

2000-0280

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RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) / PRIVACY ACT (PA) REQUEST

RESPONSE TYPE FINAL PARTIAL

REQUESTER

Michael Ravnitzky

DATE

AUG 31 2000

PART I. - INFORMATION RELEASED

- No additional agency records subject to the request have been located.
- Requested records are available through another public distribution program. See Comments section.
- APPENDICES **C** Agency records subject to the request that are identified in the listed appendices are already available for public inspection and copying at the NRC Public Document Room.
- APPENDICES **B** Agency records subject to the request that are identified in the listed appendices are being made available for public inspection and copying at the NRC Public Document Room.
- Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, NW, Washington, DC.
- APPENDICES **A** Agency records subject to the request are enclosed.
- Records subject to the request that contain information originated by or of interest to another Federal agency have been referred to that agency (see comments section) for a disclosure determination and direct response to you.
- We are continuing to process your request.
- See Comments.

PART IA - FEES

AMOUNT *

\$ 60.80

* See comments for details

- You will be billed by NRC for the amount listed. None. Minimum fee threshold not met.
- You will receive a refund for the amount listed. Fees waived.

PART I.B - INFORMATION NOT LOCATED OR WITHHELD FROM DISCLOSURE

- No agency records subject to the request have been located.
- Certain information in the requested records is being withheld from disclosure pursuant to the exemptions described in and for the reasons stated in Part II.
- This determination may be appealed within 30 days by writing to the FOIA/PA Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Clearly state on the envelope and in the letter that it is a "FOIA/PA Appeal."

PART I.C COMMENTS (Use attached Comments continuation page if required)

Many of the NUREG documents you requested are being released in their entirety and are being placed in the NRC Public Document Room (PDR). We have identified with an asterisk (*) the records being released in their entirety on the enclosed Appendix B.

The fees for processing your request are as follows:

304 pages duplication (excludes 100 free pages) @ \$.20 per page = \$60.80.

In a telephone conversation with Natalie Brown on August 25, 2000, you agreed to pay the fees in the amount indicated above. You will be bill by the NRC Division of Accounting.

SIGNATURE - FREEDOM OF INFORMATION ACT AND PRIVACY ACT OFFICER

Carol Ann Reed

**APPENDIX A
RECORDS BEING RELEASED TO THE REQUESTER
(If copyrighted identify with *)**

<u>NO.</u>	<u>DATE</u>	<u>DESCRIPTION/(PAGE COUNT)</u>
1.	9/1997	NUREG/BR-0053, Rev. 4, Regulations Handbook. (30 pages)
2.	1997-1998	NUREG/BR-0017, The NRC Guide to Learning Opportunities. (25 pages)
3.	1998	NUREG/BR-0057, LPDR Update. (4 pages)
4.	1997	NUREG/BR-0057, LPDR Update. (4 pages)
5.	6/1999	NUREG/BR-0080, Translations of Foreign Documents. (22 page)
6.	1997	NUREG/BR-0149, Rev. 1, The Office of the Inspector General. (10 pages)
7.		NUREG/BR-0161, NRC's Differing Professional Views and Opinions Process. (2 pages)
8.	2/1996	NUREG/BR-0224, Guidelines for Conducting Public Meetings. (10 pages)
9.		NUREG/BR-0201, Commissioner's Assistant Handbook. (18 pages)
10.	8/1999	NUREG/BR-0137, Nuclear Material Safety and Safeguards. (7 pages)
11.		NUREG/BR-0146, The IG at the NRC, Office of the Inspector General. (29 pages)
12.		NUREG/BR-0188, Distribution List Descriptions for NRC Reports and Documents. (22 pages)
13.	12/1995	NUREG/BR-0136, NRC Drug Testing Manual. (32 pages)

14. NUREG/BR-0118, Rev. 1 The White Flint North Complex An Owner's Manual. (32 pages)
15. 3/1996 NUREG/BR-0225, ACRS/ACNW Members' Handbook. (29 pages)
16. 4/1997 NUREG/BR-0243, ACRS/ACNW Administrative Manual. (34 pages)
17. NUREG/BR-0230, RCM-96 Response Coordination Manual. (31 pages)
18. 3/1999 NUREG/BR-0075, NRC Field Policy Manual. (29 pages)
19. 11/1993 NUREG/BR-0150, RTM-93 Response Technical Manual. (34 pages)

**APPENDIX B
RECORDS BEING PLACED IN THE PDR**

<u>NO.</u>	<u>DATE</u>	<u>DESCRIPTION/(PAGE COUNT)</u>
1.	9/1997	* NUREG/BR-0053, Rev. 4, Regulations Handbook. (30 pages)
2.	1997-1998	* NUREG/BR-0017, The NRC Guide to Learning Opportunities. (25 pages)
3.	1998	*NUREG/BR-0057, LPDR Update. (4 pages)
4.	1997	*NUREG/BR-0057, LPDR Update. (4 pages)
5.	6/1999	*NUREG/BR-0080, Translations of Foreign Documents. (22 page)
6.	1997	*NUREG/BR-0149, Rev. 1, The Office of the Inspector General. (10 pages)
7.		*NUREG/BR-0161, NRC's Differing Professional Views and Opinions Process. (2 pages)
8.	2/1996	*NUREG/BR-0224, Guidelines for Conducting Public Meetings. (10 pages)
9.		*NUREG/BR-0201, Commissioner's Assistant Handbook. (18 pages)
10.	8/1999	*NUREG/BR-0137, Nuclear Material Safety and Safeguards. (7 pages)
11.		*NUREG/BR-0146, The IG at the NRC, Office of the Inspector General. (49 pages)
12.		*NUREG/BR-0188, Distribution List Descriptions for NRC Reports and Documents. (83 pages)
13.	12/1995	*NUREG/BR-0136, NRC Drug Testing Manual. (62 pages)

14. *NUREG/BR-0118, Rev. 1 The White Flint North Complex An Owner's Manual. (57 pages)
15. 3/1996 NUREG/BR-0225, ACRS/ACNW Members' Handbook. (29 pages)
16. 4/1997 NUREG/BR-0243, ACRS/ACNW Administrative Manual. (34 pages)
17. 3/1999 *NUREG/BR-0075, NRC Field Policy Manual. (36 pages)
18. *NUREG/BR-0230, RCM-96 Response Coordination Manual. (338 pages)
19. 11/1993 *NUREG/BR-0150, Vol. 1, Rev. 4, RTM-93 Response Technical Manual. (436 pages)

**APPENDIX C
RECORDS ALREADY AVAILABLE IN THE PDR**

<u>NO.</u>	<u>DATE</u>	<u>ACCESSION NUMBER</u>	<u>DESCRIPTION/(PAGE COUNT)</u>
1.	11/30/89	9608210192	NRR Technical Newsletter, Vol. 1, Number 6 (11 pages)
2.	07/31/89	9608210189	NRR Technical Newsletter, Vol. 1, Number 5 (8 pages)
3.	03/31/89	9608210187	NRR Technical Newsletter, Vol. 1, Number 4 (7 pages)
4.	09/30/90	9608210146	NRR Technical Newsletter, Vol. 2, Number 2 (6 pages)
5.	04/30/90	9608210145	NRR Technical Newsletter, Vol. 2, Number 1 (8 pages)
6.	05/31/92	9205180137	NRR Technical Newsletter, Vol. 4, Number 1 (16 pages)
7.	02/28/91	9107010073	NRR Technical Newsletter, Vol. 2, Number 3 (11 pages)
8.	10/31/92	9211130059	NRR Technical Newsletter, Vol. 4, Number 2 (12 pages)
9.	03/31/92	9205180138	NRR Technical Newsletter, Vol. 3, Number 1 (9 pages)
10.	08/31/94	9409270191	NRR Technical Newsletter, Vol. 6, Number 2 (8 pages)
11.	02/28/94	9403140170	NRR Technical Newsletter, Vol. 6, Number 1 (31 pages)
12.	01-12/1994	9508290356	Computer Codes and Mathematical Models, Vol. 10. (106 pages)

NUREG/BR-0053, Revision 4

**United States
Nuclear Regulatory Commission**

Regulations Handbook

Edited by: M. T. Lesar

September 1997

**Division of Administrative Services
Office of Administration**



B/1

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FOREWORD

The NRC Regulations Handbook is designed to assist the NRC staff in drafting and preparing rulemaking documents for publication in the Federal Register. The handbook contains procedures, requirements, and background information essential to those who develop or review rulemaking actions for the NRC. The handbook was first published in August 1982 as NUREG/BR-0053; supplements to the handbook were issued April 1983, June 1984, and September 1985; and it was revised in its entirety in November 1987, December 1989, and June 1995. This is the fourth complete revision of the handbook. This revision reflects amendments to Management Directive 6.3, "The Rulemaking Process" which are intended to ensure that Agreement States are provided an opportunity to comment on draft rulemaking plans and rulemaking actions, to specify conditions under which a rulemaking plan is not needed, and to clarify certain NRC organizational responsibilities during the rulemaking process. This revision also incorporates changes required by the Small Business Regulatory Enforcement Fairness Act, the Paperwork Reduction Act of 1995, and Executive Order 12898 concerning environmental justice in rulemaking. In addition, this revision reflects significant changes that have occurred since June 1995 in the rulemaking process and NRC procedures. These changes include delegated rulemaking authority to the Chief Financial Officer and the Chief Information Officer; further guidance concerning the preparation, submittal, and processing of petitions for rulemaking; revised regulatory analysis guidelines; the use of direct final rules; amended guidance issued by the Office of the Federal Register; and NRC reorganizations and consolidation.

The handbook is intended to serve as a guidance tool for the professional staff who prepare, review, and coordinate rulemaking items; it provides all the

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

The handbook also provides guidance to the staff who prepare packages containing a Federal Register rulemaking document for transmittal to the Office of the Federal Register. The handbook contains information and examples that may prove helpful to administrative, program support, and clerical personnel involved in the preparation or tracking of rulemaking packages.

Because the rulemaking process changes continuously, the handbook is designed to incorporate future supplements. Specific instructions to update the handbook will accompany any revised material.

Questions concerning the use of the handbook or the rulemaking process, suggestions for improving the content or format of the handbook, or corrections of any errors or inconsistencies in the handbook should be directed to the author, Mr. Michael T. Lesar, Rules and Directives Branch (301-415-7163) or by E-mail (MTL).



David L. Meyer, Chief
Rules and Directives Branch
Office of Administration

PART 1 - THE NRC RULEMAKING PROCESS

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1.1 Administrative rulemaking.

(a) The Administrative Procedure Act.

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

(i) Provides the public, with stated exceptions, the right to participate in the rulemaking process by commenting on proposed rules;

(ii) Requires that the effective date of a regulation be not less than 30 days from the date of publication unless there is good cause for an earlier date;

(iii) Provides for the publication of agency statements of organization and procedural rules; and

(iv) Establishes the standard of judicial review of administrative actions.

