report, i.e., radiographer, lab technician, production manager, general administrative expert, etc.

(5) Other Federal rules with which the proposed rule conflicts or overlaps. 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) Significant alternatives to the proposed rule that minimize economic impact on small entities. If any alternative regulatory provisions were considered, describe them generally here. 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 community considering such factors as employment, business failures, and the concentration of firms in the market.

(d) Guidance A guidance document for implementing the Regulatory Flexibility Act and preparing the required regulatory analyses is available from the Division of Rules and Records. Questions concerning the Regulatory Flexibility Act may be directed to J.M. Felton, Director, Division of Rules and Records (ext. 27211) or John Philips, Chief, Rules and Procedures Branch (ext. 27086).

3.21 List of subject index terms.

The OFR, in accordance with 1 CFR 18.20, requires each agency to include a list of subject index terms for each part affected in a proposed rule document. 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.

(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 proposed rule document. The list of subject index terms must appear in each proposed rule document submitted for publication in the Federal Register on or after April 1, 1982. The NRC shall present the list of subject index terms in alphabetical order as follows:

Example:

LIST OF SUBJECTS IN 10 CFR PART 20

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

(b) The NRC shall use the subject index terms developed by the Rules and Procedures Branch (RPB) and approved by the OFR to complete the list of subject terms entry. 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 desires to use additional terms, it shall consult with the RPB (ext. 27086).

3.23 Words of issuance.

The words of issuance ("pursuant to" clause) are the words by which the regulatory text is legally prescribed and tied to the CFR. Words of issuance describe the general effect of the document and may also present the general rulemaking authority of the agency. However, the words of issuance do not satisfy the requirement that each proposed rule document contain a citation of the authority under which it is issued. (See 3.27 of this handbook.) The words of issuance directly precede the heading of the first CFR part the document proposed to amend or add.

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.

3.25 Amendatory language.

(a) A proposed rule document suggests changes or additions to the CFR. The regulatory text of each proposed rule document published by the NRC must fit into the existing text of 10 CFR Chapter I. Amendatory language gives the instructions on how to change the CFR by identifying each specific change to CFR text.

(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; and

(2) Describe how the CFR unit is being changed.

(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 notice of correction.

(1) Added.

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

Example:

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.

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. The Rules and Procedures Branch (RPB) 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 corrected. The error must be corrected before the next annual revision date of 10 CFR Chapter I by the OFR.

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, 1982 (47 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, 1982 (47 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 a CFR unit is transferred to another position and renumbered.

Example:

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.

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

Example:

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

(6) 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 instruction 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:

(7) Nomenclature change. Nomenclature change means that a term or phrase is changed throughout a CFR unit. It is most commonly used to change an official designation or the title of an agency office. The OFR usually requires 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. The RPB shall determine, in consultation with the OFR, when marked pages must accompany a nomenclature change.

Example:

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

(8) 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. The suspended provision continues to appear in the CFR, however, the OFR will insert an editorial note explaining the status of the provision. The NRC is responsible for issuing the follow-up document necessary to remove the suspended provision or to lift the suspension.

Example

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, 1981, to October 1, 1981.

(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.

Examples:

1. In §73.3, paragraphs (d) and (f) are revised and paragraphs (h) and (i) are redesignated as paragraphs (j) and (k) and new paragraphs (h) and (i) are added to read as follows:
2. 10 CFR 50.20 is amended by removing paragraph (f)(2) and by revising paragraphs (a)(5)(iii) 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 3.27(c) and (d) of this handbook concerning the placement of 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 amendment 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: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233) sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958 as amended (42 U.S.C. 2273); §33.17(a) issued under sec. 161b, 68 Stat. 948 (42 U.S.C. 2201(b)).

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 3.33 of this handbook.)

4. Section 33.16 is revised to read as follows:

§33.16 Application for other specific licenses.

An application filed under Part 30 of this chapter for a specific license other than one of broad scope will be considered by the Commission as an application for a specific license of broad scope under this part if the requirements of the applicable sections of this part are satisfied.

3.27 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. Generally, a 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: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§35.2, 35.14(b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31 (b) and (c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and

§§35.14(b)(5)(ii), (iii) and (v) and (f)(2), 35.25 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

(b) Content. The Rules and Procedures Branch (RPB) maintains a list of current, complete authority citations for each part in 10 CFR Chapter I. The drafter may contact RPB on ext. 27086 to obtain the current authority citation for insertion into his or her document.

(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: INSPECTIONS

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: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2093, 2111, 2133,

2134, 2201, 2236, 2282); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§19.11(a), (c), (d), and (e) and 19.12 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§19.13 and 19.14(a) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

(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 1 - STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

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

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); secs. 201, 203, 204, 205, 209, 88 Stat. 1242, 1244, 1245, 1246, 1248, as amended (42 U.S.C. 5841, 5843, 5844, 5845, 5849). 5 U.S.C. 552, 553.

1. Section 1.34 is revised to read as follows:

§1.34 Office of Public Affairs

The Office of Public Affairs (a) develops policies and administers programs at NRC headquarters and Regional Offices to inform the public and the news media about NRC policies, programs, and activities; and (b) keeps NRC management informed on media coverage of activities of interest to the agency.

(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:

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

AUTHORITY: Secs. 53, 63, 81, 161, 182, 183, 60 Stat. 930, 933, 935, 948, 953, as amended; (42 U.S.C. 2073, 2093, 2111, 2201, 2232, 2233); sec. 202, 206, 88 Stat. 1244, 1246; 42 U.S.C. 5842, 5846.

For the purposes of sec. 223, 68 Stat. 958, as amended; (42 U.S.C. 2273); §§71.61-71.63 issued under sec. 161o, 68 Stat. 950, as amended; (42 U.S.C. 2201(o)).

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 on 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: Secs. 62, 63, 64, 65, 161, 182, 183, 68 Stat. 932, 933, 948, 953, 954, as amended. (42 U.S.C. 2092, 2093, 2094, 2095, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846).

Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §40.41(c) issued under sec. 161b., 68 Stat. 948 (42 U.S.C. 2201(b)); and §§40.23(e)(3), 40.61 and 40.62 issued under sec. 161o., 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

(e) Short-form authority citation. (1) If a brief document amends portions of a CFR part and only a portion of the complete part authority is relied on to issue the amendment, the NRC may present a short-form authority citation for the document. The short-form citation is intended to meet the Administrative Procedure Act requirement that a document contain an authority citation but prevent the imbalance that occurs when a lengthy citation is given for a brief amendment. The RPB generally determines when a short-form authority citation is appropriate for a document. The short-form citation is most commonly used in --

(i) Documents that make minor, nonsubstantive amendments;

(ii) Documents that make conforming or clarifying amendments;

(iii) Correction documents.

Example: Short-form authority citation.

The authority citation for this document is: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201).

(2) If the short-form authority citation is used, it is placed directly after the "List of Subjects" entry in the documents.

3.29 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 I Regulatory text must --

(1) Be drafted exactly as it is to appear in the CFR.

(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.<br>(i), (ii), (iii), etc.<br>(A), (B), (C), etc. |
| Note: Underlined symbols are printed in italics. | (<u>1</u>), (<u>2</u>), (<u>3</u>), etc.<br>(<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) | (1) | (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 is also 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:
§35.12 Specific licenses to individual physicians for human use of byproduct material.

(a) An application of an individual physician or groups of physicians for a specific license for human use of byproduct material will be approved if --

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;

(3) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(4) The applicant has extensive experience in the proposed use, the handling, and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician(s) shall furnish suitable evidence of experience with the application. A statement from the medical isotope committee in the institution where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of experience.)

(b) The Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use byproduct material on the premises of a medical institution unless --

(1) The use of byproduct material is limited to --

(i) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(ii) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(iii) The performance of in vitro diagnostic studies; or

(iv) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(2) The physician brings the byproduct material with him and removes the byproduct material when he departs. (The institution cannot receive, possess, or store byproduct material other than the amount of material remaining in the patient); and

(3) The medical institution does not hold a byproduct material license under §35.11.

(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 an organizational problem caused by an overly complex

structure. This results in a structural imbalance created by inserting too much material within the section. In addition, a user will have more difficulty locating important material buried within a section. Access to information within a regulation is 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 13.7 of this handbook; Arranging material for ease of use.)

(iv) 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, produce, 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 or to produce new special nuclear material.

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

These numbers are not permitted because they are not compatible with the electronic printing system used to merge Federal Register amendments into CFR text.

(i) The NRC may not use a hyphenated number or alpha character in designating a unit within any CFR part that does not contain a unit designated in this fashion.

(ii) 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, it is recommended that any new material be designated in standard fashion as the OFR will ultimately require that each part containing designations using hyphenated numbers or alpha characters be recodified to remove them.

(iii) Any future deviation from standard CFR designation must be approved, in advance, by the OFR.

(iv) Any questions on the assignment of new section or part numbers should be directed to the Rules and Procedures Branch (RPB) ext. 27086. In addition, the assignment of any new part or section numbers must be made after consultation with RPB to prevent confusion resulting from duplicative or overlapping part or section numbers.

(c) Plan for the future. The NRC may 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 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 this fashion [1], [2], [3], or in superscript ($^{1}$, $^{2}$, $^{3}$ etc.). 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 footnote contained in the amended part. It may not be necessary to redesignate existing footnotes to reflect added or removed footnotes. Contact RPB for assistance in designating footnotes in amended text.

(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 also be set out in presenting the amendment.

3.31 Regulatory text: Headings.

(a) General. Each CFR unit larger than a paragraph is given a brief heading that describes the content of that unit. The NRC shall ensure that each heading in its regulations is brief, accurate, and useful to an individual seeking specific information. Headings are the primary indication of the content of a regulation. 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 impact 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 a signpost for a user 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 the user with 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 to a user 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 help the user find 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, state with particularity 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...

* * * * *

3.33 Form of amendment: Section level.

(a) Each amendment made at the section level requires three elements. These elements must appear in the order listed below:

(1) Proper amendatory language.

(2) The section heading of the section being changed.

(3) The regulatory text of the section being changed.

In addition to these elements, the part heading and 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

The authority citation for Part 35 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§35.2,

35.14(b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31(b) and (c) are issued under sec. 161b. 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§35.14(b)(5)(ii), (iii) and (v) and (f)(2), 35.25 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

Amendatory language

1. 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 3.29(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

The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended; 42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201. Sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended; (42 U.S.C. 2273); §§20.101, 20.102, 20.103(a), (b), and (f), 20.104a) and (b), 20.105(b), 20.106(a), 20.201, 20.202(a), 20.205, 20.207, 20.301, 20.303, 20.304 and 20.305 are issued under sec. 161b, 68 Stat. 948, as amended, (42 U.S.C. 2201(b)); and §§20.102, 20.103(e), 20.401-20.407, 20.408(b) and 20.409 are issued under sec. 161o, 68 Stat. 950, as amended, (42 U.S.C. 2201(o)).

Amendatory language

1. In §20.104, paragraph (b) is revised to read as follows:

Section heading

§20.104 Exposure of minors.

Indicates that paragraph (a)is unchanged

* * * * *

Revised text

(b) A licensee may not possess, use, or transfer licensed material in a manner that would expose any individual within a restricted area, who is under 18 years of age, to airborne radioactive material possessed by the licensee in an average concentration in excess of the limits specified in Appendix B, Table II, of this part. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

Indicates that the rest of the section is unchanged

* * * * *

Amendatory language

2. In §20.106, paragraph (c)(4)(ii) is revised to read as follows:

Section heading

§20.106 Radicactvity in effluents to unrestricted areas.

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

* * * * *

Indicates that paragraphs (c)(1) through (c)(3) and (c)(4)(i) are unchanged

(c) * * *
(4) * * *

Revised text of paragraph (c)(4)(ii)

(ii) In water at points of use downstream from the point of release of the effluent.

Indicates that the rest of the section, paragraphs (c)(4)(iii), (c)(5), (d), and (e) are unchanged

* * * * *

Amendatory language

3. Section 20.402 is amended by revising paragraphs (a) and (b)(3) and adding (b)(6) to read as follows:

Section heading

§20.402 Reports of theft or loss of licensed material.

Revised text of paragraph (a)

(a) Each licensee shall report by telephone to the Director of the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D, immediately after its occurrence becomes known to the licensee, any loss or theft of licensed material in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas.

Indicates that paragraphs (b)(1) and (b)(2) are unchanged. The paragraph designation and three asterisks are necessary to place this amendment within paragraph (b)

(b) * * *

Revised text of paragraph (b)(3)

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

Indicates that paragraphs (b)(4) and (b)(5) are unchanged

* * * * *

Added text of paragraph (b)(6)

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

Indicates that the rest of the section is unchanged

* * * * *

Part heading

PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

Amendatory language and text of revised authority citation

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

AUTHORITY: Sec. 161, 68 Stat. 948; sec. 234, Pub. L. 91-161, 83 Stat. 444; sec. 206, 88 Stat. 1246 (42 U.S.C. 2201, 2282, 5846).

Amendatory language

5. 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

3.35 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 order listed.

(1) Proper amendatory language.

(2) The part heading.

(3) A table of contents for the part.

(4) The authority citation.

(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 Control of weapons and dangerous material.
160.5 Violations.
160.6 Posting.
160.7 Effect on other laws.

Authority citation

AUTHORITY: Sec. 161, 68 Stat. 948, (42 U.S.C. 2201); sec. 229, 70 Stat. 1070 (42 U.S.C. 2278a); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §160.5 is issued under sec. 161i, 68 Stat. 948, as amended (42 U.S.C. 2201(i)).

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.

3.37 Proper cross referencing techniques.

(a) A cross reference is a reference from one unit of the CFR to another unit. A cross reference may only be used to reference an existing unit of CFR text. Cross referencing is not to be confused with incorporation by reference, a legal device that may be used to give material the force and effect of law without printing the material in the Federal Register (See 3.39 of this handbook, Incorporation by reference).

(b) Cross references are used to avoid repeating long passages of text. Properly used, cross references may contribute to greater clarity in a regulation.

(c) Cross references must be used sparingly. Too many cross references indicate a structural complexity that increases the burden on a user. Excessive cross referencing is a symptom of organizational problems in a regulation. Do not --

(1) Use cross references to link provisions of a regulation into a complex network that is difficult to comprehend without knowing the entire system; and

(2) Add material to existing CFR units and use a cross reference as a superficial device to establish its relationship to the surrounding material.

(d) If a cross reference is necessary, include the title or a brief description of the referenced provision.

Example:

See 10 CFR 73.50, Requirements for Physical Protection of Licensed Activities.

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

(f) 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 | |
|---|---|
| When referencing | Write |
| 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 | |
|---|---|
| When referencing | Write |
| 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 | |
|---|---|
| When referencing | Write |
| A Section | §20.15 |
| A Paragraph | §20.15(a) |

| References within the same SECTION | |
|---|---|
| When referencing | Write |
| A Paragraph | Paragraph (b) of this section |
| A subdivision within a paragraph | Paragraph (b)(1)(i) of this section |

3.39 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.

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

(i) Material is eligible for incorporation by reference if 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.

(ii) Material is eligible for incorporation by reference if 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 ten Federal Register pages or contain highly specialized, technical matter that may pose difficulties in composition or printing.

(iii) Material is eligible for incorporation by reference if it is readily available to 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 it is easily available to the public for purchase and inspection. That is --

(A) It may be inspected at the Office of the Federal Register, the agency's central and regional offices, or in depository libraries; and

(B) It may be purchased 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;

(iii) Contain a brief subject description;

(iv) Contain a statement of availability; and

(v) Include an approval statement that indicates the date 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 on January 1, 1982. 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 10007. It is also available for inspection at the Nuclear Regulatory Commission's Public Document Room, 1717 H Street, NW., Washington, D.C.

(1) As used in this section, references to Section III 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 the Rules and Procedures Branch (RPB). RPB will coordinate each request for incorporation by reference with the OFR.

(d) Each incorporation by reference must be reapproved by the OFR on an annual basis. The OFR ties its reapproval to the revision date of 10 CFR Chapter I (January 1 of each year). Each change in the content or status of material incorporated by reference must be indicated to RPB. RPB will also coordinate the annual reapproval of materials incorporated by reference with the OFR.

PART 5 - FINAL RULES

5.1 Final rule documents: Description.

(a) Each document prepared by the Nuclear Regulatory Commission (NRC) that is published in the Rules and Regulations section of the Federal Register must meet the format requirements of this part. The Office of the Federal Register (OFR) classifies documents for publication in one of four sections of the Federal Register. These sections are: Presidential Documents, Rules and Regulations, Proposed Rules, and Notices. Documents published in the Rules and Regulations section are usually those documents that have general applicability and legal effect as defined in 1 CFR 1.1. Documents published in the Rules and Regulations section 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.

(2) 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.

(3) 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 or suspend the effective date of a previously published final rule;

(iv) Withdraw an interim or 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.

(4) Policy statements. The Administrative Procedure Act (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. The Administrative Conference of the United States also recommends the preservation of policy statements and interpretations in the CFR when they are of continuing interest to the public (1 CFR 305.76-2). When the staff

develops a policy statement, it should contact the Division of Rules and Records (DRR). DRR will contact the Office of the Executive Legal Director and the Office of the General Counsel to determine whether the policy statement is to be included in 10 CFR Part 8.

(b) NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Final Rule 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 9.3 of this handbook for information on preparing a correction document.

## 5.3 Final rule documents: Anatomy.

This section presents a dissection of a typical final rule document. Each essential element of a final rule is identified. This section is designed to help a writer identify the required elements of a final rule document and create a complete and correct document. The section of 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 15.3 of this handbook) reflects the format used in typing a document for publication in the Federal Register.

SAMPLE: FINAL RULE

| | | |
|---|---|---|
| HEADINGS (5.5) | Agency Heading | NUCLEAR REGULATORY COMMISSION |
| | CFR Part Heading | 10 CFR Part 50 |
| | Subject Heading | Reporting of Changes to the Quality Assurance Program |
| PREAMBLE | Captioned Headings (5.7) | AGENCY: Nuclear Regulatory Commission. |
| | | ACTION: Final rule. |
| | | SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require holders of nuclear power plant construction permits and holders of operating licenses to implement the approved quality assurance program and to inform the Commission in writing of certain quality assurance program changes that affect the description of the quality assurance program included in their Safety Analysis Report and accepted by the Commission within 30 days of making any change. The amendments will provide greater assurance that quality assurance |

programs approved by the Commission do not have their effectiveness reduced by subsequent changes.

EFFECTIVE DATE: January 8, 1982.

FOR FURTHER INFORMATION CONTACT: (Name of contact person) Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington D.C. 20555, telephone 301-443-0011.

Statement of Considerations (5.9)

SUPPLEMENTARY INFORMATION: The quality assurance (QA) requirements of 10 CFR Part 50 "Domestic Licensing of Production and Utilization Facilities," are one of the cornerstones of the Commission's "defense-in-depth" concept for ensuring safe operation of nuclear power plants.

* * * * *

The amendments require that construction permit holders and licensees implement the approved quality assurance program, provide a current description of the program, evaluate all changes to the approved program and, for certain changes that meet the criteria in the rule submit the evaluation to the NRC for review.

PROCEDURAL REGULATORY REQUIREMENTS

National Environmental Policy Act (5.13)

ENVIRONMENTAL IMPACT: NEGATIVE DECLARATION

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51 that promulgation of this regulation is not a major Federal action significantly affecting the the human environment and therefore an environmental impact statement is not required. The environmental impact appraisal and negative declaration on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

Paperwork Reduction Act (5.15)

PAPERWORK REDUCTION REVIEW

This rule contains information collection requirements that were reviewed by the Office of Management and Budget.

OMB approval was granted on Oct. 30, 1981, OMB approval no. 3150-0011.

Regulatory Analysis (5.17)

## 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. Interested persons may examine a copy of the regulatory analysis at the NRC Public Document Room, 1717 H St. NW., Washington, D.C. Single copies of the analysis may be obtained from (insert name, address, and phone number of staff contact).

Regulatory Flexibility Act (5.19)

## REGULATORY FLEXIBILITY ACT CERTIFICATION

As required by the Regulatory Flexibility Act of 1980, 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 Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

SUBJECT INDEX TERMS (5.21)

## LIST OF SUBJECTS IN 10 CFR PART 50

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

WORDS OF ISSUANCE (5.23)

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 adopting the following amendments to 10 CFR Part 50.

PART HEADING

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION OF FACILITIES

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

AUTHORITY CITATION (5.27)

AUTHORITY: Secs. 103, 104, 181, 182, 183, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2239); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1248 (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Sec. 50.78 also issued under sec. 122, Stat. 939 (42 U.S.C. 2152). Secs. 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Secs. 50.100-50.102 issued under sec. 188, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§50.10(a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§50.10(b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§50.55(e), 50.59(b), 50.70, 50.71, 50.72, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

AMENDATORY LANGUAGE (5.25)

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

REGULATORY TEXT (5.29-5.35)

§50.54 Conditions of licenses.