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

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

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

(b) The Code of Federal Regulations.

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

(2) The CFR is divided into 50 titles according to subject matter. These titles are divided into chapters, chapters are divided into parts, and parts are divided into sections. NRC regulations are contained in Title 10, "Energy," Chapter I, "Nuclear Regulatory Commission," Parts 0-199. Each part has a heading that reflects its content. Each part sets out the regulations that pertain to a regulatory activity or program of the NRC. Some parts set out procedural requirements and information pertaining to internal agency organization and procedures that describe how the agency conducts its activities. The NRC has not used all of the parts between 0 and 199. The unused parts are reserved for future NRC use.

(c) The Federal Register.

(1) The Federal Register is published each Federal workday by the Office of the Federal Register (OFR), National Archives and Records Administration. The Federal Register provides a uniform system for publishing Presidential documents, final rules, proposed rules, advance notices of proposed rulemaking, petitions for rulemaking, general notices, policy statements, semiannual agendas of regulations, meeting announcements, and other agency documents

concerning the conduct of public business. These documents are discussed in subsequent sections of this handbook.

(2) The publication of a document in the Federal Register has certain legal effects.

(i) Publication provides official notice of a document's existence and content.

(ii) Publication creates a rebuttable presumption that the text is a true copy of the original document and that the document was duly issued, prescribed, and promulgated.

(iii) The contents of the Federal Register are judicially noticed by a court of law.

(3) The OFR's publication requirements for the different types of documents published in the Federal Register are covered in this handbook. However, the OFR may occasionally modify these requirements. Questions regarding the most current OFR requirements for publication or special publication requests should be directed to the Rules and Directives Branch (RDB), Office of Administration (ADM) (415-7163).

1.3 NRC rulemaking.

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

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

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

(3) The receipt of a petition for rulemaking.

(b) The NRC complies with the laws and regulations applicable to the rulemaking process as it develops a regulation.

(c) The NRC has established policy governing the rulemaking process in MD

6.3. The policies established in the directive and the procedures of this handbook are intended to ensure that --

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

(2) Schedules for rulemaking actions are established and met;

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

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

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

1.5 Rulemaking initiation.

(a) Applicability. The procedures in this section apply to all NRC headquarters and regional employees who are involved in the rulemaking process.

(b) Rulemaking plan. If an office that is subject to the procedures described in this section desires to recommend the initiation of a rulemaking action, the office shall submit a memorandum to the Office of Nuclear Regulatory Research (RES) that presents the request.

(1) RES shall prepare a rulemaking plan as described in Section 1.7 of this handbook.

(2) RES shall prepare a memorandum to the Executive Director for Operations (EDO) that transmits the rulemaking plan and recommends whether the rulemaking action is justified or not on the basis of information contained in the rulemaking plan.

(c) Commission action. If the Commission directs the staff to undertake a rulemaking action, the staff shall request that RES develop a rulemaking plan for the action to the extent practicable. A Commission paper that recommends rulemaking should not be prepared before following the procedures in this section and before considering the need for public participation.

(d) Rulemaking plan approval.

(1) The EDO approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the EDO by the Commission. (See MD 9.17, "Organization and Functions, Office of the Executive Director for Operations.")

(2) The Chief Financial Officer (CFO) approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the CFO by the Chairman

(see the memorandum from the Chairman to the Acting Chief Financial Officer dated February 18, 1997).

(3) The Chief Information Officer (CIO) approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the CIO by the Chairman (see the memorandum from the Chairman to the Chief Information Officer dated June 13, 1997).

(4) The Commission approves or denies the rulemaking plan, or major modifications to a plan, for any rulemaking that is not within the authority delegated to the EDO, the CFO, or the CIO.

(e) Rulemaking plan unnecessary. A rulemaking plan is not required for rulemaking actions in certain situations.

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

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

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

(ii) The need to obtain Commission approval for proceeding without preparing a rulemaking plan does not diminish the authorities specifically

delegated to the EDO, OGC, and office directors regarding matters that are a significant threat to public health and safety.

1.7 The rulemaking plan.

(a) RES, with the assistance of OGC, the office requesting the rulemaking, and the offices participating in the rulemaking, shall develop a proposed rulemaking plan for each contemplated rulemaking. RES is responsible for developing the rulemaking plan even if another office has lead responsibility for the rulemaking.

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

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

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

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

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

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

(4) The plan must indicate whether there are any known problems that could affect Agreement State implementation of the contemplated rulemaking action. If the rulemaking may affect Agreement States, the plan must include a suggested Agreement State compatibility classification for the proposed rule.

If the compatibility classification for Agreement State regulations is "C" or "H&S," the plan must identify the essential objectives of each section of the proposed rule. Agreement States will be provided an opportunity to comment on the draft rulemaking plan through the procedures presented in Section 1.9 of this handbook.

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

(6) The plan must indicate whether the contemplated rulemaking will be a major rule, as defined by the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121) and provide a basis for the determination. (See Appendix F of this handbook for a definition of "major rule" and an explanation of the Act's requirements.)

(7) The plan must identify the resources that will be required to complete and to implement the contemplated rulemaking action, including the resources needed to develop all the supporting documents identified in paragraph (b)(5) of this section. The discussion must indicate whether these resources are included in the current five-year plan. This discussion must also identify the office that will be responsible for each activity.

(8) The plan must indicate whether the EDO, CFO, or CIO may issue the rule under the rulemaking authority delegated to the EDO, CFO, or CIO by the Commission.

(9) The plan must identify the lead office and name the key staff within each office who will be involved in the contemplated rulemaking action.

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

(ii) The plan must indicate whether a steering group or working group format will be used to develop the contemplated rulemaking action.

(10) The plan must discuss whether enhanced public participation should be employed in the rulemaking process. The plan also must describe any special measures or procedures to be employed in the rulemaking process such as the issuance of a direct final rule or the use of negotiated rulemaking.

(11)(i) The plan must include a schedule for preparing the necessary supporting information, completing the proposed rule, analyzing public comment, and completing the final rule. The schedule must be established on the basis of --

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

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

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

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

(ii) Unless the contemplated rulemaking action would require the development of a GEIS or a regulatory guide, every effort should be made to

complete the rulemaking action within 18 months from the date the EDO approves initiation of the rulemaking.

(iii) A rulemaking plan should not be submitted when there are significant gaps in the technical basis for formulating or implementing the rule.

(c) RES shall make the rulemaking plan available to the appropriate advisory committee.

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

(1) RES shall make the approved rulemaking plan available to the NRC staff through the NRC electronic rulemaking bulletin board system.

(2) ADM shall include a new regulatory agenda entry on the next version of the NRC Regulatory Agenda that is forwarded for inclusion in internal NRC electronic rulemaking bulletin board system. If the intended action will be a major rule, ADM shall include an entry for it in the NRC Regulatory Plan that is submitted to the OMB as required by Executive Order 12866.

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

1.9 Agreement State review.

(a)(1) After offices have concurred in the rulemaking plan, the Office of State Programs (OSP) provides the Agreement States with a copy of the plan, marked "pre-decisional." Agreement States have a 45-day comment period. If a rulemaking plan is not required, OSP notifies Agreement States of the rulemaking action.

(2) At the same time, the Conference of Radiation Control Program Directors (CRCPD) Council Chair that is responsible for suggested State regulations will be notified by the RES CRCPD point of contact.

(3) The Commission is provided with an information copy of the draft rulemaking plan.

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

(c)(1) If the Commission approves the rulemaking plan the following actions are taken to inform Agreement States and the public of the staff's intention to proceed with the development of a proposed rule.

(i) RES places the approved plan on the electronic rulemaking bulletin board system.

(ii) RES creates an entry for the Regulatory Agenda and forwards the entry to the Office of Administration for inclusion in the next NRC Regulatory Agenda and the Unified Agenda of Regulatory and Deregulatory Actions.

(iii) The RES CRCPD point of contact notifies the CRCPD Council Chair responsible for suggested State regulations of the plan's approval so that the

parallel development of a suggested State regulation could begin, if such an action is desired.

(2) If the Commission does not approve the rulemaking plan, OSP notifies the Agreement States and the RES CRCPD point of contact notifies the CRCPD Council Chair responsible for suggested State regulations that the plan was not approved.

(d) If a proposed rule is clearly applicable to Agreement State interests, Agreement State involvement will be sought on preliminary versions of the proposed rule through the external rulemaking bulletin board.

1.11 Advisory committee review.

(a) After the proposed rule is approved, the lead office shall forward it to the appropriate advisory committee for review. The advisory committees are the --

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

(b) The staff shall formally document and respond to any consensus committee comments or recommendations concerning the rulemaking action.

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

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

1.13 Concurrence on a rulemaking action.

(a) Each office director and the General Counsel shall designate an office representative and an alternate for each rulemaking action.

(1) The designee, and his or her alternate in the designee's absence, is responsible for --

(i) Keeping office management informed of the policy issues that could affect office interests or constitute a basis for legal objection and of the designee's proposed position regarding these issues;

(ii) Speaking or signing for his or her office on the rulemaking regarding concurrence or conditions for concurrence or no legal objection by writing the concurrence letter or identifying specific issues that prevent concurrence or no legal objection; and

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

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

(b) Office concurrence means that --

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

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

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

(4) The office has reviewed the rulemaking action and agrees that it is consistent with current rules and other authoritative statements of agency

policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards.

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

(1) From OGC's standpoint, concurrence means that the recommended action is legally sufficient, is consistent with existing policy or is sound future policy, and is supported by OGC.

(2) No legal objection means that the recommended action is legally sufficient but either that OGC has no particular interest in or contribution to make to the policy aspects of the recommendation or that the reviewing attorney disagrees with the recommendation on policy grounds. If the reviewing attorney disagrees with the recommendation on policy grounds, he or she shall formally communicate the policy disagreement and the supporting reasons with the originating office, branch chief or above, or the proposed signer of the document, as appropriate, and to appropriate OGC management.

(3) OGC review and processing may not be held up because of policy disagreements that do not have a legal basis (see paragraph (d)(3) of this section).

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

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

(3) An office may not withhold office concurrence or no legal objection on the basis of policy disagreements that do not have a legal basis. A rulemaking document is considered legally sufficient when all relevant facts are presented and these facts are considered in light of applicable laws. Applicable laws include the Constitution, treaties, statutes, regulations, Executive orders, judicial decisions, agency adjudicatory decisions, contracts and agreements, and binding Commission policy and staff requirements memoranda.

1.15 Scheduling concurrences.

(a) At both the proposed rule and final rule stage, the originating office shall transmit each rulemaking action for which concurrence is being requested to all concurring offices simultaneously. The transmittal must include a hand-carried official hard copy with cover memorandum and an electronic copy through the internal NRC rulemaking bulletin board.

(1) The originating office shall notify the EDO, key technical staff within the concurring office, and the appropriate advisory committee of the availability of the rulemaking action on the internal rulemaking bulletin board.

(2) Each concurring office shall establish an internal logging and concurrence tracking system that is applicable to rulemaking actions. Each concurring office shall log the receipt of the hard copy rulemaking document in the internal tracking system. The designee or the alternate for the rulemaking action shall sign a receipt for the originating office's transmittal.

(3) Concurrence should be requested from all other NRC offices that are affected by or interested in the rulemaking action; OGC; RDB, ADM; the Information and Records Management Branch, Office of the Chief Information Officer (OCIO), to coordinate OMB review and approval of any new or amended information collection requirements; and the Office of Enforcement (OE) to ensure that an appropriate criminal penalty statement is included. OE will determine whether the "criminal penalties" section for each part affected by the rulemaking action must be amended to reflect the rulemaking action. OE also will determine whether any changes to the Enforcement Policy are warranted.

(i) The Office of the Chief Financial Officer reviews rulemaking actions submitted to the Commission to ensure that the resources required to complete and to implement the rulemaking have been properly addressed.

(ii) The OCIO reviews rulemaking actions submitted to the Commission to ensure that potential information technology impacts have been properly addressed.

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

(b) Each concurring office shall respond to the originating office by hand-carried memorandum or by NRC mail and through the rulemaking bulletin board within 20 calendar days. The responding office shall --

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

(2) Concur or provide no legal objection on the provision that specific policy or legal recommendations of the concurring office can be accommodated;

(3) State the policy reasons for withholding concurrence or for the legal objection and present the suggested solutions that would result in concurrence, and send a copy of this memorandum to the Office of the Executive Director for Operations (OEDO); or

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

(c) Within 20 calendar days of the receipt of concurrence memoranda, the proposing office shall --

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

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

(d) Within 20 calendar days of receipt of a proposed or final rule, the OEDO shall --

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

(2) Notify the Commission of the intent to issue the rule under the authority of the EDO; or

(3) Return the rulemaking proposal to the staff for modification or resolution of questions within a specified schedule.

1.17 Commission consideration.

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

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

1.19 Processing for publication.

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

(2) RDB conducts a final review of the regulation to ensure compliance with the publication requirements of the OFR and to verify that the regulation is complete. RDB then transmits the regulation to SECY for signature and transmittal to the OFR for filing and publication.

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

(d) RDB forwards letters to appropriate congressional committees, with enclosed copies, of the regulation to the Office of Congressional Affairs (OCA) to ensure that these committees having oversight responsibility for the NRC are notified of the agency's regulatory activities. RDB also forwards to OCA the letters to the Speaker of the House, the President of the Senate, and the General Counsel for the General Accounting Office necessary to comply with Small Business Regulatory Enforcement Fairness requirements applicable to final rules. The originating office coordinates the preparation and issuance of the public announcement with the Office of Public Affairs so that the release of

the public announcement coincides with the publication of the regulation in the Federal Register.

(e) If the regulation is likely to have a significant impact on the quality of the human environment, the staff ensures that the draft or final GEIS, prepared as required under the National Environmental Protection Act and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," is made available for public comment. If the regulation is subject to the Regulatory Flexibility Act, RDB sends a copy of the regulation and any related analyses to the Chief Counsel for Advocacy of the Small Business Administration. After the regulation is published in the Federal Register, copies of the published document are sent to all affected licensees as well as any interested person who has requested placement on a mailing list for NRC notices.

1.21 Timely resolution of petitions for rulemaking.

(a) The EDO established procedures to ensure that the resolution of a petition for rulemaking is accomplished on a timely basis (see the memoranda from the EDO to office directors dated August 13, 1986, and April 6, 1988). These procedures require that the resolution of a petition for rulemaking occur within 12 months from the date the notice of receipt of the petition was published in the Federal Register. A petition is considered resolved when the lead program office to which the petition is assigned has determined the regulatory decision for the petition: a petition may be resolved by deciding to grant the petition (all or in part) and proceeding with a rulemaking action or by deciding to deny the petition. However, the regulatory decision for a petition (resolution) does not complete the action on the petition. It only represents the decision on the course of action the NRC will follow to complete action on the petition by either granting or denying it. Action on a petition is completed and the petition is closed when the NRC formally grants the petition by completing and publishing the final rule necessary to grant the petitioner's request or when the NRC denies the petition by publishing a notice of this action in the Federal Register and advising the petitioner of this action in writing. Action on a petition also may be completed if the petitioner withdraws the petition.

(b) Each office is required to report the status of each petition for rulemaking for which it is responsible. These status reports, which are submitted to RDB, coincide with the updating of the NRC Regulatory Agenda. The status reports must indicate the scheduled resolution of each petition for rulemaking. The schedule for the resolution of each petition is included in the Agenda. RDB submits a summary report to the EDO that indicates the current status, including the scheduled resolution date, of each petition for

rulemaking. This report includes the reason for any extension of the petition and the new resolution date proposed by the assigned office.

(c) Any proposed extension of the resolution date must be approved by the EDO before the targeted resolution date expires. The EDO reviews the proposed extensions of resolution dates concurrently with the review of completion of rulemaking dates. The EDO may approve the proposed resolution date, direct the assigned office to resolve the petition by the original target date, or establish a new resolution date.

(d) In December 1996, the NRC issued Regulatory Guide 10.12, "Preparation of Petitions for Rulemaking Under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents." This guide encourages industry and the public to submit more detailed supporting information as part of the petition than is required by 10 CFR 2.802 for a petition to be acceptable for processing. If the petition for rulemaking requests amendments that would reduce the regulatory burden through the elimination of requirements that would be marginal to safety and involves requirements that are safety neutral, the submission of more detailed information, as outlined by Regulatory Guide 10.12, would enable the NRC staff to process the petition in a more expeditious manner.

PART 3 - PROPOSED RULES

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3.1 Proposed rule documents: Description.

(a) Each document the Nuclear Regulatory Commission (NRC) prepares for publication in the Proposed Rules section of the Federal Register must meet the format requirements specified in 1 CFR Chapter I. The requirements applicable to a proposed rule are discussed in this part. The Office of the Federal Register (OFR) classifies documents for publication in one of four sections of the Federal Register. These sections are: Presidential Documents, Rules and Regulations, Proposed Rules, and Notices. Documents published in the Proposed Rules section generally announce contemplated amendments to the agency's regulations or anticipated agency rulemaking actions and provide the public with an opportunity to comment on the proposed changes. As a result, documents published in the Proposed Rules section are subject to greater public scrutiny and are included in the numerical finding aids compiled by the OFR. The OFR classifies the following types of NRC documents for publication in the Proposed Rules section of the Federal Register.

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

(2) Documents that relate to previously proposed rules. The OFR classifies each document that relates to a previously published proposed rule as a proposed rule for purposes of publication in the Federal Register. This type of document may --

- (i) Extend a comment period;
- (ii) Announce a public hearing or meeting on a proposed regulation;

(iii) Publish or announce the availability of information supplemental to a rulemaking;

(iv) Withdraw a proposed rule;

(v) Terminate a proposed rule proceeding; or

(vi) Correct a previously published proposed rule.

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

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

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

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

(4) Regulatory agendas. The NRC publishes an agenda of regulations under agency development in the Federal Register each April and October. The agenda,

which is included in the Unified Agenda of Federal Regulatory and Deregulatory Actions, consists of regulatory actions that have been approved by the Commission, the Executive Director for Operations (EDO), the Chief Financial Officer, or the Chief Information Officer. This agenda is intended to comply with the requirements of the Regulatory Flexibility Act (Pub. L. 96-354; 5 U.S.C. 601 et seq.) and to implement the program for improving regulatory planning and review contained in Executive Order 12866. Because these documents often provide the public with advance notice of anticipated NRC rulemaking activities, the OFR classifies them as proposed rules for publication in the Federal Register. The NRC also issues an update of its agenda of regulations approved by the EDO for development (NUREG-0936). The NRC agenda also includes a summary of petitions for rulemaking pending before the Commission (10 CFR 2.802(g)). The NRC announces the availability of its agenda in a document published in the Proposed Rules section of the Federal Register and places a copy of the updated agenda in the NRC Public Document Room, 2120 L Street NW. (Lower Level), 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. Therefore, each draft policy statement prepared by the NRC should comply with the format requirements specified in Section 3.7 of this handbook. The Rules and Directives Branch (RDB) should review each draft policy statement to determine whether it meets all procedural and format requirements for publication and can be properly integrated into the NRC Rules and Regulations after it is published in the Federal Register.

(b) NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Proposed Rules section of the Federal Register. Within NRC, the originating office has the primary responsibility for identifying and correcting errors that appear in a published proposed rule document. See Section 9.5 of this handbook for information on preparing a correction document. The originating office shall coordinate the preparation of a correction notice with the RDB.

(c) The NRC may issue a rule in final form without first publishing a proposed rule if the action qualifies as an exception under the Administrative Procedure Act (5 U.S.C. 553(b)) and the Office of the General Counsel (OGC) approves this course of action. See Section 5.9(f) of this handbook for more information on issuing a rule in final form without requesting public comment. If the NRC does not expect to receive significant adverse comment on a noncontroversial, routine regulatory amendment, the NRC may issue a direct final rule and request public comment on the action in a companion proposed rule. See Section 5.1(a)(2) of this handbook for more information on issuing a direct final rule.

(d) The Administrative Procedure Act does not specify a minimum public comment period for a proposed rule. However, in Executive Order 12662 implementing the United States - Canada Free Trade Implementation Act, a 75-day comment period was mandated for substantive technical rulemaking actions. The North American Free Trade Agreement (NAFTA) has superseded the U.S. - Canada Act. OGC has indicated that an Executive Order implementing NAFTA, expected to be issued soon, does not address the public comment period with as much precision as the E.O. 12662. Because the new Executive Order will be more vague, OGC believes that there will probably be no exceptions to the requirement for a 75-day comment period.

3.3 Proposed rule documents: Anatomy.

This section dissects a typical proposed rule document. Each essential element of a proposed rule is identified to help a writer meet the required elements of a proposed rule document and create a complete and correct document. The number of the section in this handbook that discusses each required element in detail is indicated in parentheses. The format used in this and other examples to present document text generally reflects the format used in printing the Federal Register. However, the format used in the sample proposed rule document (see Section 15.2 of this handbook) reflects the format used in typing a document for publication in the Federal Register.

SAMPLE: PROPOSED RULE

Agency Heading	NUCLEAR REGULATORY COMMISSION
HEADINGS: CFR Citation Heading (3.5)	10 CFR Part 50
RIN Heading	RIN 3150-AA11
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 construction permits and holders of operating licenses for nuclear power plants 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 (75 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able

to ensure consideration only for comments received on or before this date.

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

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

Examine comments received, the environmental assessment, and the regulatory analysis at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C.