(a)(1) Each licensee shall implement the quality assurance program described or referenced in the Safety Analysis Report and modified by changes to the Safety Analysis Report.

(2) Each licensee shall submit to the appropriate NRC Regional Office within 90 days of the effective date of the regulation the current description of the quality assurance program unless the description previously approved has not been changed.

(3) After the effective date of this rule, the licensee may make changes to a previously submitted quality assurance

program description. The change may not decrease the effectiveness of the program so that the revised program no longer meets the criteria of Appendix B to 10 CFR Part 50. Prior to making any change to a previously submitted QA program description, the licensee shall prepare a written evaluation identifying the change, the reason for the change, and the basis for concluding that the change satisfies the criteria of Appendix B to 10 CFR Part 50. A copy of this evaluation must be maintained at the facility for three years.

(4) For changes made to the quality assurance program affecting the program description included in the Safety Analysis Report which (i) change or affect the authority, independence, or management reporting levels previously established for organizations or persons performing quality assurance functions; or (ii) change or affect the controls previously established over activities affecting the quality of the nuclear power plant structures, systems, and components, the evaluation described in paragraph (a)(3) of this section must be submitted within 30 days of making any such change to the appropriate NRC Regional Office shown in Appendix D to Part 20 of this chapter, with one copy sent to the Resident Inspector and one copy sent to the Chief of the Document Management Branch, TIDC, ADM, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

* * * * *

SIGNATURE BLOCK

Dated at Washington, D.C., this ___ day of _____, 1982.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

5.5 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; and

(3) Indicate the subject matter of the document.

Example:
NUCLEAR REGULATORY COMMISSION
10 CFR Parts 30 and 35
Testing Radioisotope Generators

(b) The "CFR Part" 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 I).

(c) Occasionally, a document appearing 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 follow-up 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

Testing Radioisotope Generators; Confirmation of Effective Date

5.7 Preambles: Format requirements.

Each document the NRC prepares for publication in the Rules and Regulations section of the Federal Register must begin with a preamble. Previously the preamble was also known as the Statement of Considerations. Although the preamble contains no regulatory text, it presents the information necessary to understand the basis and purpose of the regulation. Each preamble must comply with the format requirements of the OFR set out in 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 document for essential information. The OFR will not print a document in the Rules and Regulations section of the Federal Register that does not meet the format requirements described in this section.

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

Example:
AGENCY: Nuclear Regulatory Commission.

(b) ACTION. This caption is designed to identify 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 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: Interim rule.
ACTION: Interim rule with request for comment.

(c) SUMMARY. The Summary is a brief description, written in language that a non-expert will understand, that allows the reader to determine the subject and intended effect of the regulation being adopted. Generally, the Summary paragraph is a single paragraph of three or four sentences. The Summary paragraph is not intended to be a detailed abstract or a complete summation of the document.

(1) The Summary paragraph 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 must be contained in three or four brief sentences 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 NRC documents by the OFR, and

may result in the OFR returning the 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, or specific details; and

(iv) Describe what the document does rather than how it affects the CFR (e.g., Write "upgrade 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, 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 contains 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, 1981.

(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, 1981 for §§2.744(e), 2.790(d)(1), 73.2(jj) and (ll), and 73.21(a), (b), and (c)(1). All remaining sections will be effective on January 20, 1982.
EFFECTIVE DATE: The amendments to §§30.7, 30.21, and 30.30 are effective December 21, 1981. The amendments to §§30.40(a) and (b), 30.41(a)(3), and 30.70 are effective January 20, 1982. The amendments to Part 40 are effective February 17, 1982.

(e) ADDRESSES. This caption contains 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 a NUREG series report or any other document referred to in the final rule.

Example:

ADDRESSES: Copies of the public record may be inspected at: NRC Public Document Room, 1717 H Street, NW., Washington, D.C. A hearing concerning licensee requirements under this regulation will be held at: The Auditorium, General Services Administration, 18th and F Streets NW., Washington, D.C.

(f) FOR FURTHER INFORMATION CONTACT. This caption contains the name and telephone number of a person who can answer questions or provide additional information concerning the document. Two or more persons may be listed as contacts concerning different aspects of a document.

Example: A single contact person.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427-1234

Example: Two contact persons.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 telephone (301) 492-9876 or (Name of contact person), Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-0102.

5.9 Preambles: Supplementary Information.

The Supplementary Information section of the preamble serves as the regulatory history of the document. The Supplementary Information section in a final rule contains the background information and specific detail necessary to explain the basis and purpose of the regulation.

(a) 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 in order to present an adequate explanation of the regulation. In order 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 rulemaking history of the proceeding;

(4) The alternatives considered in developing the regulation;

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

(6) The public comments received; and

(7) How, if at all, the regulation was modified in response to public comment or any other factors.

(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. By providing a table of contents that consists of the headings used in the Supplementary Information portion of the preamble, the drafter can also provide the user with a quick overview of the information presented.

Example: The purpose of this example is to illustrate 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. Environmental Statement: Negative Declaration.
IX. Paperwork Reduction Review.
X. Regulatory Analysis.
XI. Regulatory Flexibility Act Certification.
XII. List of Subjects.

BACKGROUND

Under current NRC regulations, no person may possess, use or transfer technetium-99 or low-enriched uranium (defined in 10 CFR 70.51(a)(2) as that uranium whose isotope content is less than 20 percent uranium-235 by weight) as contaminants in metals except as authorized in a specific license issued by the NRC under 10 CFR Part 30, "Rules of General Applicability

to Domestic Licensing of Byproduct Material," or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," as appropriate. The effect of the requirements for specific licenses has been to inhibit trade in metal scrap contaminated with small amounts of these two radioactive materials and prevent recycling by the secondary metals industry of smelted alloys containing these two radioactive materials as residual contamination.

RULEMAKING INITIATION

The Department of Energy has underway Cascade Improvement Programs and Cascade Upgrading Programs begun by the AEC at all three U.S. uranium enrichment plants--Oak Ridge, TN, Portsmouth, OH, and Paducah, KY. In the early 1970s, a market survey showed that no scrap dealers or processors would purchase any of the metal scrap generated by the programs if their customers would be required to hold specific licenses to possess or use recycle contaminated scrap.

* * * * *

(c) The Supplementary Information section should not contain a list of the changes made in the regulation that simply restate amendatory language in the preamble. If a detailed breakdown of the changes made in a large regulation is necessary, the information may be presented in tabular form. Where appropriate, a detailed description of the substantive changes made in the regulation may be included.

(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.

(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 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 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 generically. Comments of a minor or clarifying nature should be lumped together.

(iv) 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 twenty-six (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 at 1717 H Street NW., Washington, D.C.

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 effectively fulfill its mandate, 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 Department of Labor, take enforcement action against the employer because the employer is engaged in illegal discrimination.

Based on 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 which adversely affect an employee are not prohibited by the new regulation.

Based on 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, e.g., 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. Conforming amendments will be made to Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste" when and if that proposed rule (46 FR 38081, July 24, 1981) becomes final.

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, it was recommended that either civil penalties be imposed on the individual that 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. Based on a review of the accusations to DOL it appears that, at an early stage, DOL

accomplishes termination of the proceedings when it appears to be an unwarranted accusation.

(e) If the NRC has not published a notice of proposed rulemaking, the NRC shall indicate the exemption under the Administrative Procedure Act (5 U.S.C. 553) under which it waives notice and comment procedures.

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

(i) An interpretive rule that is not, of itself, substantive or binding;

(ii) A general statement of policy that does not establish a binding norm imposing substantive rights or obligations;

(iii) A rule of agency organization, procedure, or practice; or

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

(2) If the NRC determines that a proposed rule is not required, the NRC shall insert a statement indicating that decision and the reasons for it in the Supplementary Information section of the preamble to the final rule.

Example:

Because this is a nonsubstantive amendment dealing with a minor procedural matter, good cause exists for finding that the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) are unnecessary and for making the amendment effective on publication in the Federal Register.

5.11 Procedural requirements for rulemaking.

(a) Sections 5.13 through 5.19 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 consider 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) An assessment of the environmental impact of the final rule under the National Environmental Policy Act and 10 CFR Part 51 (see 5.13 of this handbook);

(2) Obtaining the approval of the Office of Management and Budget (OMB) for each new or changed information collection requirement under the Paperwork Reduction Act (see 5.15 of this handbook);

(3) An analysis of the economic impact, in terms of costs and benefits, of the final rule as required by the Commission's Value/Impact Guidelines in SECY-77-388A (see 5.17 of this handbook). This analysis will be referred to as the regulatory analysis; and

(4) An analysis of the economic impact of the final rule on small entities under the Regulatory Flexibility Act (see 5.19 of this handbook).

(b) It is important that the environmental assessment and economic analyses precede, or are prepared concurrently with, the development of the proposed rule. The 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 published in final form.

(c) The content of the analyses required under the Commission's regulatory analysis guidelines and the Regulatory Flexibility Act are 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 5.19 of this handbook). The regulatory flexibility analysis may be performed as a part of the regulatory analysis.

(d) After the final rule has been developed, the NRC determines whether it imposes or changes any information collection requirement. If the final rule adds or changes an information collection requirement affecting 10 or more persons, the NRC submits it to OMB for approval. OMB must approve the information collection requirements before they may become effective. (See NRC Manual Chapter 0230).

5.13 National Environmental Policy Act (NEPA).

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 into the decisionmaking process for NRC's domestic licensing and related regulatory actions.

(a) The NRC shall prepare an environmental impact statement on each licensing and regulatory action that --

(1) Is a major Federal action significantly affecting the quality of the human environment (see 10 CFR 51.5(a)); or

(2) Involves a matter which the Commission has determined should be covered by an environmental impact statement. (See 10 CFR 51.5(a)(12) and (b)).

(b) A statement concerning environmental impact must appear in the Supplementary Information section of the preamble to each final rule that has potential environmental impact.

(1) 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 10 CFR

Part 51, the NRC has prepared a final environmental impact statement for this regulation.

The final environmental impact statement is available for inspection in the NRC Public Document Room, 1717 H St. NW., Washington, D.C. Single copies of the final environmental impact statement are available from (Name, address, and telephone number of contact person).

Note: Availability of the environmental impact statement must also be indicated under the ADDRESS caption of the preamble.

(2) If the environmental impact of a licensing and regulatory action has been evaluated and it is determined that an environmental impact statement need not be prepared, the NRC shall prepare a negative declaration; that is, a statement that NRC has determined not to prepare an environmental impact statement for the action, and an environmental impact appraisal setting forth the basis for that determination (10 CFR 51.7). In addition, the NRC shall include the following statement in the Supplementary Information section of the preamble to the final rule presenting the negative declaration required by 10 CFR 51.5(c) and 51.7.

ENVIRONMENTAL IMPACT: NEGATIVE DECLARATION

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The environmental impact appraisal and negative declaration on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

5.15 Paperwork Reduction Act.

(a) General. The Paperwork Reduction Act of 1980 (Pub. L. 96-511; 41 U.S.C. Chapter 15) is intended to reduce the time, effort, and financial resources that the private sector expends in providing information to the Federal government. The Act is also intended to reduce the cost to the Federal government of collecting, using, and disseminating information and to ensure that the information collected by the Federal government is useful. The Act requires each Federal agency to obtain approval from the Office of Management and Budget (OMB) for each information collection activity that affects ten or more persons. The NRC complies with this 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 and, where appropriate, the expiration date. (See NRC Manual Chapter 0230).

(b) Coverage. The Act applies to any document that imposes a recordkeeping, application, or reporting requirement on ten 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 request appearing in an added or amended regulation must be approved by OMB before it becomes effective. In addition, each existing information collection request, including recordkeeping, application, and reporting requirements, that appears in 10 CFR Chapter I must be reapproved by OMB when the current GAO or OMB clearances expire. An information collection request appearing in NRC regulations is invalid and non-enforceable unless --

(1) It is approved by OMB; or

(2) The Commission overrides an OMB denial.

(d) Standard statements. One of the following statements concerning compliance with the Paperwork Reduction Act must appear in the Supplementary Information section of the preamble to each final rule that contains an information collection requirement. Information collection requirements include any reporting, recordkeeping, or application requirement.

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

PAPERWORK REDUCTION REVIEW

This rule contains information collection requirements that were reviewed by the Office of Management and Budget. (Insert one of the three optional statements: (1) OMB approval was granted on (date); (2) OMB denial was rejected by the Commission in SECY-XX-XXX; or (3) Public comments resulted in the revision of the information collection requirements. After Commission

affirmation, formal request for OMB review and clearance will be reinitiated. OMB review of the revised information collection requirements may take 60 to 90 days from Federal Register publication. Information collection requirements will not be effective until the end of the review period. If OMB denies approval, the Commission will be notified).

(i) If OMB has approved the information collection request, the NRC shall add the following to the paperwork reduction review statement.

> The information collection requirements contained in this regulation have been approved by OMB. OMB approval no. _____.

(ii) If OMB review and approval of an information collection request affects the effective date of the regulation, the NRC shall add the following to the paperwork reduction review statement.

> The Nuclear Regulatory Commission has submitted this rule to the Office of Management and Budget for any review appropriate under the Paperwork Reduction Act (Pub. L. 96-511). The date the information collection requirements in this rule becomes effective reflects the inclusion of the 60-day period the Act allows for this review.

(2) OMB clearance not required. If OMB clearance is not required for an information collection request, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

> PAPERWORK REDUCTION REVIEW
>
> The information collection requirement contained in this rule is required by law or to obtain a benefit and submitted to

nine or fewer people. Therefore, OMB clearance under Pub. L. 96-511 is not required.

(e) Guidance. Questions concerning the procedures and requirements of the Paperwork Reduction Act may be directed to Steve Scott, Chief, Document Management Branch, TIDC (ext. 28585).

5.17 Regulatory analysis.

(a) The NRC requires the preparation of a regulatory analysis for each substantive regulatory action, including each final or interim rule. A regulatory analysis is required for each amendment or addition to NRC regulations in 10 CFR Chapter I that could impose a significant burden on the public.

(1) A regulatory action is an action taken in support of NRC's mission to protect the safety of the public, the national security, and the environment. These actions govern the issuance of licenses to produce, transport, store, dispose of, or utilize nuclear material. Regulatory actions include changes to conditions that a prospective licensee must meet and under which an existing licensee must operate. A substantive regulatory action generally includes any change or addition to NRC's regulations that imposes an obligation or confers a benefit.

(2) A regulatory analysis is generally equivalent to the value/impact analysis. The value/impact guidelines adopted by the Commission in January 1978 (SECY-77-385A) remain in effect.

(3) A regulatory analysis may also satisfy the requirements of the Regulatory Flexibility Act by considering the economic effect of the rule on small entities (see 5.19 of this handbook).

(b) A regulatory analysis allows the NRC to compare the consequences of each identified alternative that satisfies a particular regulatory objective. The regulatory analysis must identify the costs and undesirable side effects as compared to the relative merit or benefit of each alternative regulatory solution. A regulatory analysis, as an objective

attempt to estimate the relative or absolute differences in the effectiveness of alternative regulatory approaches, provides a formal statement of reasons for selecting the alternative chosen for the adopted regulation.

(c) The regulatory analysis explicitly documents each judgment and assumption that was made in developing the adopted regulation. This allows the Commission, the public, and the licensees to understand and evaluate the alternative used in the adopted regulation. In addition, the preparation of the regulatory analysis assumes that each issue and the related problems associated with the issues are identified for each contemplated alternative.

(d) The depth and extent of a regulatory analysis depends primarily on the anticipated magnitude of the costs and benefits associated with the regulation. Generally, a more extensive regulatory analysis is required when --

(1) The regulatory action will result in large costs and impacts or significant benefits and safety improvements;

(2) It is likely that the public or the licensees will contest the characterization of the problem or the selected alternative; and

(3) More information is available at the final rule stage.

(e) Each regulatory analysis must stand on its own. Although a regulatory analysis may list, and discuss, if appropriate, any related regulatory action, the regulatory analysis is self-contained for each regulatory action.

(f) Each regulatory analysis contains the following elements:

(1) Objective. A statement of what the regulation is intended to accomplish.

(i) How does it affect licensee practices?

(ii) How does it affect public health and safety?

(2) Background. A description of the problem and the analytical approaches to the problem.

(i) Identify the safety or health hazard.

(ii) Identify the various factors that must be weighed in reaching a decision.

(3) Alternatives. An identification of a set of reasonable approaches for dealing with the problem.

(i) What assumptions must be made to conclude the alternatives would be effective?

(ii) What major uncertainties could affect conclusions about the desirability of each alternative?

(4) Benefit and cost estimates.

(i) What are the major benefits of each alternative? How would each reduce hazards or increase safety and by how much?

(ii) What are the estimated costs or other adverse impacts of each alternative? Who would incur the cost?

(iii) What are the potential undesirable side effects of each alternative?

(5) Specification of criteria. A description of the standards by which the alternatives are judged and on which the recommendation is based.

(6) Final decision. Describe the alternative selected and the justification for choosing that alternative over the others.

(g) If a regulatory analysis has been prepared for a final rule, a statement must be inserted in the Supplementary Information section of the preamble to the final rule that references the regulatory analysis and describes how an interested person may examine the analysis.

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. Interested persons may examine a copy of the regulatory analysis at the NRC Public Document Room, 1717 H St. NW., Washington, D.C. Single copies of the analysis may be obtained from (insert name, address, and phone number of staff contact).

5.19 Regulatory Flexibility Act.

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354; 5 U.S.C. 601 et seq.) requires that each Federal agency fit regulatory and informational requirements to the scale of the entity being regulated. The Act requires that agencies consider the economic effect of its regulations on small entities. In the case of NRC, the Act is particularly applicable to byproduct, source, and special nuclear material licensees.

(a) Requirements. The Act applies to each proposed rule issued after January 1, 1981.

(1) The Act does not apply if --

(i) A rule is first issued in final form without a notice of proposed rulemaking; or

(ii) If the notice of proposed rulemaking was published in the Federal Register before January 1, 1981.

(2) If the rule has "a significant economic impact on a substantial number of small entities," the Act requires that NRC prepare a final regulatory flexibility analysis and make this analysis available to the public. The Act provides that a regulatory flexibility analysis may be combined with any other analysis as long as it meets the requirements of the Act. The NRC may prepare the regulatory flexibility analysis as a portion of the regulatory analysis that considers the costs and benefits of the final rule (see 5.17 of this handbook).

(3) The NRC need not prepare a final regulatory flexibility analysis if --

(i) The rule does not have a significant economic impact on a substantial number of small entities; and

(ii) The Commission certifies this to be the case in the rule.

(b) 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 ACT

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 $500-750 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. A copy of the analysis is available for inspection in the NRC Public Document Room, 1717 H St. NW., Washington, D.C. Single copies of the analysis may be obtained from (insert name, address, and telephone number of staff contact).

(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 support this conclusion. The statement must include detailed information on the number and type of small entities involved and the effect of the rule on them. A simple unsubstantiated conclusion is insufficient.

REGULATORY FLEXIBILITY CERTIFICATION STATEMENT

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 2000 specific licensees under 10 CFR 35.11 or 35.12. These licenses are issued principally to medical institutions. Small business entities, primarily physicians in private practice, comprise about 275 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.

(c) The 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. In addition, the Act requires that the final 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; and

(3) A statement of each significant alternative to the rule consistent with the stated objective of applicable statutes and designed to minimize any significant economic impact of the rule on small entities that was considered by NRC and a statement of the reason why NRC rejected each alternative.

(d) Emergency provisions. The Act permits the NRC to delay the completion of a regulatory 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 NRC should limit its interpretation of "emergency situation" to something that could have an immediate and significant impact on public health and safety.

(e) Guidance. A document concerning the requirements and procedures implementing the Regulatory Flexibility Act is available from the Division of Rules and Records, Office of Administration. Questions concerning the Regulatory Flexibility Act may be directed to J.M. Felton, Director,

Division of Rules and Records (ext. 27211), or John Philips, Chief, Rules and Procedures Branch (ext. 27086).

5.21 List of subject index terms.

The OFR, in accordance with 1 CFR 18.20, requires each agency to include a list of subject index terms for each part affected in a final rule document. 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.

(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 on or after April 1, 1982. The NRC shall present the list of subject index terms in alphabetical order as follows:

Example:

LIST OF SUBJECTS IN 10 CFR PART 20

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

(b) The NRC shall use the list of subject index terms developed by the Rules and Procedures Branch (RPB) and approved by the OFR to complete the list of subject terms entry. 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 desires to use additional terms, it shall consult with the RPB (ext. 27086).