Obtain single copies of the environmental assessment, and the regulatory analysis from: (name, address, and telephone number of staff contact).

For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information section.

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

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.

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

Electronic Access

(This portion of the statement of considerations contains detailed instructions on how to obtain information or submit comments electronically.)

PROCEDURAL
REGULATORY
REQUIREMENTS:

National
Environ-
mental
Policy Act
(3.13)

Finding of No Significant Environmental
Impact: Availability

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

The determination of this Environmental Assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC welcomes public participation. The NRC has also committed to complying with Executive Order 12898 - Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. The NRC uses the following working definition of "environmental justice:" the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the Environmental Assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

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

The environmental assessment is available for inspection at the NRC Public Document Room,

2120 L Street NW. (Lower Level), Washington, D.C.
Single copies of the environmental assessment are
available from (insert name, address, and
telephone number of contact person).

**Paperwork
Reduction Act
(3.15)**

Paperwork Reduction Act Statement

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

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

1. Is the proposed information collection necessary for the proper performance of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by Internet electronic mail at BJS1@NRC>GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-), Office of Management and Budget, Washington, DC 20503.

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

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

**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, 2120 L Street NW. (Lower Level), 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 Certification

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

**Backfit Analysis
(3.21)**

Backfit Analysis

As required by 10 CFR 50.109, the Commission has completed a backfit analysis for the proposed rule. The Commission has determined, on the basis of this analysis, that backfitting to comply with the requirements of this proposed rule will provide a substantial increase in protection to public health and safety or the common defense and security at a cost that is justified by the substantial increase. The basis for this determination reads as follows: (Here insert the text of the backfit analysis).

**SUBJECT INDEX TERMS
(3.23)**

List of Subjects In 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire prevention, Intergovernmental relations, Nuclear power plants and reactors,

Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

WORDS OF ISSUANCE
(3.25)

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 50.

PART HEADING

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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

AUTHORITY CITATION

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

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

AMENDATORY LANGUAGE
(3.27)

2. In §50.54, paragraphs (a)(1) through (a)(4) are 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 3 years.

REGULATORY TEXT
(3.31 - 3.37)

(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.

* * * * *

SIGNATURE BLOCK

Dated at Rockville, Maryland, this ___ day of _____, 1999.

For the Nuclear Regulatory Commission.

John C. Hoyle,
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;
- (3) Provide the unique regulation identifier number (RIN) of the proposed rule; and
- (4) Indicate the subject matter of the document.

Example:

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

(b) The "CFR Citation" heading must contain the number of each part the document proposes to amend or establish. Even if the document proposes to 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 1).

(c) The "RIN" heading provides the unique number assigned to the rulemaking action. This number is used to identify the rulemaking action in the Unified Agenda of Federal Regulatory and Deregulatory Actions. The Office of Management and Budget (OMB) has requested that this number be included in

the headings of each rulemaking document published in the Federal Register. RDB assigns a RIN to each regulatory action. For assistance in determining whether a RIN has been assigned to a proposed rule, contact RDB (415-6863).

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

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

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-BB22

Testing Radioisotope Generators; Extension of Comment Period

3.7 Preambles: Format requirements.

Each proposed rule the NRC prepares for publication in the Federal Register must begin with a preamble. Within NRC, the preamble also is known as the Statement of Considerations. Although the preamble contains no regulatory text, it contains the information necessary for the user to understand the basis and purpose of the regulation. Each preamble must comply with the format requirements of 1 CFR 18.12. These requirements, which are discussed below, arrange basic information in a uniform format that allows a user to scan the beginning of the document for essential information. The OFR will not print a proposed rule document that does not meet the format requirements described in this section.

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

Example:

AGENCY: Nuclear Regulatory Commission.

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

ACTION: Proposed rule.

ACTION: Proposed rule: Extension of comment period.

ACTION: Proposed rule: Correction.

ACTION: Proposed rule: Notice of hearing (or meeting).
ACTION: Proposed rule: Withdrawal (or termination).
ACTION: Advance notice of proposed rulemaking.
ACTION: Petition for rulemaking.
ACTION: Petition for rulemaking: Denial.
ACTION: Petition for rulemaking: Withdrawal.
ACTION: Proposed policy statement.
ACTION: Proposed rule: Availability of supplemental information.

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

(1) The Summary must answer these questions:

(i) What does this document do?

(ii) Why is this action necessary?

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

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

(2) The answers must to these questions 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 documents by the OFR, and may result in the OFR returning a document to the NRC for required revisions.

(3) The Summary must --

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

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

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

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

Example:

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

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

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

- (i) Comment closing deadlines;
- (ii) Public hearing or meeting dates; and
- (iii) Other dates that may be relevant to public knowledge of the proceeding.

(2) Information concerning public hearing procedures, meeting agenda, content of materials available for public inspection, and other matters should be presented in the Supplementary Information portion of the preamble, not under the DATES caption.

Example:

DATES: The comment period expires December 31, 1998. Comments received after this date will be considered if it is practical to do so, but the

Commission is able to ensure consideration only for comments received on or before this date. Public hearings will be held on November 19 and 26, 1999.

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

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

(i) Mailing public comments;

(ii) Hand-delivering public comments;

(iii) Submitting comments electronically;

(iv) Attending a public hearing or meeting;

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

(vi) Obtaining other documents referred to in the proposed rule.

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

Example:

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

Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C.

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

For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information Section.

(f) **FOR FURTHER INFORMATION CONTACT.** This caption identifies a person who can answer questions or provide additional information concerning the

document. The name and telephone number of the designated individual must be presented. The NRC may include the person's title, mailing address, and e-mail address. Two or more persons may be listed as contacts concerning different aspects of a document.

Example: One contact person.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-234; XXX@NRC.GOV.

Example: Two contact persons.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-9876; e-mail XXX@NRC.GOV, or (Name of contact person), Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-0102; e-mail XXX@NRC.GOV.

3.9 Preambles: Supplementary Information.

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

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

- (1) The purpose of the proposed regulation;
- (2) The need for the proposed regulation;
- (3) The laws or directives that authorize the proposed regulation;
- (4) The relationship of the proposed regulation to existing regulations;
- (5) The genesis of the proposed regulation;
- (6) The alternatives considered in developing the proposed regulation;
- (7) The estimated economic impact of the alternatives considered on those likely to be affected by the proposed regulation or the need for their cooperation in developing this analysis;
- (8) The substantive provisions of the proposed regulation on a section-by-section basis;
- (9) The issues to be commented on in the proposed regulation;
- (10) A description of any noncompliance or penalty provisions;

- (11) A history of the rulemaking proceeding to this point;
- (12) The views, concerns, and comments raised by Agreement States during the development of the proposed rule; and
- (13) 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 also can 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. Section-by-Section Analysis of Substantive Changes
- IX. Agreement State Compatibility
- X. Finding of No Significant Environmental Impact:
Availability.
- XI. Paperwork Reduction Act Statement.
- XII. Regulatory Analysis.
- XIII. Regulatory Flexibility Certification.
- XIV. Backfit Analysis.

I. 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 Parts 30 or 70, 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 the secondary metals industry from recycling smelted alloys containing these two radioactive materials as residual contamination.

II. Rulemaking initiation

The Department of Energy has underway Cascade Improvement Programs and Cascade Upgrading Programs begun by the AEC at both U.S. uranium enrichment plants -- Portsmouth, Ohio, and Paducah, Kentucky. 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 may not simply list the changes made in the regulation. A substantive description of the significant changes that are proposed by the regulation must be included. This description should present a section-by-section analysis of the substantive provisions of the proposed regulatory text.

Example:

Section-by-Section Analysis

Section 170.11 - Exemptions.

This section would be amended to add a new paragraph indicating that amendments to materials portable gauge licenses issued in accordance with NUREG 1556 that change only the name of the Radiation Safety Officer (RSO) would be exempt from amendment fees. This change is consistent with the recent Business Process Redesign (BPR) initiative and NUREG-1556, Volume

1, issued for public comment October 3, 1996 (61 FR 51729). No amendment fees would be assessed for the amendments issued in accordance with NUREG 1556 to portable gauge licenses because the regulatory program would include commitments from the licensee concerning RSO qualifications and if those commitments are included in the amendment application then there would be no technical review conducted by the NRC. The NRC expects NUREG 1556 to be finalized before the final fee rule becomes effective. If not, then this proposed change will not be included in the final fee regulation.

Section 170.20 - Average cost per professional staff-hour.

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

* * * * *

(d) If the NRC published an advance notice of proposed rulemaking (ANPRM), the substantive comments received on the ANPRM must be discussed in the Supplementary Information section of the preamble to the proposed rule. This 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, this 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 both in 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).

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

(f) If a proposed rule references an NRC publication (NUREG), the NRC shall include a statement in the Supplementary Information section of the preamble to the proposed rule that indicates how an interested person may obtain a copy of the referenced material. The statement is inserted as a single spaced footnote following the first reference to a NUREG in the proposed rule.

(1) If the referenced NUREG is in draft form, the NRC shall use the following statement of availability.

¹Those considering public comment may request a free single copy of draft NUREG-XXXX by writing to the U.S. Nuclear Regulatory Commission, Printing and Graphics Branch, Washington, DC 20555-0001. A copy is also available for inspection and/or copying in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C.

(2) If the referenced NUREG is in final form, the NRC shall use the following statement of availability.

¹Copies of NUREGS may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C.

(g) If the NRC is encouraging public participation through electronic means, the proposed rule must contain instructions on how the public may obtain or submit information to the NRC electronically.

Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld or connecting to the NRC interactive rulemaking web site, "Rulemaking Forum." The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the rulemaking also are available for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC subsystem on FedWorld can be accessed directly by dialing the toll free number: 1-800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." For further information about options available for NRC at FedWorld, consult the "Help/Information Center" from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct-dial telephone number for the main FedWorld BBS: 703-321-3339; Telnet via Internet: fedworld.gov (192.239.93.3); File Transfer Protocol (FTP) via Internet:ftp:fedworld.gov (192.239.92.205); and World Wide Web using: <http://www.fedworld.gov> (this is the Uniform Resource Locator (URL)).

If using a method other than the toll-free number to contact FedWorld, access the NRC subsystem from the main FedWorld menu by selecting "F - Regulatory, Government Administration and State Systems," then selecting "A - Regulatory Information Mall." At that point, take the "A - U.S. Nuclear Regulatory Commission" from the displayed menu to the NRC Online Main Menu. An alternative is to go directly to the NRC Online area by typing "/go nrc" at the FedWorld command line. Accessing NRC from FedWorld's Main Menu allows the user to return to FedWorld by selecting the "Return to FedWorld" option from the NRC Online Main Menu. However, accessing NRC at FedWorld by using NRC's toll-free number provides the user with full access to all NRC systems, but does not provide access to the main FedWorld system.