5.23 Words of issuance.

The words of issuance ("pursuant to" clause) are the words by which the regulatory text is legally prescribed and tied to the CFR. Words of issuance describe the general effect of the document and may also present the general rulemaking authority of the agency. However, the words of issuance do not satisfy the requirement that each final rule document contain a citation of the authority under which it is issued. (See 5.27 of this handbook.) The words of issuance directly precede the heading of the first CFR part the document amends or adds.

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 adopting the following amendments to 10 CFR Parts 30, 50, and 73.

5.25 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 gives the instructions on how to change the CFR by identifying each specific change to CFR text.

(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; and

(2) Describe how that CFR unit is being changed.

(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 notice of 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.

Example:

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).

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. The Rules and Procedures Branch (RPB) 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.

Example:

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 corrected. The error must be corrected

before the next annual revision of 10 CFR Chapter I by the OFR. 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, 1982 (47 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, 1982 (47 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 a CFR unit is transferred to another position and renumbered.

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.

(5) Removed. Removed means that an existing CFR unit is being removed from 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) 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 instruction 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:

(7) Nomenclature change. Nomenclature change means that a term or phrase is changed throughout a CFR unit. It is most commonly used to change an office designation or the title of an agency official. The OFR usually requires 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. The Rules and Procedures Branch (RPB) shall determine, in consultation with the OFR, when marked pages must accompany a nomenclature change.

Example:

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

(8) 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 whenever possible by stating the duration of the suspension in the document announcing the action. The suspended provision continues to appear in the CFR, however, the OFR will insert an editorial note explaining the status of the provision. The NRC is responsible for issuing the follow-up document necessary to remove the suspended provision or to lift the suspension.

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, 1981, to October 1, 1981.

(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.

Examples:

1. In §73.3, paragraphs (d) and (f) are revised and paragraphs (h) and (i) are redesignated as paragraphs (j) and (k) and new paragraphs (h) and (i) are added to read as follows:
2. 10 CFR 50.20 is amended by removing paragraph (f)(2) and by revising paragraphs (a)(5)(iii) 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 5.27 (c) and (d) of this handbook covering the placement of 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. 553, the NRC is adopting the following amendment to 10 CFR Part 33.

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

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

AUTHORITY: Secs. 81, 161, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958 as amended (42 U.S.C. 2273); §33.17(a) issued under sec. 161b., 68 Stat. 948 (42 U.S.C. 2201(b)).

1. 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.

2. 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 5.33 of this handbook).

3. Section 33.16 is revised to read as follows:

§33.16 Application for other specific licenses.

An application filed under Part 30 of this chapter for a specific license other than one of broad scope will be considered by the Commission as an application for a specific license of broad scope under this part if the requirements of the applicable sections of this part are satisfied.

5.27 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. Generally, 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: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§35.2, 35.14(b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31(b) and (c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§35.14(b)(5)(ii), (iii) and (v) and (f)(2), 35.25 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

(b) Content. The Rules and Procedures Branch (RPB) maintains a complete list of the current authority citation for each part in 10 CFR Chapter I. The drafter may contact RPB on ext. 27086 to obtain the current authority citation for insertion into his or her document.

(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; INSPECTIONS

Sec.
19.1 Purpose.
19.2 Scope.
19.3 Definitions.
19.4 Interpretations.
19.5 Communications.
19.11 Posting of notices to workers.
19.13 Notifications and reports to individuals.
19.14 Presence of representatives of licensees and workers during inspections.
19.15 Consultation with workers during inspections.
19.16 Requests by workers for inspections.
19.17 Inspections not warranted; informal review.
19.30 Violations.
19.31 Application for exemptions.
19.32 Discrimination prohibited.

AUTHORITY: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§19.11(a), (c), (d), and (e) and 19.12 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C 2201(b)); and §§19.13 and 19.14(a) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

(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 1 - STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

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

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); secs. 201, 203, 204, 205, 209, 88 Stat. 1242, 1244, 1245, 1246, 1248, as amended (42 U.S.C. 5841, 5843, 5844, 5845, and 5849). 5 U.S.C. 552 and 553.

1. Section 1.34 is revised to read as follows:

§1.34 Office of Public Affairs.

The Office of Public Affairs (a) develops policies and administers programs at NRC headquarters and Regional Offices to inform the public and the news media about NRC policies, programs and activities; and (b) keeps NRC management informed on media coverage of activities of interest to the agency.

(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:

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

AUTHORITY: Secs. 53, 63, 81, 161, 182, 183, 68 Stat. 930, 933, 935, 948, 953, as amended (42 U.S.C. 2073, 2093, 2111, 2201, 2232, 2233); sec. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§71.61-71.63 issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o))

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

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

AUTHORITY: Secs. 62, 63, 64, 65, 161, 182, 183, 68 Stat. 932, 933, 948, 953, 954, as amended. (42 U.S.C. 2092, 2093, 2094, 2095, 2201, 2232, 2233); sec. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846).

Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §40.41(c) issued under sec. 161b., 68 Stat. 948 (42 U.S.C. 2201(b)); and §§40.23(e)(3), 40.61 and 40.62 issued under sec. 161o., 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

(e) Short-form authority citation. (1) If a brief document amends portions of a CFR part and only a portion of the complete part authority is relied on to issue the amendment, the NRC may present a short-form authority citation for the document. The short-form citation is intended to meet the Administrative Procedure Act requirement that a document contain an authority citation but prevent the imbalance that occurs when a lengthy citation is given for a brief amendment. The RPB generally determines when a short-form authority citation is appropriate for a document. The short-form citation is most commonly used in -

(i) Documents that make minor, nonsubstantive amendments;

(ii) Documents that make conforming or clarifying amendments; or

(iii) Correction documents.

Example: Short-form authority citation.
The authority citation for this document is: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201).

(2) If the short-form authority citation is used, it is placed directly after the "List of Subjects" entry in the document.

5.29 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 I. Regulatory text must --

(1) Be drafted exactly as it is to appear in the CFR.

(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 are 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.<br>(i), (ii), (iii), etc.<br>(A), (B), (C), etc. |
| Note: Underlined symbols are printed in italics. | (*1*), (*2*), (*3*), etc.<br>(*i*), (*ii*), (*iii*), 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) | (1) | (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 is also 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:
§35.12 Specific licenses to individual physicians for human use of byproduct material.

(a) An application by an individual physician or groups of physicians for a specific license for human use of byproduct material will be approved if --

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter.

(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;

(3) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(4) The applicant has extensive experience in the proposed use, the handling, and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician(s) shall furnish suitable evidence of experience with the application. A statement from the medical isotope committee in the institution where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of experience.)

(b) The Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use byproduct material on the premises of a medical institution, unless --

(1) The use of byproduct material is limited to --

(i) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(ii) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(iii) The performance of in vitro diagnostic studies; or

(iv) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(2) The physician brings the byproduct material with him and removes the byproduct material when he departs. (The institution cannot receive, possess, or store byproduct material other than the amount of material remaining in the patient); and

(3) The medical institution does not hold a byproduct material license under §35.11.

(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 an organizational problem caused by an overly complex

structure. This results in a structural imbalance created by inserting too much material within the section. In addition, the user will have more difficulty locating important material buried within a section. Access to information within a regulation is 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 13.7 of this handbook; Arranging material for ease of use.)

(iv) 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, produce, 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 or to produce new special nuclear material.

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

These numbers are not permitted because they are not compatible with the electronic printing system used to merge Federal Register amendments into CFR text.

(i) The NRC may not use a hyphenated number or alpha character in designatng a unit within any CFR part that does not contain a unit designated in this fashion.

(ii) 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, it is recommended that any new material be designated in standard fashion as the OFR will ultimately require that each part containing designations using hyphenated numbers or alpha characters be recodified to remove them.

(iii) Any future deviation from standard CFR designation must be approved, in advance, by the OFR.

(iv) Any questions on the assignment of new section or part numbers should be directed to the Rules and Procedures Branch (RPB) ext. 27086. In addition, the assignment of any new part or section numbers must be made after consultation with RPB to prevent confusion resulting from duplicative or overlapping part or section numbers.

(c) Plan for the future. The NRC may 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 or interim 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 ([1],[2],[3], etc.). 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 footnote contained in the amended part. It may not be necessary to redesignate existing footnotes to reflect added or removed footnotes. Contact the RPB on ext. 27086 for assistance in designating footnotes in amended text.

(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 also be set out in presenting the amendment.

5.31 Regulatory text: Headings.

(a) General. Each CFR unit larger than a paragraph is given a brief heading that describes the content of that unit. The NRC shall ensure that each heading in its regulations is brief, accurate, and useful to an individual seeking specific information. Headings are the primary indication of the content of a regulation. 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 impact 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 a signpost for a user 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 the user with 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 to a user 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 help the user find 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, state with particularity 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 per[illegible] the Secretary or the Assistant Secretary specifies...

* * * * *

5.33 Form of amendment: Section level.

(a) Each amendment made at the section level requires three elements. These elements must appear in the order listed below:

(1) Proper amendatory language.

(2) The section heading of the section being changed.

(3) The regulatory text of the section being changed.

In addition to these elements, the part heading and 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. 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

The authority citation for Part 35 continues to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§35.2,

35.14(b), (e) and(f), 35.21(a), 35.22(a), 35.24, and 35.31(b) and (c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§35.14(b)(5)(ii), (iii) and (v) and (f)(2), 35.25 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

Amendatory language

1. 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 5.29(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 follows 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 adopting the following amendments to 10 CFR Parts 20 and 21.

Part heading

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

Unchanged authority citation

The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended, (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201). Secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended, (42 U.S.C. 2273); §§20.101, 20.102, 20.103(a), (b), and (f), 20.104(a) and (b), 20.105(b), 20.106(a), 20.201, 20.202(a), 20.205, 20.207, 20.301, 20.303, 20.304 and 20.305 are issued under sec. 161b, 68 Stat. 948, as amended, (42 U.S.C. 2201(b)); and §§20.102, 20.103(e), 20.401-20.407, 20.408(b) and 20.409 are issued under sec. 161o, 68 Stat. 950, as amended, (42 U.S.C. 2201(o)).

Amendatory language

1. In §20.104, paragraph (b) is revised to read as follows:

Section heading

§20.104 Exposure of minors.

Indicates that paragraph (a) is unchanged

* * * * *

Revised text

(b) A licensee may not possess, use, or transfer licensed material in a manner that would expose any individual within a restricted area, who is under 18 years of age, to airborne radioactive material possessed by the licensee in an average concentration in excess of the limits specified in Appendix B, Table II, of this part. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

Indicates that the rest of the section is unchanged.

* * * * *

Amendatory language

2. In §20.106, paragraph (c)(4)(ii) is revised to read as follows:

Section heading

§20.106 Radioactivity in effluents to unrestricted areas.

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

* * * * *

Indicates that paragraphs (c)(1) through (c)(3) and (c)(4)(i) are unchanged

(c) * * *
(4) * * *

Revised text of paragraph (c)(4)(ii)

(ii) In water at points of use downstream from the point of release of the effluent.

Indicates that the rest of the section, paragraphs (c)(4)(iii), (c)(5), (d), and (e) are unchanged

* * * * *

Amendatory language

3. Section 20.402 is amended by revising paragraphs (a) and (b)(3) and adding (b)(6) to read as follows:

Section heading

§20.402 Reports of theft or loss of licensed material.

Revised text of paragraph (a)

(a) Each licensee shall report by telephone to the Director of the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D, immediately after its occurrence becomes known to the licensee, any loss or theft of licensed material in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas.

Indicates that paragraphs (b)(1) and (b)(2) are unchanged. The paragraph designation and three asterisks are necessary to place this amendment within paragraph (b)

(b) * * *

Revised text of paragraph (b)(3)

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

Indicates that paragraphs (b)(4) and (b)(5) are unchanged

* * * * *

Added text of paragraph (b)(6)

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

Indicates that the rest of the section is unchanged

* * * * *

Part heading

PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

Amendatory language and text of revised authority citation

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

AUTHORITY: Sec. 161, 68 stat. 948; sec. 234, 83 Stat. 444; sec. 206, 88 Stat. 1246 (42 U.S.C. 2201, 2282, 5846).

Amendatory language

5. 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.

5.35 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 order listed.

(1) Proper amendatory language.

(2) The part heading.

(3) A table of contents for the part.

(4) The authority citation.

(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 Control of weapons and dangerous material.
160.5 Violations.
160.6 Posting.
160.7 Effect on other laws.

Authority citation

AUTHORITY: Sec. 161, 68 Stat. 948, 42 U.S.C. 2201); sec. 229, 70 Stat. 1070 (42 U.S.C. 2278a); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §160.5 is issued under sec. 161i, 68 Stat. 948, as amended (42 U.S.C. 2201(i)).

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 16C 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.

5.37 Proper cross referencing techniques.

(a) A cross reference is a reference from one unit of the CFR to another unit. A cross reference may only be used to reference an existing unit of CFR text. Cross referencing is not to be confused with incorporation by reference, a legal device that may be used to give material the force and effect of law without printing the material in the Federal Register (See 5.39 of this handbook, Incorporation by reference).

(b) Cross references are used to avoid repeating long passages of text. Properly used, cross references may contribute to greater clarity in a regulation.

(c) Cross references must be used sparingly. Too many cross references indicate a structural complexity that increases the burden on a user. Excessive cross referencing is a symptom of organizational problems in a regulation. Do not --

(1) Use cross references to link provisions of a regulation into a complex network that is difficult to comprehend without knowing the entire system; and

(2) Add material to existing CFR units and use a cross reference as a superficial device to establish its relationship to the surrounding material.

(d) If a cross reference is necessary, include the title or a brief description of the referenced provision.

Example:

See 10 CFR 73.50, Requirements for Physical Protection of Licensed Activities.

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

(f) 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 | |
|---|---|
| When referencing | Write |
| 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 | |
|---|---|
| When referencing | Write |
| 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 | |
|---|---|
| When referencing | Write |
| A Section | §20.15 |
| A Paragraph | §20.15(a) |

| References within the same SECTION | |
|---|---|
| When referencing | Write |
| A Paragraph | Paragraph (b) of this section |
| A subdivision within a paragraph | Paragraph (b)(1)(i) of this section |

5.39 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.

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

(i) Material is eligible for incorporation by reference if 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.

(ii) Material is eligible for incorporation by reference if 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 ten Federal Register pages or contain highly specialized, technical matter that may pose difficulties in composition or printing.

(iii) Material is eligible for incorporation by reference if it is readily available to the class of people affected by it. This means that, to the extent necessry 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 it is easily available to the public for purchase and inspection. That is --

(A) It may be inspected at the Office of the Federal Register, the agency's central and regional offices, or in depository libraries; and

(B) It may be purchased 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;

(iii) Contain a brief subject description;

(iv) Contain a statement of availability; and

(v) Include an approval statement that indicates the date 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 on January 1, 1981. 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 10017. It is also available for inspection at the Nuclear Regulatory Commission's Public Document Room, 1717 H Street, NW., Washington, D.C.

(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 the Rules and Procedures Branch (RPB). RPB will coordinate each request for incorporation by reference with the OFR.

(d) Each incorporation by reference must be reapproved by the OFR on an annual basis. The OFR ties its reapproval to the revision date of 10 CFR Chapter 1 (January 1 of each year). Each change in the content or status of material incorporated by reference must be indicated to RPB. RPB will also coordinate the annual reapproval of materials incorporated by reference with the OFR.

PART 7 - ADVANCE NOTICES OF PROPOSED RULEMAKING

7.1 Description.

(a) The Nuclear Regulatory Commission (NRC) may choose to begin a rulemaking proceeding by publishing an advance notice of proposed rulemaking (ANPRM). However, the publication of an ANPRM does not represent a commitment by the NRC to issue a proposed or final rule on the matter in question. This remains a matter of agency discretion. Public response to the ANPRM is a primary factor in determining whether or not the rulemaking proceeding continues beyond this explanatory stage.

(b) In an ANPRM, the NRC generally describes a problem or situation and may present an outline of the anticipated regulatory response to the problem. An ANPRM is an appropriate beginning for a rulemaking proceeding when the NRC desires information concerning --

(1) The extent and seriousness of the problem under consideration;

(2) The appropriateness of a regulation as a 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 other related areas.

(c) The NRC may propose several alternative solutions in an ANPRM and request public comment on each alternative. Although regulatory text is not essential in an ANPRM, NRC may choose to present its

anticipated action as an amendment to the regulations in 10 CFR Chapter I in order 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 in order to direct public attention to the type and nature of the changes under consideration.

(d) Because an ANPRM serves as the first public notice that a rulemaking proceeding is anticipated, the Office of the Federal Register (OFR) classifies ANPRMs as proposed rules and publishes them in the Proposed Rule section of the Federal Register. As a result, each ANPRM prepared by the NRC must meet the format requirements for proposed rules set out in Part 3 of this handbook. This part discusses the particular requirements of Part 3 as they apply to an ANPRM.

7.3 Headings.

(a) Each advance notice of proposed rulemaking (ANPRM) 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 would affect; and

(3) Indicate the subject matter of the document.

Example:

NUCLEAR REGULATORY COMMISSION
10 CFR Part 34
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 ANPRM. If the ANPRM 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) Occasionally a follow-up document is necessary to supplement a previously published ANPRM. 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

Certification of Industrial Radiographers; Public Meeting

7.5 Preamble format requirements.

Because an advance notice of proposed rulemaking (ANPRM) is classified for publication in the Proposed Rule section of the Federal Register, each ANPRM 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 ANPRM that does not meet these format requirements. These format requirements are discussed, in detail, in section 3.7 of this handbook. The following example illustrates how the format requirements are applied to an ANPRM.

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 _____. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: (301) 443-1357.

7.7 List of subject index terms.

The OFR, in accordance with 1 CFR 18.20, requires each agency to include a list of subject index terms for each part affected in an advance notice of proposed rulemaking (ANPRM). The list of subject index terms is intended to identify the major topics of the ANPRM and the categories of persons affected by it in a standard fashion. 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 each ANPRM. 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 present the list of subject index terms in alphabetical order as follows.

Example:

LIST OF SUBJECTS IN 10 CFR PART 34
Packaging and containers, Penalty, Radiation protection, Radiography, Reporting requirements, Scientific equipment, Security measures.

7.9 Authority citations.

Each advance notice of proposed rulemaking (ANPRM) 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 ANPRM, it is sufficient to cite NRC's basic rulemaking authority as the authority for issuing the ANPRM. The NRC shall present the authority citation in an ANPRM directly after the "List of Subjects" entry in the document. The NRC shall present the authority citation in this fashion.

Example:

The authority citation for this document is: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201).

7.11 Document text.

The principles of clarity and style discussed in Part 13, "Writing Techniques," of this handbook apply to an advance notice of proposed rulemaking (ANPRM) in the same manner as they would apply to a proposed rule or a final rule.

(a) The explanatory text of an ANPRM is generally presented under the "Supplementary Information" heading. In the explanatory text of an ANPRM, the NRC shall include a discussion of --

(1) Any background or historical information relevant to the proceeding;

(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; and

(6) Specific areas where the NRC needs further information or where NRC is requesting public comment.

(b) If the NRC is presenting alternative approaches or solutions in the ANPRM, each alternative must be clearly identified as an alternative and labeled. This facilitates public comment on the ANPRM as well as NRC analysis and response to public comment.

Example:

Alternative 1: Certification of industrial radiographers by a third party.

(c) To the extent possible, the NRC should include a list of questions for public comment. This practice tends to channel public response to an ANPRM into areas most useful in evaluating the rulemaking action.

Example:

In light of the previous discussion, the NRC is particularly interested in receiving comments concerning the following:

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. Since 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 follow established procedures? What rights should radiographers have with respect to enforcement actions?

12. Would a small licensee, because of its size, bear a disproportionate economic impact 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 ANPRM, the NRC shall meet the requirements applicable to regulatory text in a proposed rule document. These requirements are outlined in Part 3 of this handbook.

(1) Amendatory language (3.25).

(2) Regulatory text: CFR codification (3.29).

(3) Regulatory text: Headings (3.31).

(4) Form of amendment: Section level or Part level (3.33 or 3.35).

PART 9 - NOTICES AND CORRECTIONS

9.1 Writing a notice document.

(a) General description. Each document the Nuclear Regulatory Commission (NRC) submits for publication in the Federal Register that does not contain regulatory text or relate to a rulemaking proceeding is published as a notice document. Generally, NRC notice documents deal with NRC licensing activities. NRC notice documents frequently affect a named party, usually the licensee or prospective licensee. Although some NRC notice documents are required to be published by law, many are published voluntarily to provide general information in the public interest. Types of NRC notice documents include--

(1) Applications 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) Abnormal occurrence reports;

(5) Committee meeting announcements;

(6) The issuance and availability of regulatory guides; and

(7) The availability of technical reports and certain environmental statements.

(b) Headings. The headings of a notice document must identify NRC as the issuing agency and indicate the subject matter of the document.