To see the NRC area and menus, including the Rules Menu, contact FedWorld using Telnet. Although this will enable the user to download documents and leave messages, the user will not be able to write comments or upload files (comments). FedWorld may be contacted using FTP; although all files can be accessed and downloaded, uploads are not allowed; all that is visible is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is included. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the World Wide Web, like FTP, that mode only provides access for downloading files and does not display the NRC Rules Menu.

The NRC's interactive rulemaking web site may be accessed through the NRC home page (<http://www.nrc.gov>). This site provides the same access as the FedWorld bulletin board, including the facility to upload comments as files (any format), if the user's web browser supports that function.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Telephone: 301-415-5780; e-mail: AXD3@nrc.gov. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, Telephone: 301-415-6215; e-mail: CAG@nrc.gov.

3.11 Procedural requirements for rulemaking.

(a) Sections 3.13 through 3.21 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 Section 3.13 of this handbook);

(2) OMB approval for each new or amended information collection requirement under the Paperwork Reduction Act (see Section 3.15 of this handbook);

(3) A regulatory analysis prepared in accordance with the Regulatory Analysis Guidelines approved by the Commission in a Staff Requirements Memorandum issued June 30, 1995 (SECY-95-028), and issued as NUREG/BR-0058, Rev. 2. A regulatory analysis examines the economic impact, in terms of costs and benefits, of alternatives considered in developing the proposed rule (see Section 3.17 of this handbook);

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

(5) A backfit analysis prepared in accordance with 10 CFR 50.109, 72.62, or 76.76 (see Section 3.21 of this handbook.)

(b) The environmental assessment and economic analyses should precede, or be 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 Section 3.19 of this handbook). Section 5.2 of the Regulatory Analysis Guidelines requires that factors necessary to evaluate the economic impact on small entities be addressed in the regulatory analysis (see Section 3.17 of this handbook).

(d) If the proposed rule will add or amend an information collection requirement affecting 10 or more persons, the NRC must obtain OMB approval of the information collection requirement. The clearance package necessary to obtain OMB approval must be prepared at the same time the proposed rule is being prepared. The NRC may not submit a proposed rule that adds or amends an information collection requirement for signature and publication until the clearance package requesting OMB approval has been forwarded to OMB. Please note that the information collection requirements must be approved by OMB before the final rule is submitted for signature and publication. Section 5.1 of the Regulatory Analysis Guidelines requires that factors needed to obtain OMB approval be addressed in the regulatory analysis.

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 an environmental impact statement on each major Federal action significantly affecting the quality of the human environment. The intent of the Act is to build the consideration of environmental aspects of proposed actions into the decisionmaking process of the agency.

(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 51.20(a)(1)); or

(2) Involves a matter that the Commission has determined should be covered by an environmental impact statement (See 10 CFR 51.20(a)(2) and (b)).

(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. This statement must indicate that either --

(1) An environmental impact statement has been prepared for the proposed regulation;

(2) An environmental assessment and a finding of no significant impact have been prepared for the proposed regulation; or

(3) The proposed regulation is one of the types of actions included in the list of categorical exclusions set out in 10 CFR 51.22(c).

(c) In order to fulfill a commitment made to the Council on Environmental Quality, the NRC shall consult with the States on environmental issues before issuing an environmental assessment and shall document the consultation in the

environmental assessment. The Executive Director for Operations has approved an NRC procedure for consultation with the States during the preparation of an environmental assessment for a rulemaking action (See the Memorandum from David L. Morrison to multiple addressees dated May 18, 1995). These procedures are presented in Appendix E to this handbook.

(d) In a letter dated March 31, 1994, from the Chairman to the President, the NRC voluntarily agreed to carry out the measures set forth in Executive Order 12898 mandating that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, or activities on minority populations and low-income populations. The NRC stated that these requirements applied primarily to its efforts to comply with NEPA and that it would address environmental justice aspects as part of its considerations under NEPA. The EDO signed the NRC's environmental justice procedures on October 24, 1995.

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

Environmental Impact Statement: Availability

As required by the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, the NRC has prepared a draft environmental impact statement on this proposed rule.

The draft environmental impact statement is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. Single copies of the draft environmental impact

statement may be obtained from (name, address, and telephone number of contact person).

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

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

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

(f) Unless the action is eligible for one of the categorical exclusions listed in 10 CFR 51.22(c) (see paragraph (g) of this section), the NRC shall prepare an environmental assessment on each licensing and regulatory action, including a proposed regulation, for which an environmental impact statement has not been prepared (see 10 CFR 51.21, 51.30, and 51.31). If after completing an environmental assessment for a proposed regulation, the NRC determines that an environmental impact statement need not be prepared, the NRC shall prepare and publish a finding of no significant impact (see 10 CFR 51.32, 51.33, 51.34, 51.35, and 51.119.) This finding includes a statement that the NRC has determined not to prepare an environmental impact statement for the action and explains why the NRC believes that the action will not have a

significant effect on the quality of the human environment. The NRC may either include the text of the environmental assessment in the Supplementary Information section of the preamble to the proposed rule or summarize the environmental assessment and indicate how interested persons may obtain a copy of it.

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

Finding of No Significant Environmental Impact: Environmental Assessment

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

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC welcomes public participation. The NRC has also committed to complying with Executive Order 12898- Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. The NRC uses the following working definition of "environmental justice:" the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws,

regulations, and policies. Comments on any aspect of the Environmental Assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

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

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

· Finding of No Significant Environmental Impact: Availability

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

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC welcomes public participation. The NRC has also committed to complying with Executive Order 12898- Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994, in all its actions. Therefore, the NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, the NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule but somehow were not addressed. The NRC uses the following working definition of "environmental justice:" the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the

development, implementation, and enforcement of environmental laws, regulations, and policies. Comments on any aspect of the Environmental Assessment, including environmental justice, may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the Environmental Assessment. The environmental assessment is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. Single copies of the environmental assessment are available from (insert name, address, and telephone number of contact person).

Note: Availability of the environmental assessment also must be listed under the ADDRESSES caption of the preamble.

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

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

(i) Amendments to Parts 0, 1, 2, 4, 7, 8, 9, 10, 11, 14, 19, 21, 25, 55, 75, 95, 110, 140, 150, 170, or 171 of this chapter (10 CFR 51.22(c)(1)).

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

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

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

(B) Recordkeeping requirements; or

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

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

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

Environmental Impact: Categorical Exclusion

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

3.15 Paperwork Reduction Act.

(a) General. The Paperwork Reduction Act (44 U.S.C. 3501 et seq.) is intended to minimize the burden on regulated parties resulting from the collection of information by and for the Federal Government. The Act also is intended to maximize the public benefit and practical utility of information created, collected, disclosed, maintained, used, shared, and disseminated by or for the Federal Government. The Act requires each Federal agency to obtain approval from OMB for each information collection activity that affects 10 or more persons. The factors necessary to obtain OMB approval must be addressed in the regulatory analysis (see Section 3.17 of this handbook). The NRC complies with the Act in a manner consistent with its responsibilities to ensure that public health and safety is adequately protected. An approved information collection request must display the OMB clearance number, a public protection notification, and, where appropriate, the expiration date. The Information and Records Management Branch is responsible for coordinating NRC activities necessary to comply with the Paperwork Reduction Act.

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

(1) An information collection request that is submitted to nine or fewer people must contain a statement that the request is not subject to the Paperwork Reduction Act.

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

(c) Preparation of OMB clearance package. If a proposed rule contains a new or amended information collection requirement, the clearance package necessary to obtain OMB approval must be developed at the same time the proposed rule is being developed. The proposed rule and the clearance package must be developed along parallel tracks so that when the proposed rule is submitted for signature and publication the necessary concurrences have been obtained for the clearance package and it is ready for transmittal to OMB. The NRC may not submit a proposed rule that contains a new or amended information collection requirement for publication until the clearance package necessary to obtain OMB review and approval has been transmitted to OMB.

(d) Standard statements. One of the following statements must be included in the Supplementary Information section of the preamble to each proposed rule concerning information collection requirements. Information collection requirements include any reporting, recordkeeping, third-party disclosure, or application requirement.

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

Paperwork Reduction Act Statement

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

The public reporting burden for this information collection is estimated to average ____ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public

comment on the potential impact of the information collection contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-), Office of Management and Budget, Washington, DC 20503.

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

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

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

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et

seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

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

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing this burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-), Office of Management and Budget, Washington, DC 20503.

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

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

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

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

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

Paperwork Reduction Act Statement

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

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

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

Paperwork Reduction Act Statement

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

(5) Exempt information collection requirements. If a proposed rule contains an information collection requirement that is exempt from the requirements of the Paperwork Reduction Act under 44 U.S.C. 3518(c)(1), the NRC

shall insert the following statement in the Supplementary Information section of the preamble to the proposed rule.

Paperwork Reduction Act Statement

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

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

Paperwork Reduction Act Statement

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

(e) Guidance. Questions concerning the procedures and requirements of the Paperwork Reduction Act may be directed to Brenda Jo. Shelton, Chief, Information and Records Management Branch (415-7233).

3.17 Regulatory analysis.

(a) Introduction. The Commission approved the issuance of NRC's revised Regulatory Analysis Guidelines on June 30, 1995 (SECY-95-028). The Regulatory Analysis Guidelines are printed in NUREG/BR-0058, Rev. 2, August 1995. These guidelines establish a framework for --

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

(b) Purpose. (1) The regulatory analysis is intended to ensure that NRC decisions that impose regulatory burdens on licensees are based on adequate information concerning the extent of these burdens and the resulting benefits. The regulatory analysis also ensures that decisions are made through a systematic and disciplined process that is clear to all participants and affected parties. Ultimately, the regulatory analysis ensures that the regulatory burdens imposed are needed, justified, and the minimum necessary to achieve regulatory objectives.

- (2) Each regulatory analysis must assess the following impacts:
 - (i) Direct costs or savings to licensees, the NRC, and State and local government agencies;
 - (ii) Nonradiation risk-related costs or savings to the general public;
 - (iii) Averted onsite impacts;
 - (iv) Changes in regulatory efficiency or scientific knowledge needed for regulatory purposes; and
 - (v) Conformance with formal positions adopted by national and international standards organizations.

(c) Coverage. (1) A regulatory analysis must accompany each mechanism used by the NRC staff to establish or communicate generic requirements, guidance, requests, or NRC staff positions that would place a burden on licensees.

(2) Regulatory analysis requirements for a given action may be eliminated at the discretion of the Commission, the EDO, a Deputy EDO, or the responsible NRC Office Director.

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

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

(1) If the proposed rule would impose collection requirements that require obtaining OMB approval under the Paperwork Reduction Act (see Section 3.15 of this handbook), the draft OMB clearance package must be included as a stand-alone appendix to the regulatory analysis.

(2) The regulatory analysis must contain information sufficient to address requirements mandated by the Regulatory Flexibility Act (see Section 3.19 of this handbook).