(1) If a 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 identifies the document within NRC's internal

filing system. The number may be keyed to a specific licensing proceeding. If the "Agency number" heading 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.; Consideration of Amendments to Facility Operating Licenses | Subject |

(c) Text. The principles of clarity and style discussed in Part 13, "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 writer should use this format in constructing a notice document.

Example:

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, 1981.

ADDRESS: Holiday Inn of Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20014

FOR FURTHER INFORMATION CONTACT: (Name of contact person), (301) 492-1357.

SUPPLEMENTARY INFORMATION: The primary 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 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 the questions sessions, it is planned that attendees will be grouped by NSSS affiliation. The tentative agenda is shown below.

July 7, 1981

10:00 a.m.

- Identification of Systems

* * * * *

Persons other than NRC Staff and Licensee Representatives may observe the proceedings but will be permitted to participate in the discussions only as time will allow.

Registration will be conducted prior to the meeting.

Dated at Bethesda, MD, this 3rd day of June 1981.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,
Director, Division of Licensing,
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, 1981, in Room 1046, 1717 H Street, NW., Washington, D.C. Notice of this meeting was published in the Federal Register on May 20, 1981.

(3) If a notice 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 June 30, 1981.

(4) If a notice document relates to 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 date of the issue where the document appears.

Example:

The NRC has made a determination, based on criteria published in the Federal Register (42 FR 10905) on February 24, 1977, 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 should identify the CFR title and part or section number.

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.

9.3 Writing a correction document.

(a) The NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Federal Register. The Rules and Procedures Branch (RPB) proofs only the regulatory text of final rule documents and the highly technical nature of this material may prevent RPB from discovering each error. As a result, the originating office has the primary responsibility for identifying and correcting errors that appear in published Federal Register documents.

(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 Office of the Federal Register (OFR) is responsible for making any correction necessary to reflect the content of the original document. The originating office may correct printing errors by contacting the RPB on ext. 27086 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 make the necessary correction

in the regulatory text when it is printed in the Code of Federal Regulations (CFR).

(d) If the error appeared in the original document submitted to the OFR for printing, NRC is responsible for making the necessary correction. Unless prior arrangements have been made with RPB, 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 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.

(2) If the correction is to a proposed rule or final rule document, the correction document must comply with the preamble requirements of 1 CFR 18.12.

(3) The Federal Register page and publication date of the document being corrected must be clearly identified.

(4) The error being corrected must be identified as clearly as possible.

(i) In codified text, cite the CFR unit containing the error.

(ii) In non-codified 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 correct text.

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 72, 73, and 150

Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Rule; correction.

SUMMARY: This document corrects a final rule establishing licensing requirements for the storage of spent fuel in an independent spent fuel storage installation published in the Federal Register on November 12, 1980 (45 FR 74693). The action is necessary to correct typographical errors.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 000-0000.

Accordingly, the following corrections are made in the document published on November 12, 1980 (45 FR 74693) that added 10 CFR Part 72:

1. On page 74698, column two, the third paragraph, "Procurement of..." is corrected to read "Procurement for..." §72.65 [Corrected].

2. On page 74708, column two, in §72.65(a), the word "usual" is corrected to read "unusual."

Dated at Bethesda, Md., this ____ day of _____ 1982.

For the Nuclear Regulatory Commission:

_____

William J. Dircks,
Executive Director for Operations.

PART 11 - PROCEDURES FOR HANDLING PETITIONS FOR RULEMAKING

11.1 Handling petitions: Initial contacts.

(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)). The Nuclear Regulatory Commission (NRC) has implemented 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). As set out in 10 CFR 2.802(b), a prospective petitioner is encouraged to confer with the staff prior to filing a petition for rulemaking to resolve questions regarding applicable NRC regulations sought to be amended, to clarify the procedures for filing a petition for rulemaking, or to request a meeting with appropriate NRC staff to discuss a petition. A request for information concerning a petition or a meeting with the staff should be addressed to: The Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Rules and Procedures Branch. A prospective petitioner may also telephone the Rules and Procedures Branch on (301) 492-7086 or on the toll free number (800) 368-5642 to obtain assistance.

(b) If a request for a meeting is received by any other office, it should be directed to or coordinated with the Director, Division of Rules and Records, or the Chief, Rules and Procedures Branch. All affected offices will be invited to attend any meeting held, and DRR will prepare a memorandum for the record regarding the substance of the meeting. This memorandum will be included in the official file on the petition.

11.3 Handling petitions: Preliminary processing.

(a) Upon receipt of a petition for rulemaking, or a document which may qualify as a petition for rulemaking (see criteria for this determination in §2.802(c) in the appendix to this part), the individual in possession of the document should immediately forward it to the Office of the Secretary marked: ATTENTION: Chief, Docketing and Service Branch for processing. The Office of the Secretary will control the document and send a copy to the Division of Rules and Records, Office of Administration, for a determination as to whether or not the document meets the threshold requirements for a petition for rulemaking (10 CFR 2.802(c)). 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 which 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 is reasonably available to the petitioner, and any other pertinent information necessary to support the action sought. In support of the petition, the petitioner should note any specific cases of which the petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.

(b) If the document meets the requirements of §2.802(c), the Division of Rules and Records (DRR) will assign a docket number to the petition and, within five days, forward a copy of the petition to the appropriate office with a request for a decision on whether it should be processed routinely or handled as a "fast-track" petition (a "fast-track" petition is initially published for comment in the Federal Register as a proposed rule--see §2.802(e) in the appendix to this part).

11.5 Handling petitions: Petitions found deficient.

(a) If a petition does not include sufficient information to meet the requirements of §2.802(c), the staff will follow the procedures contained in §2.802(f). The petitioner will be informed as to how the petition is deficient and be given an opportunity to submit additional information. The determination that a petition is deficient will be made by the Executive Director for Operations (EDO), based upon the recommendation of the cognizant office (normally the Office of Nuclear Regulatory Research (RES), the Office of the Executive Legal Director (OELD), or the Division of Rules and Records (DRR)). This determination should ordinarily be made within 30 days from the date of receipt of the petition by the Office of the Secretary of the Commission (SECY). The recommendation to the EDO for a determination of a deficient petition will be in a memorandum from DRR that includes a draft letter to the petitioner pointing out the aspects in which the petition is deficient.

(b) 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 may be returned to the petitioner without prejudice to the petitioner's right to file a new petition. When this occurs, DRR will draft the appropriate letter to the petitioner, obtain the concurrence of OELD and the cognizant office, and forward the letter to the EDO for signature.

(c) The Commissioners will be placed on distribution for any letter to a petitioner which states that a petition is deficient or which returns a petition to a petitioner because it is incomplete.

11.7 Procedures: Fast track determination.

(a) Occasionally, NRC receives a petition for rulemaking that requests a minor amendment to the regulations that is obviously meritorious. In order to expedite the rulemaking process, these petitions for rulemaking may be published initially for public comment in the form of a proposed rule. This "fast-track" procedure eliminates the usual step of publishing a notice of receipt of a petition for rulemaking and inviting public comment on the petition in those instances where the additional procedural step is unnecessary. "Fast-track" petitions are processed by the staff according to the procedures specified in this section and in section 11.9 of this handbook.

(b) Following a determination that a petition for rulemaking meets the criteria for a petition set out in §2.802(c), the Division of Rules and Records assigns the petition to the appropriate staff office for a decision on whether the petition will be handled in accordance with "fast-track" procedures or as a regular petition for rulemaking. The staff office to which the petition is assigned makes this determination within 15 working days according to the criteria presented in this section.

(c) Petitions requesting the following actions are candidates for "fast-track" handling:

(1) Proposed 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) Proposed action involving interpretive rules, rules of agency organization, procedure, or practice, and rules for the orderly conduct of Commission business.

(3) Proposed 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) Proposed 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) Proposed action involving a request already under consideration in an ongoing rulemaking proceeding.

(6) Any other action that is clearly meritorious and will not adversely affect the rights of other licensees or persons.

(d) Petitions requesting amendment of NRC regulations normally will not be considered under the "fast-track" procedures 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) The proposed action will have a significant economic impact on a substantial number of small entities (see discussion of Regulatory Flexibility Act requirements in sections 3.19 and 5.19 of this handbook).

(4) The proposed action will have a significant impact on NRC staff and resource commitments.

11.9 Procedures: Fast track processing.

(a) SECY receives the petition and forwards it to DRR for action. DRR makes its determination of standing under 10 CFR 2.802(c) and, if the petition meets the criteria specified in the regulation, sends, within 5 days, a copy of the petition to the appropriate office for a "fast-track" determination.

(b) The appropriate office assigns a cognizant individual to handle the petition upon receiving the petition from DRR.

(c) The cognizant individual uses established criteria to make a "fast-track" determination within 15 days of the office's receipt of the petition.

(1) If "fast-track" processing is appropriate, the assigned office transmits this determination to DRR by phone and by memorandum and begins processing the petition under "fast-track" procedures outlined in paragraphs (d) and (e) of this section.

(2) If "fast-track" processing is not appropriate, the assigned office transmits this determination to DRR by phone and by memorandum so that DRR may begin to process the petition under regular procedures.

(d) If "fast-track" processing is selected, within 90 days after DRR assigns a docket number, the assigned cognizant individual shall develop a proposed rulemaking document for transmittal to the EDO or the Commission for approval.

(e) The cognizant individual is responsible for implementation of EDO or Commission action for a proposed rule (see NRC rulemaking process section 1.7 of this handbook).

11.11 Procedures: Routine processing.

(a) If the staff determines that the "fast-track" procedure is not appropriate for a petition for rulemaking, the staff office to which the petition was assigned shall inform the Division of Rules and Records of this determination by phone and in an official memorandum. The DRR staff will prepare a notice of receipt of petition for rulemaking for Federal Register publication. The notice describes the contents of the petition and allows at least 60 days for public comment.

(b) The responsible office will establish a schedule and target date for completion of staf action on the petition. The schedule and target date are meant to r lect the time from initial staff review to when the petition is sent to the Commission or the EDO recommending the granting of the petition and publication of a proposed rule or recommending de al of the petition.

(c) The staff should note that in approving SECY-77-526, "Procedures for Petitions," in November 1977, the Commission stated:

> "Schedules for responding to specific petitions should be set individually, taking into account the priority and difficulty of the issues. However, the Commission believes that the time for response should seldom exceed 6 months for minor petitions or 12 months for major ones. When the response is rulemaking, the 6 and 12 month schedule limits can be interpreted as applying to the date of publication of the proposed rule in the Federal Register.
>
> "On petitions of substantial policy significance, the staff should submit an information paper or present a briefing to the Commission, about three months after receipt of the petition, identifying issues and options, and any preliminary staff views."

11.13 Processing after publication for comment.

(a) Routine petition (published for comment).

(1) At the conclusion of the comment period specified in the Federal Register notice of receipt of petition (normally 60 days), DRR will send a letter to the petitioner enclosing copies of any comments that have been received concerning the petition. The letter will also state the initial target date for completion of staff review of the petition and the name and telephone number of the staff person responsible for the petition. The responsible office will notify the petitioner of any subsequent changes in the target date or of the staff person to whom the petition is assigned.

(2) In some instances, a petition for rulemaking may remain active for many months following publication for comment in the Federal Register. The staff should, in these cases, contact the petitioner periodically (at least every three months) to give a status report on the processing of the petition. A petitioner may, over a period of time, change positions on a particular issue or determine that an initial concern has been satisfied by actions occurring after the petition was filed with the Commission. Thus, periodic contact with petitioners may result in withdrawal of part or all of a petition by the petitioner. Routine correspondence to the petitioner may be signed by an appropriate official in the responsible office. Copies of correspondence sent to a petitioner should be sent to DRR and to the official docket file maintained by the Office of the Secretary.

(3) If an office responsible for a petition believes that action on the petition has been completed through administrative measures other than publication of a Federal Register notice, it should consult with DRR and OELD for a final determination. Following a review of the staff actions taken during the processing of the petition, DRR will notify the responsible office if all necessary action on the petition has been completed and describe how the proceeding is to be terminated.

(b) "Fast-track" petition (published as proposed rule). At the conclusion of the comment period specified in the proposed rule, the cognizant individual in the responsible office will send 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 will also state the initial target date for completion of staff review of the comments received and development of a final rule. The responsible office will notify the petitioner of any subsequent changes in the target date or of the staff person to whom the petition is assigned.

(c) Assistance during processing.

(1) The staff of the Rules and Procedures Branch, DRR, is available to assist with the preparation and review of Federal Register notices required during the processing of petitions for rulemaking.

(2) OELD staff are available to provide legal advice to the staff during the processing of petitions for rulemaking.

(d) Staff response to significant actions. The designated contact person for a petition for rulemaking is responsible for notifying DRR, and where appropriate, OELD, of any significant action or change that occurs during the processing of the petition. Negotiations or understandings reached with a petitioner can materially affect the handling and disposition of a petition. Coordination of staff plans with DRR is necessary for actions such as the potential or actual withdrawal of a petition to enable DRR to keep the Commission informed of the status of petitions for rulemaking by means of the quarterly Regulatory Agenda.

11.15 Determining when action on a petition is complete.

Action on a petition for rulemaking may be considered "complete" when the petition or each of its parts has been withdrawn, denied, or granted.

(a) Withdrawal of petition for rulemaking.

(1) A petition or one of its parts may be withdrawn only by the petitioner. In the case of notification of withdrawal by telephone, the staff person should request that the petitioner submit an official letter of withdrawal as a record of the request. If the petitioner indicates that a written request for withdrawal will not be submitted, the staff person contacted should make a record of the conversation noting the date, name, and position of the person claiming to represent the petitioner. The staff person responsible for the petition should send a follow-up letter to the petitioner that confirms the withdrawal.

(2) In the case of a withdrawal, DRR, after consultation with the assigned task leader, will prepare a Federal Register notice that informs the public of this action. The Federal Register notice will be circulated to the responsible office and OELD for concurrence before it is submitted to the EDO for signature.

(b) Denial of petition for rulemaking.

(1) A petition or one of its parts is denied through the publication of a Federal Register notice and official written notification to the petitioner. If part of a petition is denied, the staff has a responsibility

to continue processing the remaining parts of the petition until each remaining part has been withdrawn, denied, or granted.

(2) The responsible office prepares the following documents in the case of a denial of a petition: (i) A memo to the EDO or a Commisson paper; (ii) A Federal Register notice of denial (to be signed by either the Executive Director for Operations or the Secretary of the Commission); (iii) A letter to the petitioner to be sent to the petitioner prior to publication of the notice of denial in the Federal Register (to be signed by either the Executive Director for Operations or the Secretary of the Commission); (iv) Congressional letters (to be signed by the Director of the responsible office); and (v) A draft public announcement, if appropriate, and staff response to comments. Section 1.40(o) of the Commission's regulations gives to the Executive Director for Operations the authority to deny petitions for rulemaking concerning issues of a minor or nonpolicy nature where the grounds for denial do not substantially modify existing precedent. Petitions that address major or policy issues require action by the Commission.

(3) When preparing a Federal Register notice of denial of a petition, the following format items are omitted from the Commission Paper and Federal Register notice --

(i) The Regulatory Analysis (Value/Impact Assessment);

(ii) The authority citation; and

(iii) The list of subject index terms.

See 15.10 of this handbook for a sample response to a petition for rulemaking.

(c) Granting of petition for rulemaking. A petition or one of its parts is granted through issuance of a final rule that responds to the petitioner's request or other Commission action acceptable to the petitioner, e.g., issuance of a Regulatory Guide, Policy Statement, legal interpretation, etc.

(d) Incorporation of petition for rulemaking. When similar or related issues are involved, it is frequently possible to incorporate a petition or one of its parts into an ongoing rulemaking. This can be done provided that three factors are taken into consideration. First, incorporation of the petition or one of its parts into an ongoing rulemaking may delay the completion of the ongoing rulemaking to an extent that is undesirable given the Commission's established priorities. Second, incorporation of the petition or one of its parts 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 in itself to a denial of the petition. Finally, the action to incorporate the petition should occur at a stage in the rulemaking that permits adequate consideration of the issue involved. If any of these considerations appears to be an obstacle to incorporation, the petition or the part of a petition under review should be treated separately.

(e) Points to remember.

(1) Incorporation of a petition or one of its parts 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 as noted above. Incorporation, by itself, does not "grant" or "complete" action on a petition for rulemaking. Also, 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 NUREGs, etc.) do not "grant", "deny", or "complete" action on a petition or its parts. These steps are satisfied only as noted in paragraphs (a), (b), and (c) of this section.

(2) The official docket file on a petition for rulemaking is maintained by the Office of the Secretary. The staff should send a copy of all petition-related documents for inclusion in the official docket as well as to DRR.

(3) A complete file of all petitions for rulemaking that have been filed with the NRC is maintained in the Rules and Procedures Branch, DRR. Documents concerning current petitions and petitions that have been disposed of through EDO or Commission action are published in the NRC Rules and Regulations. Questions concerning the status of any petition for rulemaking may be directed to the Rules and Procedures Branch, ext. 27086.

Appendix A to Part 11 - § 2.802

§ 2.802 Petition for rulemaking.

"(a) Any interested person may petition the Commission to issue, amend or rescind any regulation. The petition should be addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Docketing and Service Branch.

"(b) A prospective petitioner is encouraged to confer with the staff prior to the filing of a petition for rulemaking. Questions regarding applicable NRC regulations sought to be amended, the procedures for filing a petition for rulemaking, or requests for a meeting with the appropriate NRC staff to discuss a petition should be addressed to the Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Rules and Procedures Branch. A prospective petitioner may also telephone the Division of Rules and Records on (301) 492-7086 to obtain assistance.[1]

"(c) Each petition filed under this section shall:

"(1) Set forth a general solution to the problem or the substance or text of any proposed regulation or amendment, or specify the regulation which is to be revoked or amended;

"(2) State clearly and concisely the petitioner's grounds for and interest in the action requested;

[1]Editorial Note: Toll free number 800-368-5642.

"(3) Include a statement in support of the petition which shall set forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific or other data involved which is reasonably available to the petitioner, and such other pertinent information as the petitioner deems necessary to support the action sought. In support of its petition, petitioner should note any specific cases of which petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.

"(d) The petitioner may request the Commission to suspend all or any part of any licensing proceeding to which the petitioner is a party pending disposition of the petition for rulemaking.

"(e) If it is determined that the petition includes the information required by paragraph (c) of this section and is complete, the Director, Division of Rules and Records, or designee, will assign a docket number to the petition, will cause the petition to be formally docketed, and will deposit a copy of the docketed petition in the Commission's Public Document Room. Public comment may be requested by publication of a notice of the docketing of the petition in the Federal Register or in appropriate cases, may be invited for the first time upon publication in the Federal Register of a proposed rule developed in response to the petition. Publication will be limited by the requirements of section 181 of the Atomic Energy Act of 1954, as amended, and may be limited by order of the Commission.

"(f) If it is determined by the Executive Director for Operations that the petition does not include the information required by paragraph (c) of this section and is incomplete, the petitioner will be notified of that determination and the respects in which the petition is deficient and will be accorded an opportunity to submit additional data. Ordinarily this determination will be made within 30 days from the date of receipt of the petition by the Office of the Secretary of the Commission. If the petitioner does not submit additional data to correct the deficiency within 90 days from the date of notification to the petitioner that the petition is incomplete, the petition may be returned to the petitioner without prejudice to the right of the petitioner to file a new petition.

"(g) The Director, Division of Rules and Records, Office of Administration, or his designee, will prepare on a quarterly basis a summary of petitions for rulemaking pending before the Commission, including the status thereof. A copy of the report will be available for public inspection and copying in the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555."

PART 13 - WRITING TECHNIQUES

13.1 Introduction to organization.

Organization is an important factor in writing a regulation. A well organized regulation allows the user to process the information presented quickly and understand its requirements easily. Organization helps determine whether a regulation --

(a) Effectively accomplishes its intended objective;

(b) Is complete and accurate; and

(c) Is easy to use, amend, and cite.

13.3 Think before writing.

(a) The first step in good organization is careful planning before beginning to write. The time spent in thought and analysis before attempting to write saves time and effort in the writing process. A firm conceptual foundation is necessary to create a sound regulatory structure.

(b) In order to organize a regulation effectively, the writer must first determine --

(1) The need for the regulation;

(2) The intended effect of the regulation;

(3) The basic message of the regulation;

(4) The different audiences being addressed by the regulation; and

(5) The way the primary audience will use the regulation.

(c) Because the licensee is the primary audience in most Nuclear Regulatory Commission (NRC) regulations, the early analysis must consider the potential effects of the regulation on the licensee. To present a well-organized regulation, the writer should consider --

(1) The number, type, and size of the licensees affected;

(2) The effects that the regulation will have on the licensee's operations;

(3) The resources available to the licensee; and

(4) The manner in which the licensee conducts business and incorporates regulatory requirements into its operations.

13.5 Arrange the regulation logically.

(a) A well-organized regulation presents the information contained in it logically. The chosen organizational structure should emphasize the key elements of the regulation and the relationship between these elements and the intended effect of the regulation.

(b) In order to create a sound organizational structure, the writer must analyze the factors that affect the organization of the material.

(1) What factors are most important?

(2) What factors should come first?

(3) How do different factors affect one another?

(c) The most common classification used to organize material in NRC regulations is to proceed from the general to the specific. This method is often used in technical writing because it allows complex, interlocking requirements to be presented in a manner that is most easily understood. A regulation organized by this classification method begins with basic information and overall requirements and procedures. This material is followed by more specific requirements and technical procedures that are necessary to adequately cover particular subjects. The following guidelines, applicable at each organizational level within the regulation, help a writer present information logically using general to specific classification principles.

(1) Place general provisions before specific provisions.

(2) Place more important provisions before less important provisions.

(3) Place more frequently used provisions before less frequently used provisions.

(4) Place permanent provisions before temporary provisions.

(5) Place reporting, recordkeeping, inspection, and penalty provisions at the end.

13.7 Arrange the regulation for ease of use.

(a) General. A well-organized regulation allows the user to find needed information without having to read the entire regulation. A user generally approaches the regulation with a specific problem or question in mind. The writer should organize and label the regulation so that a user is able to locate the material that answers his or her questions. A regulation is organized for easy use when it --

(1) Has short units;

(2) Has descriptive headings;

(3) Includes a road map provision (see paragraph (d) of this section); and

(4) Answers frequently asked questions quickly and accurately.

(b) Short units. Each unit within the regulation, especially at the section level, should be a short, well-defined presentation of a single topic. Limiting each section to a single regulatory proposition reduces the amount of material the user must read to determine needed information.

(c) Descriptive headings. Provide each unit within the regulation with a brief heading that accurately describes the content of the unit.

(1) Descriptive section headings are particularly effective sign posts for the user. They help users identify particular portions of the regulation.

(2) Section headings, combined with part and subpart headings, should provide the user with an overall picture of the regulation.

Properly used, these headings illustrate the logic and arrangement of the regulation. The headings in the following example allow a person to find the information necessary to complete an application and prepare a package of radioactive material for shipment. Note that the description of package standards begins with the general requirements applicable to all packages and then provides the 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.

* * * * *

(3) Strategic repetition, that is repeating key words or phrases in section headings, is a device used to illustrate certain relationships

within regulatory material. Strategic repetition signals the reader that material in a number of sections deals with different aspects of the same topic. Strategic repetition may also serve to make the organizational pattern of the regulation clearer.

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) Road maps.

(1) A well-written introductory provision is a valuable aid in making a regulation accessible to the user. A good introduction not only outlines the content of the regulation, but also pinpoints the provisions of the regulation that may be applicable to particular groups or in certain situations. Descriptive headings, along with good introductory provisions, provide the user with a road map that directs him or her to needed information.

(2) The concepts section (§61.7) contained in proposed Part 61 is a good example of a "road map" provision. This section outlines the substantive content of the entire part and explains the key terms that are used in the regulation. To conserve space, the following example

presents only paragraph (a) of §61.7. The section continues with an explanation of waste classification and near-surface disposal (paragraph (b)) and the licensing process (paragraph (c)).

Example:

§61.7 Concepts.

(a) The Disposal facility. (1) Part 61 is intended to apply to land disposal of radioactive waste and not to other methods such as sea or extraterrestrial disposal. In its present form, Part 61 contains procedural requirements and performance objectives applicable to any method of land disposal. It contains specific technical requirements for near-surface disposal of radioactive waste which involves disposal in the uppermost 15 to 20 meters of the earth. Technical requirements for alternative methods will be added in the future.

(2) Near-surface disposal of radioactive waste takes place at a near-surface disposal facility, which includes all of the land and buildings necessary to carry out the disposal. The disposal site is that portion of the facility which is used for disposal of waste and consists of disposal units and a buffer zone. A disposal unit is a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit is usually a trench. A buffer zone is a portion of the disposal site that is controlled by the licensee and that lies between the boundary of the disposal site and any disposal unit. It provides controlled space to establish monitoring locations which are intended to provide an early warning of radionuclide movement, and to take mitigative measures if needed.

* * * * *

(e) Useability test. A simple test enables a writer to determine the accessibility of information contained in the regulation. Develop a list of common questions concerning the material. Give the regulation to a person not familiar with its content and determine how long it takes the person to locate the provisions containing the answers and how much of the material he or she must read to obtain the answers. If the questions are answered quickly and accurately, the regulation is probably well organized.

13.9 Use cross references sparingly.

(a) A cross reference is occasionally necessary to avoid repeating a long passage of text. When used properly, a cross reference can contribute to the clarity of a regulation by avoiding needless repetition. A cross reference may be used only when the referenced provision --

(1) Is essential to the meaning of a provision; or

(2) Limits or makes an exception to the provision.

(b) Excessive cross referencing is often a symptom of organizational problems in a regulation.

(1) Too many cross references frequently indicate a structural problem that creates an added burden for the reader. A reader should be able to understand the meaning and intent of each section without having to thumb back and forth through the regulation.

(i) Do not use cross references to link provisions of a regulation together so intricately that it is difficult to understand the requirements of one provision without knowing the entire regulation. A reader should not be forced to read the entire regulation to understand one provision.

(ii) Do not use a cross reference as a device to establish a superficial relationship between new and existing material. A cross reference does not conceal the inappropriateness of adding material where it does not belong.

(iii) Wherever possible, do not cross reference a provision to a section that contains cross references to still other sections.

This treasure hunt approach will eventually snap the tolerance of even the most determined reader.

(2) If the writer has used cross references as an organizational device, future changes to the regulation may be more d ,icult to make. It will be necessary to check the effect that each future amendment will have on each cross reference. Additional amendments may be required to renumber any cross reference affected by the change being made.

(c) The writer may eliminate unnecessary cross references by rearranging material in the regulation so that related material is close together. Group similar or related items. Specify exemptions or qualifications with the general rule. Use descriptive headings to emphasize the relationships inherent in the material.

(d) If a cross reference is necessary, include a brief description of the referenced provision with the cross reference. This brief description allows a reader to determine whether or not he or she needs to turn to the referenced provision.

Example:

SAY: See 10 CFR 9.7 for a description of the records which NRC routinely makes available to the nublic in the Public Document Room.
DON'T SAY: See 10 CFR 9.7.

13.11 Plan for the future.

(a) When writing a new regulation or revising an existing one, the writer should leave some room for future expansion. A regulation is rarely static. What is adequate and appropriate now may require adjustments to meet future conditions. The organizational structure of a regulation must allow changes to be made easily and permit new material to be added in appropriate locations.

(b) The writer can leave room for future growth by skipping every other number in designating parts and section. (Note the numbering sequence used in the examples appearing in 13.7 of this handbook.) In addition, leave 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.

13.13 Structure of a typical NRC part.

(a) NRC's primary purpose is to license and regulate the uses of nuclear energy to protect the health and safety of the public. As a result, most of the parts contained in 10 CFR Chapter I establish regulations appropriate to cover an aspect of NRC's licensing activities. The typical NRC licensing part begins with a subpart or group of parts entitled "general provisions" and ends with a subpart or group of parts that specify any recordkeeping or reporting requirements and contain any inspection or penalty provisions. The requirements applicable to the specific license covered by the part constitute the remainder of the material.

(b) The first ten sections of each part are normally reserved for use in the general provisions subpart. This subpart presents the basic explanatory material necessary to provide context for the regulatory and licensing requirements that are contained in the part. The following example presents the most common sections in their usual order of appearance in the general provisions subpart. Each listed section need not appear in each part, and certain parts may require additional sections that contain information unique to that part.

Example:

Subpart A - General Provisions

1 Purpose and scope.

2 Definitions.

3 License requirements.

4 Exemptions.

5 Communications.

6 Interpretations.

8 Reporting, recordkeeping, and application requirements: OMB approval.

(c) The regulatory requirements of a part are generally presented in a series of subparts or a series of related sections grouped under a descriptive center heading. The number of subparts or section groups in a part varies with the extent and complexity of the regulation. Regulatory requirements in a licensing part are usually presented in the following sequence.

(1) A general description of the license including scope, coverage, and application procedures.

(2) General requirements for obtaining a license.

(3) General requirements for compliance with the terms of the license.

(4) Specific requirements applicable to certain classes of licensees or types of licensed activities.

(5) Specialized or technical information applicable to specific licensed activities.

(6) Any additional procedural information that may be needed.

(d) The concluding portion of the part contains information concerning reporting and recordkeeping requirements, inspections, and penalty provisions. This material may be presented in a single subpart or in a series of subparts.

Example: An NRC licensing part.

PART 61 - LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

Subpart A - General Provisions

Sec.

General provisions appear first

61.1 Purpose and scope.
61.2 Definitions.
61.3 License required.
61.4 Communications.
61.5 Interpretations.
61.6 Exemptions.

Good road map section describes key elements of the regulation

61.7 Concepts.

Subpart B - Licenses

General license information

61.10 Content of application.
61.11 General information.
61.12 Specific technical information.
61.13 Technical analyses.
61.14 Institutional information.
61.15 Financial information.
61.16 Other information.
61.20 Filing and distribution of application.
61.21 Elimination of repetition.
61.22 Updating of application and environmental report.
61.23 Standards for issuance of a license.
61.24 Conditions of licenses.
61.25 Changes.
61.26 Amendment of licenses.
61.27 Application for renewal or closure.
61.28 Contents of application for closure.

Gap in numbering between subparts leaves room for future expansion

61.29 Post-closure observation and maintenance.
61.30 Transfer of license.
61.31 Termination of licenses.

Subpart C - Performance Objectives

General requirements

61.40 General requirement.
61.41 Protection of the general population from releases of radioactivity
61.42 Protection of individuals from inadvertent intrusion.
61.43 Protection of individuals during operations.
61.44 Stability of the site after closure.

Subpart D - Technical Requirements for Disposal Facilities

Technical requirements

61.50 Disposal site suitability requirements for land disposal.
61.51 Disposal site design for land disposal.
61.52 Land disposal facility operations and disposal site closure.
61.53 Environmental monitoring.
61.54 Alternative requirements for design and operations.
61.55 Waste classification.
61.56 Waste characteristics.
61.57 Labeling.
61.59 Institutional requirements.

Subpart E - Financial Assurances

61.61 Applicant qualifications and assurances.
61.62 Funding for disposal site closure and stabilization.
61.63 Financial assurances for institutional controls.

Added considerations

Subpart F - Participation by State Governments and Indian Tribes

61.70 Scope.
61.71 State and Tribal government consultation.
61.72 Filing of proposals for State and Tribal participation.
61.73 Commission approval of proposals.

Recordkeeping, inspection, and penalty provisions at the end

Subpart G - Records, Reports, Tests, and ~~Inspections~~

61.80 Maintenance of records, reports, and transfers.
61.81 Tests at land disposal facilities.
61.82 Commission inspections of land disposal facilities.
61.83 Violations.

13.15 Short paragraphs.

A writer may improve the clarity of a regulation by using short, compact paragraphs. Each paragraph should deal with a single, unified topic. Lengthy, complex, or technical discussions should be presented in a series of related paragraphs.

(a) A long, complicated paragraph increases the potential for reader error in determining the meaning of the passage. A reader may be forced to read a paragraph several times to understand its content. Short paragraphs reduce the demands on the reader and avoid information overloads that frequently result in misunderstanding and incorrect interpretations.

(b) In addition, the content of a short paragraph that is limited to a single topic can easily be described in a catch-line heading consisting of a word or phrase. A paragraph heading reveals important information within a section and aids a reader by pinpointing relevant material. Paragraph headings may also reveal the logical flow of material within a section and highlight related material within the regulation.

13.17 Short sentences.

(a) The long, run-on sentence is a basic weakness in regulatory writing. Long sentences, in the same manner as long paragraphs, often blur the concepts being communicated. A series of long sentences requires greater effort on the reader's part to determine the content of a regulation. As a result, the rights and duties of the regulated party may not be effectively communicated.

(b) Brevity alone does not guarantee clear writing because of the many other factors involved. However, sentence length is the greatest single factor affecting the ability of a reader to understand the sentence. A regulation writer should strive for short, direct sentences because they foster clearer thinking and more effective communication. Sentences may be shortened by --

(1) Dividing a long sentence into two or three shorter sentences;

(2) Removing all unnecessary words; or

(3) Changing the structure of the sentence to a simpler form.

(See 13.19 of this handbook for a discussion of sentence structure.)

(c) Many sentences are easily shortened by dividing them into two or three shorter sentences. Compound or compound-complex sentences that contain conjunctions (such as "but", "for", "because", "or", "and") may be divided by changing clauses into complete sentences. Other methods for shortening a long sentence include --

(1) Using a parallel listing structure (see 13.21 of this handbook); and

(2) Stating conditions, including exemptions and exceptions, in an organized manner (see 13.23 of this handbook).

(d) Sentence and clause length may be reduced by eliminating unnecessary words. When eliminating words, focus on the content words, for example, nouns, adjectives, and verbs. Word pairs, redundancies, and unnecessary qualifiers are the best targets. (See 13.31 of this handbook for help in trimming excess words.) Using a simpler sentence structure may reduce sentence length by eliminating excess words without removing necessary words. A simpler sentence structure requires fewer connecting words to effectively convey the meaning of the sentence.

13.19 Sentence construction.

The simple, active, affirmative, declarative sentence is the easiest sentence structure to understand. The more a sentence deviates from this structure, the harder the sentence is to understand. Each transformation from the basic sentence structure requires the reader to mentally translate the sentence back to its simpler form to understand its meaning. Each transformation increases the possibility that the reader will err in translating the sentence. Accordingly, the more complex the sentence, the greater the possibility for difficulty in determining the intended meaning of the sentence. In addition to sentence length, the following variables in sentence construction affect the ability of a reader to understand a sentence.

(a) Affirmative/negative. An affirmative statement is easier to understand than a negative statement. A reader is able to verify a positive construction more quickly and accurately. This is especially true in the double negative and negative type constructions frequently found in regulatory writing. Negative constructions, including exemptions, exceptions, or prohibitions, greatly increase the burden placed on the reader.

(b) Active/passive. A sentence in the active voice is easier to understand than a similar sentence in the passive voice. The active form of a statement is easier to verify and recall than the passive form. In addition, the active form generally forces the writer to

identify the actor and the action required in a sentence. This is especially important in a regulation that imposes certain requirements on specific parties (see also 13.25 of this handbook).

13.21 Listing.

(a) Listing is a valuable device for effectively simplifying regulatory writing. The writer may use the listing technique as an effective tool for shortening sentences and paragraphs. Listing makes sentences or sentence fragments that are parallel in thought parallel in form.

(1) Listing helps visually by breaking the solid mass of print presented in a block paragraph into visual chunks that aid in grouping information logically.

(2) Listing helps conceptually because it emphasizes the relationships between the various ideas and concepts contained in a regulation.

Example: Listing technique.

Before

§_____Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Atomic Energy Act of 1954, as amended, or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder. A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 57, 62, 81, 82, 101, 103, 104, 107, or 109 of the Act or section 206 of the Energy Reorganization Act of 1974, or any rule, regulation, or order issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime

and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

After

§_____Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of any provision of --

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

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

(3) A regulation issued under the requirements of the 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 for violation of --

(1) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(2) Any rule, regulation, or order issued under the requirements of the Act;

(3) Any term, condition, or limitation of any license issued under the Act; or

(4) Any violation for which a license may be revoked under section 186 of the Act.

(c) Any person who willfully violates any provision of the Atomic Energy Act or any regulation or order issued under the requirements of the Act may be guilty of a crime and, upon conviction, be punished by fine or imprisonment or both, as provided by law.

(b) Follow these guidelines when using the listing technique in a regulation:

(1) Each item in a list must belong to the same classification.

(2) Each item in a list must correspond to the introductory language for the list in substance and form.

(3) If the introductory language for the list is a complete sentence follow these instructions:

(i) End the introduction with a colon.

(ii) Make each item in the list a separate sentence.

(4) If the introductory language for the list is not a complete sentence --

(i) End the introduction with a dash;

(ii) End each item in the list except the last with a semicolon;

(iii) After the semicolon in the next-to-last item write "and" or "or" as appropriate; and

(iv) End the last item in the list with a period.

(c) The parallel structure created through listing is a handy organizing tool. It helps the reader identify similarities, differences, and the relationships between items.

13.23 Stating conditions.

State the conditions in a regulation in a manner that most easily allows the regulated party to determine the scope and intent of the regulation. If a provision contains a cause-and-effect or an if-then relationship, or if a requirement is dependent on certain factors, the method of presentation should clearly indicate these relationships. The following rules apply in stating conditions clearly.

(a) If one or two simple conditions must be met before a rule applies, state the condition first and then state the rule. This allows the reader to determine whether or not the rule applies to him or her before learning the rule.

Example:

If a debt is paid in one lump sum after the due date, the Commission shall impose a late payment charge.

(b) If two complex conditions or more than two conditions must be met before a rule applies, state the rule first then list the conditions. This technique helps avoid the confusion created by lumping a mass of conditions before a rule. When listing conditions, follow the guidelines for listing presented in 13.21 of this handbook.

Example:

(a) The Commission may withhold a sum equal to the amount of the alleged indebtedness from the amounts accruing to the individual on termination if --

(1) Amounts accruing to the debtor on termination are available for offset to satisfy the alleged indebtedness;

(2) The amounts would not be available for offset after termination; and

(3) The time before termination does not permit a preoffset hearing.

13.25 Use verbs effectively.

- o Use verbs in the active voice
- o Use action verbs
- o Use verbs in the present tense

(a) Active voice/passive voice. The active voice is almost always preferable to the passive voice in writing a regulation.

(1) A sentence written in the active voice identifies the subject performing the action. However, in a sentence written in the passive voice, the subject is acted upon. A regulation imposes a duty upon someone who is responsible for compliance. Enforcement is not possible if the duty to act is not clearly imposed on a specific party. A sentence in the passive voice may leave ambiguity or doubt.

Example:

Active: The licensee prepares and circulates an environmental impact statement before the Commission issues a permit to construct a nuclear power plant.
Passive: An environmental impact statement will be prepared and circulated before a permit to construct a nuclear power plant may be issued.

(2) In addition to naming the actor, sentences written in the active voice are generally shorter and more direct. The passive voice, especially a complete passive construction, requires more words to express the same thought clearly.

(b) Action verbs. Avoid the tendency to substitute a nominal, that is, a phrase using a noun made from a verb or a noun substitute such as a gerund or infinitive phrase, for the base verb.

Example:

| Say | Don't say |
|---|---|
| consider | give consideration to |
| provide for | make provision for |
| authorize | grant authorization for |
| state | make a statement |

(c) Present tense. Write a regulation in the present tense. A regulation is generally of continuing effect. It speaks as of the time it is applied, not as of the time it is drafted or becomes effective. Writing in the present tense also helps avoid awkward and complicated verb forms.

Example:

Say: The fine for a license violation is $10,000.
Don't say: The fine for a license violation will be $10,000.

13.27 Impose an obligation or prohibition properly.

- o Proper use of shall, may, must
- o Proper use of may not

A regulation usually requires or prohibits the performance of certain specified actions by an individual or class of persons. This section discusses the standard conventions used in most regulatory writing to impose an obligation, indicate discretionary action, and express a prohibition.

(a) Shall. Use "shall" to impose an obligation on an individual or legal entity capable of performing the required action.

(b) Must. Use "must" as the proper mandatory form when the subject is an inanimate object. Must is also used to indicate a precondition.

(c) May. Use "may" to indicate that an individual or entity has the discretion to take a specific action but is not required to do so.

(d) May not. Use "may not" to indicate that a person or entity is prohibited from taking a specific action.

Examples:

Each licensed institution shall establish a Radiation Safety Committee.

At least one member of the committee must be a physician specializing in nuclear medicine. (Precondition.)

The required records must be readily accessible. (Inanimate object.)

The Commission may request any additional information necessary to ensure that adequate protection systems have been established.

The licensee may not use byproduct material in any manner not specified in the license.

13.29 Choose words carefully.

- o Use words consistently
- o Use concrete words
- o Use familiar words

(a) Consistency. Use consistent terminology throughout a regulation. The following guidelines will help a writer avoid the confusion and potential misinterpretation of a regulation that often occurs because of inconsistent word usage.

(1) Do not use the same word or phrase to denote different things.

(2) Do not use different words or phrases to denote the same thing.

(3) Do not use a synonym to denote differences in substance.

(b) Concrete words. Using concrete words instead of abstract words makes writing more readable and more precise. Words are symbols. They have varying degrees of abstraction and shades of meaning. Concrete words are words that are more likely to create the desired mental image in the mind of a reader. Concrete words, particularly those with a sensory base, narrow and control the types of images produced for a reader. This results in more precise communication.