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

regulatory flexibility analysis may reference information discussed in the body of the regulatory analysis.

(ii) If the NRC certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities, the regulatory analysis must contain sufficient information concerning the potential impact of the proposed rule on small entities to support this certification.

(3) If an environmental impact statement has been prepared and forms the basis for the proposed rule, a summary of the environmental impact statement is an appropriate substitute for the information and analysis requirements identified in NUREG/BR-0058, Rev. 2, Sections 4.1-4.3.

(e) Required statement. The following 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 of it.

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, 2120 L Street NW. (Lower Level), Washington, D.C. Single copies of the analysis may be obtained from (insert name, address, and telephone 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.

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

(b) Applicability. The Act applies to each rule subject to notice and comment rulemaking under the Administrative Procedure Act (5 U.S.C. 553 (b)). Therefore, the requirements of the Act apply to each proposed rule developed by the NRC. The Act does not apply if a rule is first issued in final form without notice of proposed rulemaking.

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

(1) If the NRC believes that 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 for public comment. The regulatory flexibility analysis may be combined with

other analyses as long as it meets the requirements of the Act. The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 2) require that factors necessary to evaluate the economic impact of the proposed rule on small entities be addressed in the regulatory analysis that considers the costs and benefits of the proposed rule (see Section 3.17 of this handbook).

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

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

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

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

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

§ 2.810 NRC Size Standards.

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

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

(1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$5 million or less over its last 3 completed fiscal years; or

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

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

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

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

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

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

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

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

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

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

Regulatory Flexibility Analysis

The NRC has prepared an initial regulatory analysis of the impact of this proposed rule on small entities. The preliminary analysis indicates that although the proposed rule will have an economic impact of \$1500-1750 annually on medical licensees, of which 18 percent are small entities, the proposed alternative is the least costly alternative that provides adequate protection from radiation exposure for patients and workers. A summary of this analysis appears as Appendix A to this document. A copy of the analysis is available for inspection in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), 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, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.

(ii) The NRC must make a good faith effort to prepare a thorough analysis of the impact of a proposed regulation on small entities. However, if after preparing an initial regulatory flexibility analysis or conducting a preliminary examination of the anticipated impacts of the proposed rule on small entities, the NRC needs more information on how the proposed rule will actually affect small entities or on how a rule may be modified to alleviate significant economic impact upon them, the NRC may use the following statement.

Regulatory Flexibility Analysis

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

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

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

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

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

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

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

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

Regulatory Flexibility Certification

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

The potential gains in patient protection significantly outweigh the economic impact on small medical licensees. However, the NRC is seeking

comments and suggested modifications because of the widely differing conditions under which small medical licensees operate.

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

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

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

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

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

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

(f) Initial Regulatory Flexibility Analysis. The Act requires that the initial regulatory flexibility analysis, or a summary of the analysis, be published in the Federal Register with the proposed rule. The analysis or summary is presented as an appendix to the document. If a summary is published, it must contain sufficient detail concerning the cost and benefits of the proposed rule to enable a small entity to determine how the proposed rule will affect it, and whether it requires the more detailed information contained in the analysis. An initial regulatory flexibility analysis must contain the following information:

(1) A description of the reasons why the agency is considering regulatory action. Include a short paragraph explaining the statutory, policy, program, or practical reasons for the rule or amendment. Cite the preamble for more details.

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule. Include a brief statement of objectives and cite the preamble for details. If the rule is being issued under new statutory authority, cite it here; otherwise, reference the authority citation contained in the proposed rule document.

(3) A description and, where feasible, an estimate of the number of small entities to which the proposed rule will apply. Describe the type and number of licensees affected. If a specific number of licensees is not known, use realistic estimates. To the extent possible, the NRC should --

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

(ii) Cite the NRC's size standard rule to identify the steps taken to develop a definition of a small entity that is different from the Act's definition; and

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

(4) Description of projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of reports or records.

(i) Describe these requirements generally. Reference the more detailed statement of requirements in the preamble or codified text. Obtain detailed analyses of costs and administrative burdens associated with reporting and recordkeeping from the paperwork burden analysis prepared to comply with the Paperwork Reduction Act.

(ii) Indicate the type of small entity subject to each requirement, e.g., field radiographers, private physicians, manufacturers of certain equipment. Indicate the type of professional skill needed to prepare the report, e.g.,

radiographer, lab technician, production manager, general administrative expert.

(iii) To the extent possible, analyze the long- and short-term costs of the proposed requirements and the classes of small entities that will be subject to them. These costs should include direct compliance costs as well as reporting, recordkeeping, or other administrative costs. Compare the costs of compliance for large and small entities as well as the ability of small entities to pass on these costs as price increases or user fees. Consider the resulting effects, if any, the proposed requirements may have on closures, production, operating costs, employment, or other relevant factors.

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

(5) An indication, to the extent practicable, of all relevant Federal rules that may duplicate, overlap, or conflict with the proposed rule.

Indicate "none" if there is no duplication or conflict. However, if you are aware of any duplication, indicate the provision and explain why the duplication is necessary.

(6) A description of the significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and minimize the rule's economic impact on small entities. Include a description of any

significant alternative regulatory provisions that were considered.

Alternatives that may be considered include --

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

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

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

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

(7) Economic impact of rule. Summarize the economic cost of the rule to small entities, the impact of the rule on their ability to compete within the affected industry, and the overall impact of the rule on the affected business community considering such factors as employment, business failures, and the concentration of firms in the market.

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

3.21 Backfit analysis.

(a) The NRC has established standards for the management of backfitting requirements imposed on power reactors (10 CFR 50.109). Backfitting is a process that can include both plant-specific changes and generic changes applied to one or more classes of power reactors. Essentially identical provisions were established to manage backfitting requirements imposed on gaseous diffusion plants (10 CFR 76.76). Provisions also were established to manage backfitting requirements imposed on an independent spent fuel storage installation or a monitored retrievable storage installation (10 CFR 72.62)

(b) The definition of backfitting has three components.

(1) The first component is the modification of or addition to --

(i) Systems, structures, components, or design of a facility;

(ii) The design approval or manufacturing license for a facility; or

(iii) The procedures or organization required to design, construct, or operate a facility.

(2) The second component is that the modification or addition is the result of either --

(i) A new or amended provision of the Commission's regulations; or

(ii) A regulatory NRC staff position interpreting these regulations that is either new or different from a previously applicable NRC staff position.

(3) The third component is that the modification or addition is considered a backfit only if it results from a new or amended regulation or NRC staff position issued after --

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;

(ii) Six months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

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

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

(c) Except as indicated in paragraph (e) of this section, the NRC shall prepare a systematic and documented backfit analysis for each backfit that it seeks to impose by rulemaking action. The Commission may impose a backfit on a facility that already provides adequate protection of public health and safety and common defense and security only if the backfit analysis indicates that --

(1) There would be a substantial increase in the overall protection to the public health and safety or the common defense and security derived from the backfit; and

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

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

(1) A statement of the specific objectives that the proposed backfit is designed to achieve;

(2) A general description of the activity that would be required of the licensee or the applicant to complete the backfit;

(3) The potential change in the risk to the public from the accidental offsite release of radioactive material;

(4) The potential impact on the radiological exposure of facility employees;

(5) The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of NRC resources;

(8) The potential impact of differences in facility type, design, or age on the relevance and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

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

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

(ii) A backfit is necessary to bring a facility into compliance with a license, a licensee's written commitments, or the rules and orders of the Commission; or

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

(2) If the provisions of paragraph (e)(1) of this section apply, the NRC shall prepare a documented evaluation that includes a statement of the objectives of and reasons for the proposed backfit, and the basis for treating it as an exception to the requirements of paragraphs (c) and (d) of this section.

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

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

Backfit Analysis

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

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

Backfit Analysis

The Commission has concluded, on the basis of the documented evaluation required by 10 CFR 50.109(a)(4) (or 72.62 or 76.76 as appropriate), that the backfit requirements contained in this proposed rule (Insert one of the following three options: option 1 - "are necessary to bring the facilities described into compliance with licenses or the rules and orders of the Commission or into conformance with written commitments by the licensees, and therefore," option 2 - "are necessary to ensure that the facilities described in the rule provide adequate protection to the health and safety of the public and are in accord with the common defense and security, and therefore," option 3 - "involve defining or redefining what level of protection to the public health and

safety or the common defense and security should be regarded as adequate, and, therefore,") that a backfit analysis is not required and the cost-benefit standards of 10 CFR 50.109(a)(3) (or 72.62 or 76.76, as appropriate) do not apply. The documented evaluation includes a statement of the objectives of and reasons for the backfits that would be required by the proposed rule and sets forth the basis for the Commission's conclusion that these backfits are not subject to the cost-benefit standards of 10 CFR 50.109(a)(3) (or 72.62 or 76.76, as appropriate). (Insert the text of the documented evaluation).

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

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because (Insert one of the following three options: Option 1 - "these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I." Option 2 - "these amendments do not impose more stringent safety requirements on 10 CFR Part 50 (or Part 72 or Part 76, as appropriate) licensees." Option 3 - "these amendments are mandated by (cite the appropriate act of Congress).")

3.23 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, in a standard fashion, the major topics of the proposed rule and the categories of persons affected by it.

(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. The NRC shall present the list of subject index terms in alphabetical order as follows:

Example: Format used in a document citing a single CFR Part.

List of Subjects in 10 CFR Part 20

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

Example: Format used in a document citing two or more CFR Parts.

List of Subjects

10 CFR Part 30

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

10 CFR Part 40

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

10 CFR Part 70

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

(b) The NRC shall use the subject index terms developed by the RDB and approved by the OFR in the list of subject index terms provided for each part. These terms appear in the Thesaurus of Indexing Terms. The terms provide a common vocabulary for indexing the rulemaking documents of all agencies and form the basis for the CFR Index. A 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 RDB (415-7158).

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

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

3.25 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 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 Section 3.29 of this handbook for information on authority citations). The words of issuance directly precede the heading of the first CFR part the document proposes 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.

3.27 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 1. Amendatory language uses standard terms to give instructions on how to change the CFR.

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

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

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

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

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

(1) Added.

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

Examples:

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

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

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

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

Example:

§19.3 [Amended]

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

(2) Amended. "Amended" means that an existing CFR unit is changed.

Because "amended" is a very general term compared to any other term used to describe a type of change, it is used with other amendatory terms that describe the specific nature of the change.

Examples:

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

2. 10 CFR Chapter I is amended by adding Part 103 to read as follows:

3. Section 73.97 is amended by removing paragraph (e).

(3) Corrected. "Corrected" means that a clerical or typographical error in a published document is fixed. The error must be corrected before the next annual revision date of 10 CFR Chapter I. Once the error is codified, a formal amendment is necessary to make the change. A correction is not an amendment and may not be used to write in second thoughts. Any "fine tuning" of a published regulation must be in the form of a formal clarifying amendment.

Examples:

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

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

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

Examples:

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

2. Part 33 is redesignated as Part 75.

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

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

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

Examples:

1. Part 110 is amended by removing §110.70.

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

(6) **Republished.** "Republished" means that an unchanged unit of CFR text is set out for the convenience of the reader, often to provide the context for an amendment. This term is mostly used with the introductory text of a section or paragraph. Because all regulatory text that is published or republished in

a proposed rule document may be used to update the CFR, the NRC shall present any republished text it chooses to use accurately.

Example:

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

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

Examples:

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

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

Example:

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

(9) Suspended. "Suspended" means that the effectiveness of a CFR unit is stayed temporarily or indefinitely. Suspended is not a true amendatory term

because it does not actually change the content of the CFR; it simply reflects the changed status of a particular CFR unit. The NRC should avoid an open-ended suspension by stating the duration of the suspension in the document announcing the action. During the suspension, the suspended provision is not in effect or enforceable. The suspended provision continues to appear in the CFR; however, the OFR will insert an editorial note explaining the status of the provision. The NRC is responsible for issuing the 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, 1995, to October 1, 1996.

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

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

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

(d) If an amendment makes several changes within a section, the amendatory language must clearly identify each change. All changes to the section must be described in one amendatory instruction.

Examples:

1. In §73.3, paragraphs (d) and (f) are revised, 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 Section 3.29(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 amendments to 10 CFR Part 33.

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

1. The authority citation for Part 33 is revised to read as follows:
AUTHORITY: 42 U.S.C. 2111, 2201, 2232, 2233, 5841).

2. Section 33.13 is revised to read as follows:

§33.13 Applications for specific licenses of broad scope.

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

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

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

* * * * *

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

necessary to ensure safe operations. (Note: The use of asterisks in amending CFR text is discussed in Section 3.35 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.

3.29 Authority citations.

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

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

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

Example:

1. The authority citation for Part 35 is revised to read as follows:
AUTHORITY: 42 U.S.C. 2111, 2201, 2232, 2233, 841).

(b) Content. The RDB maintains a list of currently effective authority citations for each part in 10 CFR Chapter 1. The drafter may contact RDB to obtain the current authority citation for insertion into his or her document (415-6484).

(c) Placing authority citations: When amending an entire CFR part. If a document sets out a whole CFR part, the authority citation must be placed directly after the table of contents and before the regulatory text.

Example:

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

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

AUTHORITY: 42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282), 5841.

(d) Placing authority citations: When amending a portion of a CFR part.

If a document amends only certain sections within a CFR part, a complete citation of authority must be presented.

(1) If the authority for issuing an amendment is the same as the authority listed for the whole CFR part, simply restate the entire authority. The restated authority citation is placed as the first item in the list of amendments to the part.

Example:

PART 160 - TRESPASSING ON COMMISSION PROPERTY

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

AUTHORITY: 42 U.S.C. 2201, 2278a, 5841.

2. Section 160.3 is revised to read as follows:

§160.3 Trespass.

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

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

Example:

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

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

2. Section 71.2 is revised to read as follows:

§71.2 Scope.

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

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

Example: A part authority that includes section-specific citations. The second paragraph sets out the section-specific authorities.

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

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

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

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

3.31 Regulatory text: CFR codification.

(a) Amending the CFR. The regulatory text of a proposed rule document will, if adopted as a final rule, be codified in the CFR. NRC regulations are codified in 10 CFR Chapter I. The regulatory text of each NRC proposed rule document must be presented as an amendment to 10 CFR Chapter 1. Regulatory text must --

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

(b) CFR structure. (1) The basic structure of the CFR consists of a hierarchy of designated CFR units. The major components of this structure are illustrated in the following table.

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

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

(3) The section is the basic CFR unit. Most amendments are expressed in terms of how they affect a section or a group of sections. The content of a section is limited to a short simple presentation of a single regulatory

proposition. Each section number includes the number of the part followed by a period and a sequential number. The first section in Part 25 is expressed as "§25.1." Sections in a new or revised part need not be numbered consecutively. Using all odd or even sequential numbers in designating sections within a new or revised part leaves room for future expansion.

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

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

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

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

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

Example:

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

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

Example:

§30.63 Violations.

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

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

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

or

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

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

(1) For violations of --

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

(ii) Section 206 of the Energy Reorganization Act;

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

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

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

(iii) The NRC shall avoid overly detailed subdivision within a section by dividing a long, complex section into a series of smaller, more compact sections. Divisions below the third level of designation generally indicate that the drafter is attempting to include too much material within the section.

As a result, a user will have more difficulty locating the important material buried within a section. A user finds information within a regulation primarily through the section heading. If sections are too long, there are fewer headings, and those headings cannot adequately reflect the material contained in the section. (See Section 13.7 of this handbook; Arranging material for ease of use.)

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

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

Example:

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

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

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

(1) To manufacture, make, 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 does not permit the use of hyphenated numbers (§117-2.1 or §11-7.201) or numbers with alpha characters (Part 115a, §115a.1, or §115.1a) in designating units within the CFR system.

(i) The NRC may, if necessary, continue to use a hyphenated number or alpha character in a CFR part that already contains a unit designated in this fashion. However, any new material must be designated in standard fashion.

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

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

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

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

(e) Footnotes. The NRC should avoid the use of footnotes in the text of a regulatory document. Explanatory notes and references should be presented within document text. If a footnote is essential, care must be taken in the manner and form in which it is designated and presented 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. 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 page.

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

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

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

3.33 Regulatory text: Headings.

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

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

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

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

Example:

Part 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

* * * * *

Subpart D - Application for Package Approval

71.31 Contents of application.

71.33 Package description.

71.35 Package evaluation.

- 71.37 Quality assurance.
 - 71.39 Additional information.
 - Subpart E - Package Standards
 - 71.41 Demonstration of compliance.
 - 71.43 General standards for all packages.
 - 71.45 Lifting and tie-down standards for all packages.
 - 71.47 External radiation standards for all packages.
 - 71.49 Additional requirements for Type B packages.
 - 71.51 Fissile material categorization and exemptions.
 - 71.53 General requirements for all fissile material packages.
 - 71.55 Specific standards for a Fissile Class I package.
 - 71.57 Specific standards for a Fissile Class II package.
 - 71.59 Specific standards for a Fissile Class III shipment.
- * * * * *

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

Example:

Subpart C - General Licenses

- 71.12 General license: NRC approved package.
- 71.14 General license: DOT specification container.
- 71.16 General license: IAEA package.
- 71.18 General license: Type A, Fissile Class II package.
- 71.20 General license: Restricted, Fissile Class II package.
- 71.22 General license: Type A package, Fissile Class III shipment.
- 71.24 General license: Restricted, Fissile Class III shipment.

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

Example:

§2.730 Motions.

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

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

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

* * * * *

3.35 Form of amendment: Section level.

(a)(1) Each amendment made at the section level requires three elements.

These elements must appear in the following order--

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

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

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

Example:

Words of issuance

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 35.

Part heading

PART 35 - HUMAN USES OF BYPRODUCT MATERIAL

Unchanged authority citation

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

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

Amendatory language

2. Section 35.2 is revised to read as follows:

Section heading

§35.2 License requirements.

Regulatory text

A person subject to these regulations may not receive, possess, use, or transfer byproduct material for any human use unless in accordance with a specific or general license issued under the regulations in this part and Parts 30 and 32 or 33 of this chapter.

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

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

(2) Three asterisks in a row represent text within a paragraph that is not being amended. Three asterisks are used with the paragraph designator to indicate levels of designation that are not affected by an amendment to a paragraph below the first level of designation. (See Sections 3.31(b)(4) and (5) of this handbook concerning paragraph designation.)

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

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

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

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

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

Example:

This example serves two purposes. It illustrates --

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

Words of Issuance

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 20 and 21.

Part heading

PART 20 - STANDARDS FOR
PROTECTION AGAINST RADIATION

Unchanged authority
citation

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

AUTHORITY: 42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 5841, 5842, 5846.

Amendatory language

2. In §20.1101, paragraph (b) is revised to read as follows:

Section heading

§20.1101 Radiation protection programs.

Indicates that paragraph

* * * * *

(a) is unchanged

Revised text

(b) The licensee shall use, to the extent practicable, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Indicates that the rest of
the section is unchanged

* * * * *

Amendatory language

3. In §20.1204, paragraph (c)(1)

is revised to read as follows:

Section heading §20.1204 Determination of internal exposure.

Indicates that paragraphs * * * * *

(a) and (b) are unchanged

Indicates that the introductory (c) * * *

text of paragraph (c) is unchanged

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

Indicates that the rest of * * * * *

the section is unchanged

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

Section heading §20.2201 Reports of theft or loss of licensed material.

Indicates that paragraph (a) * * * * * is unchanged

Indicates that the introductory (b) * * *

text of paragraphs (b)(1) and (1) * * *

(b)(1)(i) and (ii) are unchanged.

The paragraph designation and three asterisks are necessary to place this amendment within paragraph (b)(1)

Revised text of paragraph (b)(1)(iii) (iii) A statement of disposition or probable disposition of the licensed material involved;

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

Added text of paragraph (b)(1)(vi) (vi) Procedures or measures that have been or will be adopted to prevent a recurrence of the loss or theft of licensed material.

Indicates that the rest of
the section is unchanged

* * * * *

Part heading

PART 21 - REPORTING OF DEFECTS AND
NONCOMPLIANCE

Amendatory language

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

Revised authority citation

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

Amendatory language

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

Section heading

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

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

* * * * *

Revised text of paragraph (c)

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

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

3.37 Form of amendment: Part and subpart level.

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

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

Example:

Amendatory language

1. Part 160 is revised to read as follows:

Part heading

PART 160 - TRESPASSING ON
COMMISSION PROPERTY

Table of Contents

Sec.
160.1 Purpose.
160.2 Scope.
160.3 Trespass.
160.4 Unauthorized introduction of weapons or dangerous material.
160.5 Violations.
160.6 Posting.
160.7 Effective date of prohibition on designated locations.
160.8 Applicability of other laws.

Authority citation

AUTHORITY: 42 U.S.C. 2278a, 5841).

Regulatory text

§160.1 Purpose.

The purpose of this regulation is to protect and secure Nuclear Regulatory Commission property.

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

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

(c) The table of contents at the part level lists section numbers and headings contained in a part 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.

3.39 Proper cross-referencing techniques.

(a) A "cross-reference" is a reference from one unit of the CFR to another unit. A cross-reference only may be used to reference an existing unit of CFR text. Cross-referencing is not to be confused with incorporation by reference, a legal device that may be used to give material the force and effect of law without printing the material in the Federal Register (See Section 3.41 of this handbook, Incorporation by reference).