Example:

Say: The operator must be able to see the entire control panel.

Don't say: The systems integration specialist must be able to visually perceive the entire directional response module.

(c) Familiar words. Use words that are likely to be familiar to the reader. Words that are common to and frequently used in normal communication are more easily recognized and understood by the average reader. Familiar words, especially content words with a high degree of frequency, contribute to more readable writing. Always choose a familiar word over an unfamiliar word. Among familiar words, prefer the simple word to the stuffy word.

Example:

| Say | Don't say |
|---|---|
| End | Terminate |
| Use | Utilize |
| Explain | Elucidate |

13.31 Be concise.

- o Avoid redundancies
- o Remove compound prepositions
- o Trim word clusters

Do not use more words than necessary to convey the intended meaning of the regulation. The writer, through careful editing, can remove surplus words. Removing surplus words results in shorter sentences without affecting content words or the connecting or function words necessary to convey the meaning of the sentence.

(a) Avoid redundancies. Do not repeat words or ideas unnecessarily.

(1) Do not present both the positive and negative statements of an idea when one alone is sufficient. The positive statement is usually preferable.

(2) Avoid word pairs if the words have the same effect or where the meaning of one includes the other.

Examples: Word pairs to avoid.

Any and all
Authorized and empowered
Each and every
Full and complete
Order and direct
Sole and exclusive
Authorize and direct
Means and includes
Necessary and desirable

(b) Prepositions. Avoid compound prepositions and roundabout prepositional phrases when the same meaning can be conveyed with a single word. These phrases only bloat a sentence with needless words that tend to obscure the intended meaning.

Examples:

| Say | Don't say |
|---|---|
| then | at that point in time |
| today | as of this date |
| now | at the present time |
| by | by means of |
| for | for the purpose of |
| because | for the reason that |
| for | from the point of view of |
| concerning | in connection with |
| to | in order to |
| in | in terms of |
| if | in the event that |
| like | in the nature of |
| by | on the basis of |
| because | on the grounds that |
| before | prior to |
| after | subsequent to |
| to | with a view to |
| about | with reference to |
| about | with regard to |

(c) Word clusters. Most word clusters are bad habits that a writer uses consistently. Trimming these "throat clearing" constructions is good editorial practice.

Examples:

| Say | Don't say |
| --- | --- |
| during | during the time that |
| for | for the period of |
| by, under | in accordance with |
| often | in many cases |
| sometimes | in some instances |
| doubtless | there is no doubt that |
| until | until such time as |

13.33 Use jargon sparingly.

- o Use jargon only where necessary
- o Explain key terms or concepts

Jargon is the technical language used by people in the same field to communicate. Normally, most writers weed out jargon in editing their work. However, some jargon is inescapable in NRC's highly technical regulatory writing. The writer may use jargon only when the language is appropriate to communicate technical concepts to the party being regulated. Even then, the writer should explain key technical words or concepts that may be unfamiliar to the non-technical reader. The explanation may appear the first place the term is used in regulatory text, in the definitions or concepts section, or in the preamble to the document.

Examples:

1. Anticipated Transients Without Scram (ATWS). An ATWS event takes place if an abnormal operating condition (anticipated transient) occurs at a nuclear power plant which could cause the reactor protection system to initiate a rapid shutdown (scram) of the reactor but the reactor shutdown system fails to function.

2. NRC licenses institutions and individual physicians in private practice to use byproduct materials on humans under the group medical license. Radioactive materials licensed under 10 CFR Part 35 are divided into six groups. Each group has similar requirements for user training and experience, facilities and equipment, and radiation safety procedures. The purpose of this grouping is to reduce administrative

costs by eliminating the need for licensees to seek an amendment to their license each time they wish to use an additional radiopharmaceutical in a group for which they are licensed. Under the grouping procedure, the NRC treats an application for use of a radiopharmaceutical in a group as an application for any radiopharmaceutical in that group.

13.35 Avoid legalisms.

- o Avoid legal word pairs
- o Eliminate legalisms

(a) Legal word pairs. These legal redundancies are the lawyer's version of the word pairs discussed in 13.31 (a) of this handbook. Legal word pairs stem from periods in English history when the English lawyer had two languages to choose from. The lawyer frequently used a word from each language, joined in a pair, to express a single meaning. This doubling enabled persons of each language to understand the intent of the law. However, this doubling became traditional and persists long after the practical purpose for it has ended. In drafting a regulation, replace a needless string of words having the same meaning with one of the words or a new word.

Examples: Avoid these legal word pairs.

Alter or change
Cease and desist
Force and effect
Full and complete
Order and direct
Perform and discharge
Unless and until

(b) Legalisms. Substitute simple everyday words for legalisms. Legalisms may create a false sense of precision that often obscures gaps in analysis.

(1) Do not use "such" or "said" as adjectives to refer back to things already mentioned. The extra precision supposedly gained in preferring these terms to the more commonly used "the" or "this" is illusory. If only one reactor is mentioned, there is no danger of anyone mistaking "the" reactor or "this" reactor for any other. If more than one reactor is mentioned, "such" reactor or "said" reactor does not indicate which of several is meant.

(2) Avoid vague legalistic references such as "aforementioned," "hereby," "herein," "hereinafter," "hereinabove," and "therein." Identify the intended reference precisely.

(3) Other legalisms to avoid in regulation drafting are identified in the following examples.

Examples:

| Say | Don't say |
|---|---|
| Postpone action | abeyance |
| Allow, permit | afford an opportunity |
| End, conclude | finalize |
| Completely | fullest possible extent |
| Carry out | implement |
| Issue | promulgate |
| Under | pursuant to |
| End | terminate |
| Use | utilize |
| verify | verification |

13.37 Avoid ambiguity.

- o Word order
- o Word meaning

(a) Word order. The position of words in a sentence is the primary means of indicating their relationship. Ambiguity resulting from word order can be avoided by keeping related sentence elements together and unrelated sentence elements apart.

(1) Place modifiers as close to the words they are intended to modify as possible. A modifier will tend to attach itself to the nearest word eligible for modification.

Example:

Don't say: Appeals of fines, which may not exceed $1,000, must be made within 30 days. (What may not exceed $1,000, the appeal or the fine?)
Say: Appeals of fines may not exceed $1,000. An appeal must be made within 30 days.
Unless you mean: Fines may not exceed $1,000. Appeals of fines must be made within 30 days.

Don't say: The licensee may use the building only for storage.
Say: The licensee may use the building for storage only.
Unless you mean: Only the licensee may use the building for storage.

(2) Avoid using indefinite pronouns as references.

Example:

Say: After the shift supervisor appoints an assistant, the assistant shall supervise.....
Don't say: After the shift supervisor appoints an assistant, he or she shall supervise..... (Does the shift supervisor or the assistant supervise?)

(b) Word meaning. The most common source of ambiguity in word meaning results from the use of plural nouns. Using a singular noun instead of a plural noun avoids the problem of whether the rule applies separately to each member of a class or jointly to the class as a whole.

Example:

Don't say: The guard shall issue security badges to the employees who work in Building D and Building E.
Say: The guard shall issue a security badge to each employee who works in either Building D or Building E.
Unless you mean: The guard shall issue a security badge to each employee who works in both Building D and Building E.

PART 15 - SAMPLE DOCUMENTS

15.1 Advance notice of proposed rulemaking. [7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

Consideration of Degraded or Melted Cores in Safety Regulation

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission is considering amending its regulations to determine to what extent commercial nuclear power plants should be designed to cope with reactor accidents beyond those considered in the current "design basis accident" approach. In particular, this rulemaking will consider the need for nuclear power plant designs to be evaluated against a range of degraded core cooling events and assess the need for design improvements to cope with these events and the resulting core damage. This advance notice of proposed rulemaking is being issued to invite advice and recommendations on several questions concerning design and operational improvements for dealing with degraded core cooling.

DATE: The comment period expires_____. Comments received after this date will be considered if it is practical to do so but assurance of consideration cannot be given except as to comments received before this date.

ADDRESSES: Mail comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Deliver comments to: Room 1121, 1717 H St. NW., Washington, D.C., between 8:15 a.m. and 5:00 p.m.

Examine copies of comments received at: The NRC Public Document Room, 1717 H St. NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 443-1111.

SUPPLEMENTARY INFORMATION:

HISTORICAL BACKGROUND

The Nuclear Regulatory Commission is responsible for licensing and regulating nuclear power plants. Before a nuclear power plant can be built at a particular site, a construction permit must be obtained from the NRC. As a major part of the application for a construction permit, the applicant files a Safety Analysis Report. This report presents the design criteria and preliminary design information for the proposed nuclear power plant and provides information on the proposed site. The report also discusses various abnormal conditions and accident situations and describes safety features to be provided to prevent accidents or, if they should occur, to mitigate their effects on public health and safety.

In nuclear power plants, large amounts of radioactive material are generated during fission of nuclear reactor fuel. Although this radioactive material generally remains in the fuel pellets, significant amounts can be released to the reactor coolant during accident conditions. For appreciable

amounts of radioactive material to be released from the fuel, it must experience damage from one or more of several possible causes. For example, a hydraulic-mechanical accident at normal fuel temperatures can burst fuel cladding, resulting in release of radioactive material normally retained in the gap between the fuel pellets and the fuel clad. A more serious type of accident involving higher fuel temperatures might, in addition to rupturing fuel cladding, cause oxidation of the cladding. This, in turn, would cause hydrogen to be generated and released that would compound the severity of the accident. A still more serious accident might involve very high fuel temperatures and oxidation of a large fraction of the core's zirconium. In this case, not only would large amounts of hydrogen be released to the containment building, but other thermal reactions could result in the release of radioactive material normally held captive in the fuel pellets. Finally, an accident so severe that core melting occurs could release large amounts of radioactive material to the environment if reactor containment integrity were also to be lost.

Based on these considerations, a broad range of nuclear power plant abnormal conditions and accidents with the potential to cause fuel clad damage and release of radioactive material to the environment have been identified and categorized for analysis. Attempting to prevent abnormal conditions and accidents and mitigating their potential consequences have been the primary objectives of nuclear power plant safety design. The Safety Analysis Report is a key document supporting the adequacy of this aspect of nuclear power plant design.

As discussed in 10 CFR 50.34(a), the applicant is required in the Safety Analysis Report to determine margins of safety for both normal and abnormal operations and to determine "the adequacy of structures, systems, and components

provided for prevention of accidents and the mitigation of the consequences of accidents." To assist the applicant in complying with this regulation, the NRC has published Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power plants,"[1] which describes the information to be provided in the Safety Analysis Report. In particular, section 15 of Regulatory Guide 1.70 provides guidance to an applicant concerning "design basis assumptions acceptable to the NRC for purposes of determining adequacy of the plant design to meet 10 CFR Part 100 criteria." Regulatory Guide 1.70 explains that these design basis assumptions can, for the most part, be found in regulatory guides that deal with radiological releases and suggests use of Regulatory Guides 1.3 and 1.4, "Assumptions Used for Evaluation of the Potential Radiological Consequences of a Loss-of-Coolant Accident."[1] Regulatory Guide 1.70 further states that "This analysis should be referred to as the 'design basis analysis'." Operating events corresponding to design basis assumptions are termed "design basis accidents," and satisfactory analysis conclusions concerning them allow a judgment that the facility can be operated without undue risk to the health and safety of the public.

Accidents under consideration include a range of loss-of-core-cooling, core damage, and core-melting events both inside and outside historical design envelopes. Furthermore, the Commission will consider whether to require more coherent consideration of this range of core damage events in the design of both normal operating systems and engineered safety features.

Therefore, this advance notice of proposed rulemaking is being published to provide the regulated industry and the public an opportunity to provide

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[1]Available from the Nuclear Regulatory Commission by writing to the Director, Division of Technical Information and Document Control, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

advice and recommendations to the Commission on what should be the content of a regulation requiring improvements to cope with degraded core cooling and with accidents not covered adequately by traditional design envelopes. The rulemaking proceeding will address the objectives of the regulation, the design and operational improvements being considered, the effect on other safety considerations, and the costs of design improvements compared to expected benefits.

In addition to this document, the Commission's Office of Nuclear Regulatory Research is making a direct mailing to affected licensees and other known interested persons to ensure that they are aware of this advance notice of proposed rulemaking.

## SUMMARY OF FEATURES BEING CONSIDERED FOR PROPOSED RULE

The Commission is considering initiating rulemaking that would require that a broader range of accidents of both lesser and greater severity than the design basis accidents, including a fully melted core, be considered in plant design, plant operation, and reactor safety analyses.

## SPECIFIC CONSIDERATIONS

Advice and recommendations on a proposed rule reflecting the foregoing feature and on any other points considered pertinent are invited from all interested persons. Comment is also invited on the extent to which any additional measures should be backfitted. Comments and supporting reasons are particularly requested on the following questions:

1. If loss of core cooling and resultant core damage occur in a nuclear power plant, there are certain predictable consequences. Can these consequences be mitigated substantially, and the risk of severe public health danger thereby

reduced substantially, by practical design improvements? If not, why not, or, if so, what design improvements can be made and at what estimated cost? How would your recommendations affect other safety considerations?

2. The Three Mile Island accident was terminated after the core was damaged severely but before substantial melting occurred, a condition beyond the current design-basis-accident events considered in the safety analysis. Should the NRC require that events of this type be considered in future safety analyses? If not, why not, or, if so, what criteria would you impose to judge design acceptability?

3. In weighing the costs of design and operational improvements to cope with degraded core cooling against the benefits of their use, what quantitative methods or other guidance would you suggest to facilitate preparation of a useful regulatory analysis? Would you consider useful or appropriate comparisons between nuclear power plant risks and other risks to which people are exposed?

4. What aspects of degraded cooling or melted-core accidents are sufficiently unknown or uncertain as to impede design and analysis of mitigating systems, thus requiring additional research or experimentation?

The preliminary views expressed in this notice may change in light of comments received. In any case, there will be an opportunity later for additional public comment in connection with any proposed rule that may be developed by the Commission.

LIST OF SUBJECTS IN 10 CFR PART 50

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

The authority citation for this document is: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201).

Dated at Washington, D.C., this ____ day of _____, 1982.

For the Nuclear Regulatory Commission.

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Samuel J. Chilk,
Secretary of the Commission.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Measurement of Radiopharmaceutical Dosage Activity

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission proposes to amend its regulations on human uses of byproduct material to require specific medical licensees to assay each radiopharmaceutical dosage before it is administered to a patient. Measurement of the total activity of radiopharmaceutical dosages helps to protect patients from unnecessary radiation resulting from errors in labeling, calculating, or dispensing dosages. The proposed rule would simplify licensing and enhance patient radiation safety by minimizing potential misadministrations.

DATE: Comment period expires _____. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Deliver comments to: Room 1121, 1717 H Street, NW., Washington, D.C., between 8:15 a.m. and 5:00 p.m. weekdays.

Copies of the regulatory analysis, OMB clearance supporting statement, and comments received may be examined at: the NRC Public Document Room at 1717 H St. NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427-2222.

SUPPLEMENTARY INFORMATION:

## BACKGROUND

NRC specific medical licensees are currently required by a license condition to measure the activity of radiopharmaceutical dosages before administering them to patients. The NRC is proposing to change the measurement requirement from a license condition to a regulation that would affect specific licensees. Changing the license condition to a regulation will --

(1) Stress that the measurement is applicable to all specific medical licensees;

(2) Increase the visibility of the measurement requirement; and

(3) Emphasize the importance of the measurement.

The activity of radiopharmaceutical dosages is measured by lowering the syringe, capsule, or vial containing the radioactive drug into an ionization chamber, such as a dose calibrator, and reading the total activity from the display. Measuring the activity before radiopharmaceuticals are administered is important because manufacturers can make mistakes in labeling. In addition, nuclear medicine personnel (technologists, radiopharmacists, or physicians) can make errors in reading labels, calculating dosages, or dispensing volumes. These errors could result in unnecessary radiation to patients who could receive either larger dosages than prescribed or additional dosages if the

initial dosages were too small. Measurement of the activity of radiopharmaceuticals administered to patients is, therefore, an important quality assurance function that can prevent certain misadministrations.

A few of the radioactive drug dosages used in nuclear medicine may be difficult to quantify accurately in a conventional dose calibrator. For example, the small activity used for vitamin B-12 studies is below the detection sensitivity of some dose calibrators. For this reason, the proposed total activity measurement is limited to activities greater than 10 microcuries. However, as provided for in the proposed rule, activities that are under this limit would be verified by placing the dosage in a dose calibrator to ensure that the activity is actually less than ten microcuries. This stipulation would help to protect patients from errors made in reading units (for example, millicuries read as microcuries) and calculations incorrect by an order of magnitude (for example, 100 instead of 10). Pure beta-emitting radionuclides, such as phosphorus-32, are exempted from the proposed measurement because of the technical problems associated with their measurement in conventional dose calibrators. Most dosages would be covered by the proposed rule since over 90 percent of the radiopharmaceuticals administered to patients contain gamma-emitting radionuclides in quantities greater than 10 microcuries.

## DESCRIPTION

The proposed rule would apply to all NRC medical licensees who have specific licenses for human use of byproduct material under § 35.11 (which applies to medical institutions) or § 35.12 (which applies to physicians in private practice outside a medical institution). The proposed § 35.15 would require these licensees to measure the total activity of all radiopharmaceutical dosages except those containing a pure beta-emitting radionuclide before

administering them to patients. Dosages with activity less than 10 microcuries would be measured only to verify that the activity did not exceed 10 microcuries. The proposed § 35.16 would require licensees to keep a record of the measurements. The record would include the following information: (1) the generic name of the radiopharmaceutical, (2) the total activity at the time of measurement (or a notation that the total activity is less than 10 microcuries), and (3) the date and time of the measurement. Licensees would keep the measurement records for 1 year as a reasonable demonstration of compliance.

When the licensee has an "in-house" nuclear pharmacy under the same license, the measurement and record made by the nuclear pharmacy would fulfill the requirements in §§ 35.15 and 35.16. However, when the licensee obtains radiopharmaceutical dosages from a nuclear pharmacy or drug manufacturer with a separate NRC license, the licensee administering the radiopharmaceutical would make the activity measurement and keep the record required by the proposed §§ 35.15 and 35.16.

## IMPACT

The impact of the measurement requirement on the affected licensees should be minimal since they already measure the activity of radiopharmaceuticals administered to patients as a license condition and thus have the equipment, personnel, and time to make the measurement. Personnel time required to perform the measurement--place the syringe in the chamber, wait for the readout, and retrieve the syringe from the chamber--is about 15 seconds. Therefore, the proposed rule would require a licensee to spend a total of about 7 hours annually to perform the measurements (derived by multiplying 15 seconds per day per assay by the average number of nuclear medicine procedures per licensee annually, about 1,712, and converting the result into

hours). In addition, based on published data, the maximum exposure to the hands of a worker during daily assay operations in a busy nuclear medicine department (12 mR/day) is estimated to be about 0.75 R per calendar quarter. This exposure results in about 4 percent of the maximum permissible dosage per quarter of 18-3/4 rems to the hands of an individual working in a restricted area as established in 10 CFR 20.101.

## PAPERWORK REDUCTION STATEMENT

The proposed rule will be submitted to the Office of Management and Budget for clearance of the information collection requirements that may be appropriate under the Paperwork Reduction Act (Pub. L. 96-511). The SF-83, "Request for Clearance," Supporting Statement, and related documentation submitted to OMB will be placed in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C. 20555. The material will be available for inspection or copying.

## REGULATORY FLEXIBILITY CERTIFICATION

Based upon the information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that, if promulgated, this rule will not have a significant economic impact upon a substantial number of small entities. The proposed rule affects about 2,000 specific licensees under 10 CFR 35.11 or 35.12. These licensees are primarily medical institutions. Small business entities, primarily physicians in private practice, comprise about 275 of the specific medical licensees. Since 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.

The impact of the recordkeeping requirement on the affected licensees should be minimal since most medical licensees currently maintain records similar to those proposed. The total time required by a licensee to make each record is estimated at about 40 seconds. Multiplying the time per licensee (1,712) and converting the result into hours yields an annual burden of about 19 hours per licensee to perform the proposed recordkeeping. 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 which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates --

(a) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a larger licensee;

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

(d) The benefits that would be gained or the detriments that would be avoided by the licensee if the proposed regulations were modified as suggested by the commenter; and

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

## LIST OF SUBJECTS IN 10 CFR PART 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting requirements.

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 amendment to 10 CFR Part 35.

## PART 35 - HUMAN USES OF BYPRODUCT MATERIAL

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

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.2, 35.14(b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31(b) and (c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14(b)(5)(ii), (iii) and (v) and (f)(2), 35.25 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Part 35 is amended by adding, immediately after § 35.14, a new undesignated centerhead to read as follows:

3. New §§ 35.15 and 35.16 are added to read as follows:

§ 35.15 Requirement to measure the activity of radiopharmaceutical dosages.

Any licensee authorized under §§ 35.11 or 35.12 for human use of byproduct material shall --

(a) Measure the total activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a radionuclide that emits electromagnetic radiation in the form of gamma rays or x-rays before the dosage is administered to a patient; or

(b) Measure to verify that the total activity does not exceed 10 microcuries for each radiopharmaceutical dosage with an activity of 10 microcuries or less.

§ 35.16 Records of measurements.

(a) The licensee shall preserve, for Commission inspection, the records of the measurements required in for 1 year following the date of the measurement.

(b) Records of the measurements made under § 35.15 must contain the --

(1) Generic name of the radiopharmaceutical;

(2) Total activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries; and

(3) Date and time of the measurement.

Dated at Bethesda, Maryland, this ____ day of _____, 1982.

For the Nuclear Regulatory Commission.

_____
William J. Dircks,
Executive Director for Operations.

15.3 Final rule. [7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

Physical Protection of Intransit Special Nuclear Material of Moderate Strategic Significance

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its physical protection regulations for special nuclear material of moderate strategic significance to improve licensee safeguards capabilities for early detection of the possible theft of this material while it is in transit. These improvements include (1) maintaining the material under lock or under the control of a responsible individual, (2) confirming the status of shipments while enroute, and (3) employment of either dedicated use transports or signature acknowledgment of custody of shipments. The intent of these amendments is to ensure close monitoring of shipments of special nuclear material of moderate strategic significance in order to achieve early detection of loss or theft of the material so that repeated thefts can be prevented.

EFFECTIVE DATE:

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Regulatory Improvements Branch, Division of Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427-3333.

SUPPLEMENTARY INFORMATION:

## BACKGROUND

The Commission has been concerned that possible multiple thefts of special nuclear material (SNM) of moderate strategic significance could result in the accumulation by an adversary of more strategically significant quantities of special nuclear material. To help prevent this, current physical protection requirements for SNM of moderate strategic significance were designed to help provide early detection of an initial theft of this material. Early detection would allow the Commission to take further action to ensure that additional thefts could be prevented. On June 15, 1981, the Commission published proposed amendments in the Federal Register (46 FR 31267) to require additional physical protection for intransit SNM of moderate strategic significance. These amendments were to improve the licensee's capabilities for early detection of possible thefts of the material by requiring (1) use of locked cargo compartments or temporary intransit storage areas containing the material while enroute, (2) periodic communications between the licensee and the transport vehicle, and (3) employment of exclusive use vehicles or signature acknowledgement of all custody transfers for road shipments. A sixty-day comment period expired on August 15, 1981. Comments were received from eight respondents.

## SUMMARY OF PUBLIC COMMENT

The proposed amendments have been modified in response to the comments received and will be published in final form, as modified, to become effective

30 days after publication of this notice. Changes were made in response to the public comments to better reflect services that could be provided by common carrier(s) and also to provide clarification where necessary. A summary of the public comments and, where appropriate, a description of the changes that resulted from them follows:

(1) Need for these amendments. All but one of the commenters questioned the need for additional physical protection requirements for the affected shipments. They suggested that current requirements allowing the NRC to order delays in these shipments to keep formula quantities of SNM from being in transit at the same time would be unnecessarily redundant with additional physical protection requirements for individual shipments.

The final amendments complement existing regulations that allow the NRC to order shipment delays for safeguards purposes. They provide for closer licensee control over shipments and better traceability so that the chances of having to delay a shipment will be decreased. With regard to the comment concerning those shipments of low enriched uranium covered by these amendments, it should be noted that it is unlikely that shipments of low enriched uranium large enough to be affected by the proposed amendments would occur. The reason that large quantity shipments of low enriched uranium are subject to these amendments is because of commitments to the International Atomic Energy Agency (IAEA).

(2) Locking requirements. The proposed amendments would have required the material to be transported in a locked cargo compartment, and during road shipments, to be kept under lock while in transit or in temporary storage enroute. Many commenters noted that these locking requirements would be impossible to comply with in the case of less-than-truckload shipments and most air shipments, the modes primarily used in past shipments. The loading

and unloading of other cargo, it was stated, precludes maintaining the material continuously under lock. Also, most aircraft do not have lockable cargo compartments. It was also stated that storage of the material in a locked area was not always feasible for import and export shipments.

It was anticipated by commenters that some carriers might refuse to carry the material if the proposed amendments became effective, and that less-than-truckload shipments would be effectively eliminated. Commenters also questioned whether the purpose of the proposed locking requirements was to prevent rather than detect theft.

The final amendments permit an alternative to the lock requirements. This alternative provides for maintaining the material under the control of a responsible individual where the use of locks is not practicable. Under this alternative, the shipment should be kept under continuous observation or be checked periodically by a responsible individual to ensure its continued integrity. Periodic checking of the shipment could be facilitated by inspecting the seals required on NRC-approved shipping containers, or by use of an appropriate seal placed on the cargo compartment or temporary storage areas containing the shipment. The responsible individual also should ensure the correct routing of the shipment, and should ensure that the licensee or its designee is notified immediately if the material is determined to be missing. The responsible individual in each case will be required to be an individual who has acknowledged by signature acceptance of custody of the material.

For air shipments, these requirements could be satisfied by requesting the signature security service provided by air carriers. This service provides routing control, surveillance, and periodic checking of shipments. For road shipments, common carriers of less-than-truckload quantities should be able to provide service consistent with these requirements under special arrangements

and at a cost less than what would be charged for an exclusive use vehicle. A revised regulatory guide will be published to reflect these changes, which will describe in further detail the appropriate means for complying with the requirements for maintaining control of the shipments.

(3) Exclusive use vehicles. Some commenters questioned the use of the term "exclusive use vehicle." It was claimed that prohibiting other cargo from being transported in the same vehicle with a shipment of SNM of moderate strategic significance would not necessarily affect the security of the shipment and thus is unjustified. The term "exclusive use vehicle" was used in the proposed amendments in reference to a type of service routinely offered in the motor freight industry. In order to avoid confusion, the term "exclusive use vehicle" does not appear in the final amendments. More descriptive language focusing only on the security aspects of these shipments has been substituted.

One commenter also suggested that the requirement for exclusive use vehicles goes beyond the stated objective of the proposed rule. Since use of an exclusive use vehicle itself would not prevent the theft of this material, it would not appear to be inconsistent with ensuring early detection of a possible theft. Also, it should be noted that the final amendments permit the use of alternative means for satisfying this objective.

(4) Communications. Some commenters considered the proposed requirement for periodic communications between the shipper, receiver, or their designee, and the transport vehicle to be unnecessary since they supplement existing requirements for tracing lost or unaccounted-for shipments and notifying authorities. It also was suggested that communications more often than every several hours would slow shipments, greatly increase operating costs, and effectively eliminate less-than-truckload shipments. Conversely, however, one commenter endorsed the proposed periodic communications requirement and

suggested exclusive use vehicles be used, equipped with satellite-based navigation receivers and transmitters.

Some commenters questioned specifically whether communications would be required during periods when the shipment was in temporary storage and whether the requirement was intended to apply to all modes or only to road shipments. With regard to the periodic communications requirement, the objective of early detection could be achieved by periodic reports from the carrier on the shipment's status relative to a predetermined itinerary. Several airfreight and motor freight carriers who have previously handled shipments of special nuclear material are known to provide the appropriate tracing services at no additional cost. Computerized data bases maintained by some of the motor freight carriers are generally updated every 10 to 14 hours, and more frequently in the case of air shipments.

Concerning the use of a satellite communications system, as suggested by one commenter, this could conceivably satisfy the proposed communications requirements but it would not be appropriate for the Commission to require a particular system design or type of hardware in preference to other acceptable alternatives.

(5) Cost effectiveness. Some commenters stated that the proposed amendments would result in cost increases that would have a significant impact on the operations of nonpower reactor facilities that must financially justify their existence even though they might be subsidiaries of much larger companies or institutions. Generally, these statements appear to have been based on the premise that the proposed amendments would force licensees to utilize exclusive use vehicles for road portions of shipments in preference to less-than-truckload shipments.

As stated earlier, the additional physical protection measures included in the proposed amendments were not intended to force licensees to utilize exclusive use vehicles for road shipments. Based upon information developed in staff inquiries, the modifications to the proposed amendments will make it possible for licensees to satisfy the additional physical protection requirements for shipments of SNM of moderate strategic significance while continuing to employ common carriers provided they can make special arrangements for the required services. This should be possible to arrange at a cost significantly less than if an exclusive use vehicle were required. Thus, the Commission has determined that the additional physical protection measures are cost effective in balancing the additional protection provided against the additional cost.

## PAPERWORK REDUCTION REVIEW

The application requirements contained in this regulation have been approved by the Office of Management and Budget, OMB approval No. 3150-0002 (expires May 31, 1983).

## REGULATORY FLEXIBILITY STATEMENT

As required by the Regulatory Flexibility Act of 1980, 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 requires certain improvements in the capabilities of physical protection systems provided by licensees to protect against the theft or loss of special nuclear material of moderate strategic significance while this material is in transit. These improvements would increase the cost of shipment of this material in absolute terms, but the total costs of transportation would generally remain less than one percent of the value of the material shipped. In addition, the number of

shipments expected to be made annually is quite low, estimated to be about thirty shipments per year based upon past experience in the nuclear industry. Approximately 37 licensees possessing special nuclear material of moderate strategic significance could be affected by these amendments, 27 of whom operate nonpower reactors. In addition to these 37 licensees, there are about six licensees possessing formula quantities of strategic special nuclear material who may occassionally choose to ship their material in less than formula quantities. All the licensees potentially affected are either large private or state universities; large corporations, each employing in excess of 500 persons having annual sales or revenues in excess of $1 million; or state or Federal agencies. Less than ten of the affected licensees are small colleges or businesses that fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards in regulations issued by the small Business Administration at 13 CFR Part 121.

## LIST OF SUBJECTS IN 10 CFR PART 73

Hazardous materials - transportation, Nuclear materials, Nuclear power plants and reactors, Penalty, Reporting requirements, Security measures.

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, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 73.

## PART 73- PHYSICAL PROTECTION OF PLANTS AND MATERIALS

1. The authority citation for Part 73 is revised to read as follows:

AUTHORITY: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, Pub. L. 96-295, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, 88 Stat. 1242, as amended, sec. 204, 88 Stat. 1245 (42 U.S.C. 5841, 5844).

Section 73.37(f) is also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 73.37(g), 73.55 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 73.20, 73.24, 73.25, 73.26, 73.27, 73.37, 73.40, 73.45, 73.46, 73.50, 73.55, 73.67 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 73.20(c)(1), 73.24(b)(1), 73.26(b)(3), (h)(6), and (k)(4), 73.27(a) and (b), 73.37(f), 73.40(b) and (d), 73.46(g)(6) and (h)(2), 73.50(g)(2), (3)(iii)(B) and (h), 73.55(h)(2), and (4)(iii)(B), 73.70, 73.71, 73.72 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 73.67 paragraph (e) is amended by revising paragraphs (e)(1)(iv), the introductory text of (e)(3), paragraphs (e)(3)(i), (e)(3)(vi), and by adding new paragraphs (e)(3)(vii), (e)(3)(viii), (e)(6) and (e)(7) to read as follows:

§ 73.67 Licensee fixed site and intransit requirements for the physical protection of special nuclear material of moderate and low strategic significance.

* * * * *

(e) * * *

(1) * * *

(iv) Check the integrity of the container and locks or seals prior to shipment, and

* * * * *

(3) Each licensee who arranges for the intransit physical protection of special nuclear material of moderate strategic significance, or who takes delivery of this material free on board (f.o.b.), the point at which it is delivered to a carrier for transport, shall --

(i) Arrange for telephone or radio communications between the transport and the licensee or its designee: (A) to periodically confirm the status of the shipment, (B) for notification of any delays in the scheduled shipment, and (C) to request appropriate local law enforcement agency response in the event of an emergency.

* * * * *

(vi) Initiate immediately a trace investigation of any shipment that is determined to be lost or unaccounted for after a reasonable time beyond the estimated arrival time at the final destination, or during the course of the shipment, and report to the Nuclear Regulatory Commission as specified in § 73.71 and to the shipper or receiver, as appropriate;

(vii) Make all shipments of the material either (A) in dedicated transports with no intermediate stops to load or unload other cargo and with no custody or vehicle transfers or temporary storage enroute or (B) under arrangements whereby the custody of the shipments and all custody transfers are acknowledged by signature, and

(viii) Maintain the material under lock or under the control of an individual who has acknowledged acceptance of custody of the material by signature.

* * * * *

(6) Submit by [1]_____, a security plan or an amended security plan describing how the licensee will comply with all requirements of

§ 73.67(e)(1), (e)(2), and (e)(3), as appropriate, including schedules of implementation.

(7) Within 180 days after the effective date of these amendments [2] _____ or 60 days after the plan(s) submitted under paragraph (e)(6) of this section is approved, whichever is later, implement the approved security plan.

* * * * *

Dated at Washington, D.C., this _____ day of _____, 1982.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

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[1] Insert date 120 days after the date of publication in the Federal Register.

[2] Insert date 210 days after the date of publication in the Federal Register.

15.4 Package prepared for EDO signature.

NOTES: The Commission has broadened the rulemaking authority that is delegated to the Executive Director for Operations (EDO) in a final rule published in the Federal Register on March 19, 1982 (47 FR 11816). The EDO, subject to general policy guidance from the Commission, now has the authority to issue all proposed or final rules except those involving --

(1) A significant question of policy; or

(2) 10 CFR Parts 0, 2, 7, 8, 9, Subpart C, and 110.

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

(1) Represents a major change in existing Commission policy;

(2) Represents a major new issue; or

(3) Will result in a major commitment of resources by a class of licensee.

This sample package presents, in proper format, the elements required when submitting a proposed or final rule to the EDO for approval and issuance. The sample package consists of three parts.

(1) The memorandum to the EDO requesting that the EDO issue the document.

(2) The Federal Register document.

(3) The note to be inserted in the Weekly Report to the Commission for a proposed rule or the Daily Staff Notes for a final rule.

This sample package has been compressed for purposes of this example. Similar amendments to each part of 10 CFR Chapter I in which regional telephone numbers are set out would normally be made in the document.

Part 1 - Memorandum to the EDO.

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

THRU: Daniel J. Donoghue, Director
Office of Administration

FROM: J. M. Felton, Director
Division of Rules and Records
Office of Administration

SUBJECT: AMENDMENT TO 10 CFR PART 21 TO REFLECT NEW TELEPHONE NUMBER FOR NRC'S REGION IV OFFICE

Attached for your signature is a Federal Register notice amending Part 21 of the NRC's regulations to reflect the new telephone number for NRC's Region IV office.

Since this action is a minor procedural matter, notice of proposed rulemaking and public procedure thereon are unnecessary, and good cause exists to make the amendment effective upon publication in the Federal Register. Congressional committees will not be notified. A public announcement will not be issued.

A note regarding the issuance of the rule will be included in the next Weekly Report to the Commission.

Coordination:

The Office of Administration, the Office of Inspection and Enforcement, and the Office of Public Affairs concur in this matter. The Office of the Executive Legal Director has no legal objection.

J. M. Felton, Director
Division of Rules and Records
Office of Administration

Approved For Publication

In a final rule published March 19, 1982 (47 FR 11816), the Commission delegated to the EDO (10 CFR 1.40(c) and (d)) the authority to develop and promulgate rules as defined in the APA (5 U.S.C. 551(4)) subject to the limitations in NRC Manual Chapter 0103, Organization and Functions, Office of the Executive Director for Operations, paragraphs 0213, 038, 039, and 0310.

The enclosed final rule entitled "Change of Telephone Number for NRC Regional IV Office" amends 10 CFR Part 21 to reflect the change in the telephone number for Region IV. The amendment is intended to inform the public of the new telephone number.

This final rule does not constitute a significant question of policy, nor does it amend regulations contained in 10 CFR Parts 0, 2, 7, 8, 9 Subpart C or 110. I therefore find that this rule is within the scope of my rulemaking authority and am proceeding to issue it.

_____
Date

_____
William J. Dircks
Executive Director
for Operations

Part 2 - The Federal Register Document. [7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

Change of Telephone Number for

NRC Region IV Office

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to change the telephone number for NRC's Region IV office located in Arlington, Texas. The amendments are intended to inform the public of the new telephone number for NRC Region IV.

EFFECTIVE DATE:

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-4444.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has changed the telephone number of its Regional Office IV in Arlington, Texas. The new telephone number for the Region IV office is (817) 465-8100.

The amendment is made to the portion of the footnote in § 21.2 that sets out the telephone number for Region IV.

Since this amendment is administrative and relates solely to a minor procedural matter, notice of proposed rulemaking and public procedure thereon are unnecessary, and good cause exists to make the amendment effective upon publication in the Federal Register.

## LIST OF SUBJECTS IN 10 CFR PART 21

Nuclear power plants and reactors, Penalty, Radiation protection, Reporting requirements.

For the reasons set out in the preamble and under 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 adopting the following amendment to 10 CFR Part 21.

## PART 21 - REPORTING OF DEFECTS AND NONCOMPLIANCE

The authority citation for Part 21 continues to read as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended; sec. 234, Pub. L. 91-161, 83 Stat. 444 (42 U.S.C. 2201, 2282); secs. 201, 206, 88 Stat. 1242, 1246, as amended (42 U.S.C. 5841, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 21.6, 21.21(a) and 21.31 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 21.21, 21.41 and 21.51 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 21.2 [Amended].

Footnote 1 of § 21.2 is amended by changing the telephone number of NRC Regional Office IV to read as follows:

* * * * *

IV (Dallas) . . . . . .(817) 465-8100

* * * * *

Dated at Bethesda, Maryland, this ____ day of _____, 1982.

For the Nuclear Regulatory Commission.

_____

William J. Dircks,
Executive Director for Operations.

Part 3 - Note for the Weekly Report or Daily Staff Notes.

DIVISION OF RULES AND RECORDS

OFFICE OF ADMINISTRATION

The Executive Director for Operations has issued a final minor amendment to Part 21 changing the telephone number of the NRC Region IV office identified in that regulation. Because the amendment was minor and of a nonpolicy nature, notice of proposed rulemaking and public procedure were unnecessary, and good cause existed to make the amendment effective on _____, 1981, the date of publication of the Federal Register.

15.5 Extension of comment period. [7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 40, 50, 70, and 72

Decommissioning Criteria for Nuclear Facilities; Draft Generic Environmental Impact Statement: Extension of Comment Period.

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft generic environmental impact statement; extension of comment period.

SUMMARY: On February 10, 1981, a Notice of Availability of Draft Generic Environmental Impact Statement was published in the Federal Register (46 FR 11666) that indicated that comments must be received before March 23, 1981. Since several interested persons have experienced delays in obtaining copies of the environmental impact statement, the NRC is issuing this notice extending the comment period.

DATES: New comment period expires April 23, 1981. Comments received after this date will be considered if it is practical to do so but assurance of consideration cannot be given except as to comments received before this date.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-5555.

Dated at Washington, D.C., this 20th day of February, 1981.

For the Nuclear Regulatory Commission.

G. D. Calkins,
Decommissioning Program Manager.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, and 32

Static Elimination Devices and Ion Generating Tubes

AGENCY: Nuclear Regulatory Commission.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Nuclear Regulatory Commission is withdrawing a notice of proposed rulemaking published in the Federal Register on April 1, 1971, in which the Atomic Energy Commission (the predecessor of the NRC) solicited comments on proposed amendments of its regulations that would establish a class exemption from licensing requirements for the possession and use of tritium, krypton-85, or polonium-210 in static elimination devices and ion generating tubes. In consideration of the length of time since public comments were requested on the proposed rule and since it will be another year or more before a Commission value/impact assessment will recommend the course of action that should be taken on static elimination devices and ion generating tubes, the Commission concludes that it should withdraw the proposed rule published April 1, 1971. The withdrawal of the proposed rule will not affect any person because it is not an action that adds, amends, or rescinds any NRC regulation.

DATE:

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 443-6666.

SUPPLEMENTARY INFORMATION: On April 1, 1971, the Atomic Energy Commission (the predecessor of the Nuclear Regulatory Commission) published in the Federal Register (36 FR 6015) proposed amendments to 10 CFR Parts 30, 31, and 32 of its regulations that would (a) in proposed new § 30.21(a) establish a class exemption from licensing requirements for the possession and use of tritium, krypton-85 or polonium-210 in static elimination devices and ion generating tubes manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the AEC authorizing transfer for use under the exemption, (b) in proposed new §§ 32.30, 32.31, 32.32, and 32.33 establish requirements for the issuance of specific licenses authorizing the distribution of the static elimination devices and ion generating tubes to persons for use under the class exemption, (c) in proposed new §§ 30.21(b) and (c) exempt those static elimination devices and ion generating tubes distributed for use under general license in § 31.3 prior to a specified date, and (d) revoke § 31.3 as of that same specified date.

A number of comments were received in response to the notice of proposed rulemaking, some of which suggested that proposed new § 32.30 may have been too restrictive in requiring a specific license for the incorporation of static elimination devices or ion generating tubes into products for commercial distribution.

Neither the Atomic Energy Commission nor the Nuclear Regulatory Commission (established by the Energy Reorganization Act of 1974 on January 19, 1975) took any further action on this rulemaking proceeding. Over the intervening years, the staff began studies (including a generic environmental impact

statement on consumer products) that eventually should result in Commission decisions on criteria for approval of consumer products and policy on the use of general licenses that might have a bearing on the regulatory control of static elimination devices and ion generating tubes containing byproduct materials.

The Commission believes that it would be premature to exempt at this time additional products containing radioactive material for consumer use in view of the studies mentioned above. In consideration of the length of time since public comments were requested on the proposed rule and since it will be another year or more before a Commission value impact assessment will recommend the course of action that should be taken on static elimination devices and ion generating tubes, the Commission concludes that it should withdraw the proposed rule published April 1, 1971.

In view of these considerations, the proposed rule is withdrawn. The withdrawal of this proposed rule, however, does not preclude the Commission from issuing similar notices in the future or commit the Commission to any course of action with regard to static elimination and ion generating devices.

Dated at Washington, D.C., this ____ day of _____, 1980.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

15.7 Withdrawal of advance notice of proposed rulemaking. [7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 9

Review of Regulations

AGENCY: Nuclear Regulatory Commission.

ACTION: Withdrawal of advance notice of proposed rulemaking.

SUMMARY: This document withdraws an advance notice of proposed rulemaking that presented for comment an experimental "plain English" version of Subpart A to 10 CFR Part 9. NRC is now performing a comprehensive review and revision for all of Part 9 that will be published for public comment when completed.

DATE:

FOR FURTHER INFORMATION CONTACT: (Name of contact person), FOIA/PA Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-7777.

SUPPLEMENTARY INFORMATION: NRC published the advance notice of proposed rulemaking (ANPRM) seeking public comment on an experimental "plain English" revision of a portion of 10 CFR Part 9 on April 17, 1979 (44 FR 22746). The public comments received generally favored the revision but offered substitutions for specific words or phrases in the ANPRM to improve the clarity of the regulation. Subsequently, the proposed plain English project was deferred because of work assignments of higher priority. Following the accident at the

Three Mile Island (TMI) nuclear plant, the Commission directed the staff to review all of the NRC regulations as part of the TMI Action Plan. The TMI Action Plan, NUREG-0660, is available for public inspection and copying in the NRC Public Document Room, 1717 H St. NW., Washington, D.C. 20555. The staff has initiated a periodic and systematic review of the NRC regulations, and notice concerning the review was published on January 23, 1981 (46 FR 7380). This is a comprehensive review to ensure, among other things, that the regulations achieve the substantive legislative goals set out in statutes which direct NRC activities and that the regulations are written in an understandable manner. In light of the fact that NRC is reviewing all of 10 CFR Part 9, the ANPRM is being withdrawn. Comments received on the ANPRM will be considered in formulation of a new rule and the proposed entire revision will be published for public comment.

Dated at Washington, D.C., this _____ day of _____, 1981.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

15.8 Correction. [7590-01]

NUCLEAR REGULATORY COMMISSION

10 CFR PART 50

Emergency Planing and Preparedness for Production and Utilization Facilities; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document corrects a proposed rule appearing in the Federal Register on September 21, 1981 (46 FR 46587), that would extend the date by which prompt public notification systems must be operational around all nuclear power plants. The action is necessary to correct a printing error and resolve an inconsistent reference to a deadline date.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Director, Division of Emergency Preparedness, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-8888.

1. On page 46588, in the second sentence of the first full paragraph in the second column, the word "insignificant" should read "significant."

2. On page 46589, in the first line of the second column, "one year" should read "seven months."

3. In the second line of §50.74(a), "one year" should read "seven months."

Dated at Bethesda, Maryland, this ____ day of _____, 1981.

For the Nuclear Regulatory Commission.

_____
William J. Dircks,
Executive Director for Operations.

15.9 Notice of availability. [7590-01]

NUCLEAR REGULATORY COMMISSION

Report to Congress on Status of Emergency

Response Planning for Nuclear Power Plants; Availability

The Nuclear Regulatory Commission has published its Report to Congress on Status of Emergency Response Planning for Nuclear Power Plants (NUREG-0755), under Sec. 109, Nuclear Regulatory Commission Appropriation Authorization, Public Law 96-295. The Commission reported on regulatory actions, emergency plan status, and evacuation time estimates.

Copies of the report are being placed in NRC's Public Document Room, 1717 H Street, NW., Washington, D.C. and in each Local Public Document Room throughout the U.S. for review by interested persons. Copies of the report may be purchased from the Sales Agent, Division of Technical Information and Document Control, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, for $4.00 each. Your check or money order should be made payable to Superintendent of Documents. GPO deposit account holders may charge orders by calling (301)492-9530. Copies will also be available at the National Technical Information Service, Springfield, Virginia 22161.

Dated at Washington, D.C., this ____ day of _____, 1982.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

15.10 Staff response to a petition for rulemaking.

NOTE: The document presented in this sample is unusual in that it does not actually grant the petitioner's request nor does it deny the petition for rulemaking. However, this document does present the elements that must be included in any published staff response to a petition for rulemaking in that it -

(1) Summarizes the issues raised in the petition;

(2) Presents NRC's response to the issues raised; and

(3) Explains the reasons for the action taken by NRC in response to the petition.

NUCLEAR REGULATORY COMMISSION [7590-01]

10 CFR PART 50

[Docket No. PRM-20-10]

Citizens United for Responsible Energy;

Granting of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Response to petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is granting in substance a petition for rulemaking submitted by Citizens United for Responsible Energy (CURE). The petition requested that NRC regulations be amended to require operators of nuclear power reactors to report abnormal incidents immediately to NRC and to a designated State agency. Recently, the Commission has established notification requirements that meet the basic intent of the requirements requested in the petition.

FOR FURTHER INFORMATION CONTACT: (Name of Contact Person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 443-1010.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has granted in substance a petition for rulemaking, dated December 27, 1977, submitted by Citizens United for Responsible Energy (CURE). A notice of filing of the petition was published in the Federal Register on January 25, 1978 (43 FR 3448),

and public comment was invited. Thirty-two comment letters were received. Twenty-five commenters opposed the petition, six supported it, and one took no clear position. Copies of the petition and the public comments are available for free inspection or copying for a fee at the NRC Public Document Room, 1717 H St. NW., Washington, D.C. 20555.

Issues Raised in Petition

The petition maintained that NRC had inadequate requirements for notification of NRC and State officials by nuclear power plant operators in the event of an abnormal occurrence. The petitioner requested NRC to rescind § 20.403, "Notification of Incidents," of 10 CFR Part 20, "Standards for Protection Against Radiation," as petitioner considered § 20.403 inadequate. The petitioner specifically requested NRC to (1) require all abnormal incidents to be reported immediately (within one-half hour) to the appropriate NRC Regional Office, (2) require that all abnormal incidents be reported immediately (within one-half hour) to a designated State agency within 200 miles of the incident, and (3) define an abnormal incident as one which involves radioactive releases to air or water.

Response to Petition

The staff began its evaluation of the petition and the public comment letters in the early part of 1978, but it was after the Three Mile Island accident when the NRC staff acted to ensure the timely flow of information from nuclear power reactor operators following significant events relating to the public health and safety. Dedicated telephone lines have been installed from all operating plants to the NRC Operations Center and Regional Offices. New regulations have been published that modified 10 CFR 20.403 and 10 CFR

Part 50, "Domestic Licensing of Production and Utilization Facilities" (45 FR 13434-5, February 29, 1980). The regulations in 10 CFR 50.47 and 50.72 are now effective. Section 50.72 includes a provision that each nuclear power reactor licensee must notify NRC as soon as possible, and in all cases within one hour, of twelve specified significant events. These include the initiation of the licensee's emergency plan (or any section of the emergency plan) as well as an accidental, unplanned, or uncontrolled radioactive release. In fact, comments have been received concerning the nctification requirements in § 50.72 and the staff has had approxmately 16 months experience implementing this regulation. The staff is now in the process of making certain minor modifications in order to clarify the notification requirements in § 50.72. One such change that the NRC staff is considering proposing to the Commission is to add the following sentence to § 50.72, "All such notifications (of the four classes of emergencies) to the NRC must be made immediately after notification to the State or local agencies and must identify that the notice is being made pursuant to this paragraph."

Likewise, on August 19, 1980, the NRC published final regulations relating to Emergency Planning and Preaparedness (45 FR 55402). These regulations, in Appendix E, Section D.3 of 10 CFR Part 50, require that "a licensee shall have the capability to notify responsible State and local governmental agencies within 15 minutes after declaring an emergency." See also 10 CFR 50.47(b)(5).

In addition, the new Emergency Preparedness regulations refer to NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," for further discussion of emergency plans. NUREG-0654 specifies that power reactor licensees should promptly notify State and local authorities when any unusual event occurs.

The effective regulations and the guidance documents, while not requiring exactly what the petitioner requested, do establish prompt notification requirements that follow the basic intent of the petition. In addition, rescission of 10 CFR 20.403 would affect all NRC licensees for source, byproduct, and special nuclear material and would not be limited to nuclear power reactor licensees. Therefore, the CURE petition is being treated by the NRC as having been granted in substance. In light of present NRC regulatory requirements concerning immediate notification of the NRC and State and local officials of significant events at nuclear power reactors, further NRC action would be unnecessary and duplicative. Accordingly, the docket has been closed.

Dated at Bethesda, Maryland, this 6th day of October, 1981.

For the Nuclear Regulatory Commission.

William J. Dircks,
Executive Director for Operations.

The "Checklist for Preparation and Review of Federal Register Rulemaking Notices" is being developed separately. The Checklist is currently in production. We anticipate its completion in the near future. For your convenience, we have structured the Handbook to permit the inclusion of the Checklist. This will allow you to include material relevant to the preparation of a Federal Register document under one cover if you choose to do so.

APPENDICES

A - Procedures for Preparation of Federal Register Packages Implementing Commission and EDO Rulemaking Actions.

B - The Administrative Procedure Act (5 U.S.C. 551-553).

C - List of Subject Index Terms.

Appendix A - Procedures for Preparation of Federal Register Packages Implementing Commission and EDO Rulemaking Actions

These procedures provide revised guidance for the preparation of packages containing Federal Register rulemaking notices, together with their accompanying documents. As in the past, all rulemaking notice packages for transmission to the Office of the Federal Register (OFR) should be submitted through the NRC's Division of Rules and Records (DRR), ADM, and the Office of the Secretary (SECY). Now, those rulemaking notice packages containing requirements subject to the Paperwork Reduction Act for transmission to the Office of Management and Budget (OMB) should be submitted through the NRC's Document Management Branch, Technical Information and Document Control (TIDC), ADM. This revision is necessary to comply with changes resulting from the Regulatory Flexibility Act, the Paperwork Reduction Act, policies established by OFR, and certain NRC internal procedural changes.

1. WHEN THE ORIGINATING OFFICE SHOULD PREPARE TWO PACKAGES

If a notice of rulemaking alters in any manner an information collection requirement imposed upon an NRC licensee, the office originating the notice shall prepare two packages for ADM in order to obtain Federal Register publication of the notice and to inform the Document Management Branch of any change in requirements that should be reflected in the Information Collection Budget.

If a notice of rulemaking does not alter such an information collection requirement, the originating office prepares only one package for transmission to DRR.

1.1. Contents of Package Prepared for DRR

The package prepared for transmission to DRR must contain the items described below.

1.1.1. Transmittal Memorandum

The transmittal memorandum for the package is sent from the originating office to Joseph M. Felton, Director, Division of Rules and Records, ADM (see Enclosure A). The memorandum should indicate, as appropriate, the following:

1. The effective date for a final rule;
2. The date by which comments must be received for an advance notice of proposed rulemaking or a proposed rule;
3. Any places in the notice after the "DATE" line in the preamble where either an effective date or comment period expiration date must be inserted before Federal Register publication;
4. The need for expedited publication, if applicable;
5. The need for special OFR publication such as printing the rule as a separate part of the Federal Register, if applicable;
6. Whether DRR should dispatch Congressional letters to OCA;
7. Whether DRR should dispatch a public announcement to PA;
8. Whether an Environmental Impact Statement, Regulatory Analysis, or other analysis is to be sent to the PDR;
9. Whether a marked-up copy of Federal Register notice or errata sheet showing Commission-requested and other changes is enclosed for transmittal to the Office of the Secretary;
10. Whether, in the case of a rule signed by the Executive Director for Operations (EDO), an item for the Daily or Weekly Information Report has been submitted to the EDO; and
11. Whether the originating office has arranged with TIDC to mail copies of the Federal Register notice to each affected licensee and to other interested persons.

### 1.1.2 Congressional Letters

Congressional letters must be prepared for every significant NRC rule in accordance with Section 303 of the Atomic Energy Act of 1954, as amended, to keep the Congress "fully and currently informed." (See Enclosure C for a list of the current standard addressees in the 97th Congress.) The office preparing the rulemaking package is responsible for identifying the Congressional oversight committees that must be notified of this action. Congressional letters (see Enclosure B) are signed by the Office Director but are not dated so that the Director, Office of Congressional Affairs, may review, date, and transmit the letters to appropriate Members of Congress. The Congressional package must contain the following:

1. One original letter plus enclosures* to the Chairman of each Congressional Committee with oversight responsibility for the rule;
2. One copy of the original letter to the Chairman plus enclosures* to the ranking minority member of each appropriate Congressional Committee with oversight responsibility for the rule;
3. One original and five copies of the concurrence page for only one of the Congressional Committee letters. On the concurrence page type: "Identical letters sent to (and list the remaining Congressional Committee Chairmen and ranking minority members)."
4. Address labels for letters to each Chairman and ranking minority member.

### 1.1.3 Public Announcement

A public announcement, if appropriate, is prepared by the originating office in consultation with Public Affairs. DRR must receive three copies of any Public Announcement.

*Enclosures usually consist of the Federal Register notice and the Public Announcement

1.1.4 Marked Copy of Rule

A marked-up copy of the Federal Register notice indicates any changes made to the rule after the Commission acted on it.

1.1.5 Letter Requesting Expedited Publication

A letter is sent to the Office of the Federal Register requesting and justifying expedited publication if, because of exigent circumstances, it is necessary. (Normal publication is three days after receipt by OFR.)

1.1.6 Federal Register Notice

The appropriate number of copies of the Federal Register notice to be included in the package depends upon the person who signs the notice as shown below:

> If the Federal Register notice is to be signed by the Secretary of the Commission and the notice is 14 or fewer pages, include the original and 2 copies of the notice; if the notice is 15 or more pages, include the original and 5 copies.**
>
> If the Federal Register notice is signed by the Executive Director for Operations and is 14 or fewer pages, include the original and 14 copies of the notice, if the notice is 15 or more pages, include the original and 17 copies.

---

**The Office of the Secretary makes additional copies of the Federal Register notice after it is signed.

1.2 Contents of Package Prepared for TIDC

The package prepared for transmission to TIDC and OMB for those rulemaking notices that contain requirements subject to the Paperwork Reduction Act must contain three copies of the Federal Register notice as prepared for publication and other elements of the OMB Clearance Package discussed in the April 24, 1981, Memorandum from the EDO to all Office Directors entitled "Implementation of the Paperwork Act." (A copy of this memorandum is included in the EDO Procedures Manueal behind the tab labeled "GAO CLEARANCE".)

To ensure that affected licensees and other known interested persons receive prompt notification of the issuance of proposed and final regulations, (1) DRR shall coordinate distribution of this notification to affected licensees with the Chief, Document Management Branch, Division of Technical Information and Document Control, ADM, and, (2) in the case of a final rule about which the NRC received public comments, the originating office shall provide a mailing list of these commenters to the Document Management Branch, TIDC, ADM, to ensure proper distribution of this notification to interested parties.

2. USE OF TERM FEDERAL REGISTER

Any reference to the Federal Register publication in an NRC rulemaking document published in the Federal Register or in the accompanying Commission paper or its enclosures is typed in initial caps only and is not underlined. The proper reference to the publishing organization is the Office of the Federal Register (OFR). (Note that when used in typewriter-prepared publications such as reports in the NUREG series or Regulatory Guides, the term Federal Register is normally underlined; this indicates that the words will appear in italics in a typeset document.)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 26 1982

MEMORANDUM FOR: Joseph M. Felton, Director
Division of Rules and Records
Office of Administration

FROM: Karl R. Goller, Director
Division of Facility Operations
Office of Nuclear Regulatory Research

SUBJECT: IMPLEMENTATION OF COMMISSION ACTION

On June 24, 1982, the Commission approved a Federal Register Notice publishing a proposed regulation relating to fitness for duty of nuclear power plant personnel.

Please implement the Commission's action by having the enclosed proposed regulation published in the Federal Register allowing 60 days for comment.

Also enclosed are the letters to the appropriate Congressional committees informing them of the Commission's action.

Karl R. Goller

Karl R. Goller, Director
Division of Facility Operations
Office of Nuclear Regulatory Research

Enclosures:

1. Federal Register Notice
2. Congressional Letters

ENCLOSURE A

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

The Honorable Alan Simpson, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The NRC has sent to the Office of the Federal Register for publication the enclosed proposed amendment to the Commission's rules in 10 CFR Part 50. The amendment, if adopted, would require licensees of nuclear power plants for which an operating license has been granted to establish, document, and implement procedures to ensure that personnel with unescorted access to protected areas are not under the influence of drugs, alcohol, or otherwise unfit for duty because of mental or temporary physical impairments that could affect their performance in any way contrary to safety.

The Commission is issuing the proposed rule for public comment and has specifically requested comments with respect to the scope, level of specificity, and methods of implementation of the rule.

Sincerely,

Robert B. Minogue, Director
Office of Nuclear Regulatory Research

Enclosure: As stated

cc: Senator Gary Hart

ENCLOSURE B

The Honorable Richard L. Ottinger, Chairman
Subcommittee on Energy Conservation and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515
ATTN: Mike Ward
316 House Annex #2

cc: The Honorable Carlos Moorhead
ATTN: Chris Warner
2322 RHOB

The Honorable Toby Moffett, Chairman
Subcommittee on Environment, Energy and Natural Resources
Committee on Government Operations
United States House of Representatives
Washington, DC 20515
ATTN: Mr. Barry Hager
B371 RHOB

cc: The Honorable Joel Deckard
ATTN: Ms. Cathy Sands
2158 RHOB

The Honorable Alan Simpson, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510
ATTN: Jim Curtiss
6233 DSOB

cc: The Honorable Gary Hart
ATTN: Keith Glaser
A728 Immigration Building

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515
ATTN: Henry Myers
1327 LHOB

cc: The Honorable Manuel Lujan
1329 LHOB

ENCLOSURE C

Appendix B - The Administrative Procedure Act (5 U.S.C. 551-553).

Sec.



§551. Definitions.

For the purpose of this subchapter -

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include-

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia; or except as to the requirements of section 552 of this title -

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; chapter 2 of title 41; or sections 1622, 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix;

(2) "person" includes an individual, partnership, corporation, association, or public or private organization other than an agency;

(3) "party" includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in an agency proceeding, and a person or agency admitted by an agency as a party for limited purposes;

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

(8) "license" includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission;

(9) "licensing" includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license;

(10) "sanction" includes the whole or a part of an agency-

(A) prohibition, requirement, limitation, or other condition affecting the freedom of a person;

(B) withholding of relief;

(C) imposition of penalty or fine;

(D) destruction, taking, seizure, or withholding of property,

(E) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees;

(F) requirement, revocation, or suspension of a license; or

(G) taking other compulsory or restrictive action;

(11) "relief" includes the whole or a part of an agency-

(A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;

(B) recognition of a claim, right, immunity, privilege, exemption, or exception; or

(C) taking of other action on the application or petition of, and beneficial to, a person;

(12) "agency proceeding" means an agency process as defined by paragraphs (5), (7), and (9) of this section; and

(13) "agency action" includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.

(14) "ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter.

§552. Public information; agency rules, opinions, orders, records, and proceedings.

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public -

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules or procedure, descriptions of forms available or the places at which the forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

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§553. Rule making.

(a) This section applies, according to the provisions thereof, except to the extent that there is involved-

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include -

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is requried by statute, this subsection does not apply -

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except -

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

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