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

(1) The reference is required by court order, statute, Executive Order, or reorganization plan;

(2) The reference is to regulations promulgated by an agency with the exclusive legal authority to regulate in a subject matter area, but the referencing agency needs to apply these regulations to its own programs;

(3) The reference is informational or improves clarity and does not impose a requirement;

(4) The reference is to test methods or consensus standards produced by a Federal agency that have replaced or preempted private or voluntary test methods or consensus standards in a subject matter area; or

(5) The reference is to the department level from a subagency.

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

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

HOW TO WRITE A CROSS-REFERENCE IN CFR TEXT

References to a different TITLE

<u>When referencing</u>	<u>Write</u>
A Chapter	1 CFR Chapter I
A Part	1 CFR Part 2
A Section	1 CFR 2.7
A Paragraph	1 CFR 2.7(a)(2)

References within the same CHAPTER

<u>When referencing</u>	<u>Write</u>
A Part	Part 30 of this chapter
A Section	§30.19 of this chapter
A Paragraph	§30.19(a) of this chapter

References within the same PART

<u>When referencing</u>	<u>Write</u>
A Section	§20.15
A Paragraph	§20.15(a)

References within the same SECTION

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

3.41 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 is published data, criteria, standards, specifications, techniques, illustrations, or similar material.

(ii) 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.

(iii) 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 to at least 10 pages in the Federal Register or contain highly specialized, technical matter that may pose difficulties in composition or printing.

(iv) Material is eligible for incorporation by reference if it is reasonably available to and useable by the class of people affected by it. This means that, to the extent necessary to ensure fairness and uniformity in the administrative process, the material is available to the public for purchase or inspection. Generally material is considered available if the public may purchase or inspect it with minimum effort. To meet this criterion, a person must be able to --

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

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

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

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

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

(iii) Contain a brief subject description;

(iv) Contain a statement of availability; and

(v) Refer to 5 U.S.C. 552(a) and 1 CFR Part 51 and include a statement indicating that the Director of the Federal Register approves the incorporation by reference.

Example: A statement of incorporation by reference that meets OFR requirements.

(b) The ASME Boiler and Pressure Vessel Code, which is referenced in the following paragraphs, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A notice of any changes made to the material incorporated by reference will be published in the Federal Register. Copies of the ASME Boiler and Pressure Vessel Code may be purchased from the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, NY 10007. It also is available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20852-2738.

(1) As used in this section, references to Section 111 of the ASME Boiler and Pressure Vessel Code refer to Section III, Division I, and include editions through the 1977 Edition and addenda through the Summer 1979 Addenda.

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

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

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

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

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

PART 5 - FINAL RULES

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5.1 Final rule documents: Description.

(a) Each document the Nuclear Regulatory Commission (NRC) prepares that is published in the Rules and Regulations section of the Federal Register must meet the format requirements specified in 1 CFR Chapter I. The requirements applicable to a final rule are discussed in this part. The Office of the Federal Register (OFR) classifies documents for publication in one of 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 usually have general applicability and legal effect as defined in 1 CFR 1.1. They inform the public of the regulations applicable to them. As a result, these documents are subject to increased public scrutiny and are included in the numerical finding aids compiled by the OFR. The OFR classifies the following types of documents for publication in the Rules and Regulations section of the Federal Register.

(1) Final rules. Final rule documents amend NRC regulations in 10 CFR Chapter I by adding new text or revising or removing existing text. In a final rule document, the NRC shall publish, in full, each change to 10 CFR Chapter I and state an effective date for each change made.

(2) Direct final rules. A direct final rule is a regulatory document that is used for noncontroversial, routine regulatory amendments. A direct final rule becomes effective in a certain number of days, usually 60 days after publication, unless the NRC receives significant adverse comments within a prescribed comment period, usually 30 days after publication. The NRC publishes a companion proposed rule with each direct final rule and announces in the direct final rule that any significant adverse comments received will be considered as comments on the companion proposed rule and that the NRC will

not initiate a separate comment period in the action. If significant adverse comments are received, the direct final rule does not take effect and the NRC publishes a document in the Federal Register that withdraws the direct final rule. A direct final rule must meet the format requirements outlined for final rules in this part.

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

(4) Documents that relate to previously published final rules. The OFR classifies each document that relates to a previously published final rule as a final rule for purposes of publication in the Federal Register. This type of document may --

- (i) Correct a previously published final rule;
- (ii) Announce a meeting or hearing on a previously published final rule;
- (iii) Change 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. Therefore, each policy statement prepared by the NRC should comply with the format requirements specified in Section 5.7 of this handbook. The Rules and Directives Branch (RDB) should review each policy statement to determine whether it meets all procedural and format requirements for publication and can be properly integrated into the NRC Rules and Regulations after it is published in the Federal Register.

(b) NRC is responsible for verifying the accuracy and completeness of each document it publishes in the Rules and Regulations section of the Federal Register. Within NRC, the originating office has the primary responsibility for identifying and correcting errors that appear in a published final rule document. See Section 9.5 of this handbook for information on preparing a correction document. The originating office shall coordinate the preparation of a correction document with the RDB.

5.3 Final rule documents: Anatomy.

This section dissects a typical final rule document. Each essential element of a final rule is identified to help a writer meet the required elements of a final rule document and create a complete and correct document. The number of the section in this handbook that discusses each required element in detail is indicated in parentheses. The format used in this and other examples to present document text generally reflects the format used in printing the Federal Register. However, the format used in the sample final rule document (see Section 15.3 of this handbook) reflects the format used in typing a document for publication in the Federal Register.

SAMPLE: FINAL RULE

	Agency Heading	NUCLEAR REGULATORY COMMISSION
HEADINGS (5.5)	CFR Citation Heading	10 CFR Part 50
	RIN Heading	RIN 3150-AA11
	Subject Heading	Reporting Changes to the Quality Assurance Program
PREAMBLE (5.7)	Captioned Headings	AGENCY: Nuclear Regulatory Commission. ACTION: Final rule. SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require holders of construction permits and holders of operating licenses for nuclear power plants 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 provide greater assurance that quality assurance programs approved by the Commission do not have their effectiveness reduced by subsequent changes.
		EFFECTIVE DATE: January 8, 1999.

FOR FURTHER INFORMATION CONTACT: (Name of contact person) Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555; telephone 301-415-0011; e-mail xxx@nrc.gov.

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.

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

PROCEDURAL REGULATORY REQUIREMENTS

National Environmental Policy Act (5.13)

Finding of No Significant Environmental Impact: Availability

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

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

The NRC requested the views of the States on the Environmental Assessment for this rule. (Indicate whether the States' comments have been addressed and whether the environmental

assessment has changed as a result of the States' comments).

The environmental assessment is available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C. Single copies of the environmental assessment are available from (insert name, address, and telephone number of contact person).

**Paperwork
Reduction Act
(5.15)**

Paperwork Reduction Act Statement

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

The public reporting burden for this information collection is estimated to average ___ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

**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, 2120 L Street NW. (Lower Level), 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 Certification

As required by the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.801).

**Backfit Analysis
(5.21)**

Backfit Analysis

As required by 10 CFR 50.109, the Commission has completed a backfit analysis for this final rule. The Commission has determined on the basis of this analysis, that backfitting to comply with the requirements of this final rule provides a substantial increase in protection to public health and safety or the common defense and security at a cost which is justified by the substantial increase. The basis for this determination reads as follows: (Here insert the text of the backfit analysis).

**Small Business
Regulatory
Enforcement
Fairness Act
(5.23)**

**Small Business Regulatory
Enforcement Fairness Act**

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

**SUBJECT INDEX
TERMS (5.25)**

List of Subjects in 10 CFR Part 50

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

**WORDS OF ISSUANCE
(5.27)**

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 50.

PART HEADING

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION OF FACILITIES

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

AUTHORITY CITATION

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

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

AMENDATORY LANGUAGE (5.29)

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

REGULATORY TEXT (5.33-5.39)

§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, 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. Before 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 10 CFR Part 50, Appendix B. A copy of this evaluation must be maintained at the facility for 3 years.

* * * * *

SIGNATURE BLOCK

Dated at Rockville, Maryland, this ___ day of _____ 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,
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;
- (3) Provide the unique regulation identifier number (RIN) of the final rule; and
- (4) Indicate the subject matter of the document.

Example:

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

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

(c) The "RIN" heading provides the unique number assigned to the rulemaking action. This number is used to identify the rulemaking action in the Unified Agenda of Federal Regulatory and Deregulatory Actions. The Office of Management and Budget (OMB) has requested that this number be included in the headings of each rulemaking document published in the Federal

Register. RDB assigns a RIN to each regulatory action. For assistance in identifying the RIN that has been assigned to a final rule, contact RDB (415-6863).

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

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

Example:

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-BB22

Testing Radioisotope Generators; Confirmation of Effective Date

5.7 Preambles: Format requirements.

Each final rule the NRC prepares for publication in the Federal Register must begin with a preamble. Within NRC, the preamble also is known as the Statement of Considerations. Although the preamble contains no regulatory text, it contains the information necessary for the user to understand the basis and purpose of the regulation. Each preamble must comply with the format requirements of 1 CFR 18.12. These requirements, which are discussed below, arrange basic information concerning the regulation in a uniform format to allow a user to scan the beginning of the document for essential information. The OFR will not print a final rule document that does not meet the format requirements described in this section.

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

Example:

AGENCY: Nuclear Regulatory Commission.

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

ACTION: Final rule.

ACTION: Final rule: Change of effective date.

ACTION: Final rule: Suspension of effective date.

ACTION: Final rule: Confirmation of effective date.
ACTION: Final rule: Correction.
ACTION: Final rule: Interpretation.
ACTION: Direct final rule.
ACTION: Interim rule.
ACTION: Interim rule with request for comment.
ACTION: Policy statement.

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

(1) The Summary must answer these questions:

- (i) What does this document do?
- (ii) Why is this action necessary?
- (iii) What is the intended effect of this action?
- (iv) Who is affected by the regulation? (For example, what class of licensee?)

(2) The answers to these questions must be 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 documents by the OFR, and may result in the OFR returning a document to NRC for required revisions.

(3) The Summary must --

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

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

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

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

Example:

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

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

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

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

Example:

EFFECTIVE DATE: September 24, 1999.

(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, 1998 for §§2.744(e), 2.790(d)(1), 73.11(j) and (m), and 73.21(a), (b), and (c)(1). All remaining sections will be effective on January 20, 1999.

EFFECTIVE DATE: The amendments to §§30.7, 30.21, and 30.30 are effective December 21, 1998. The amendments to §§30.40(a) and (b), 30.41(a)(3), and 30.70 are effective January 20, 1999. The amendments to Part 40 are effective February 17, 1999.

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

Example:

EFFECTIVE DATE: November 21, 1998. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Federal Register as of November 21, 1998.

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

- (1) Mailing or hand delivering comments on an interim rule;
- (2) Attending a public hearing or meeting;
- (3) Examining any material available for public inspection; or

(4) Obtaining other documents referred to in the final rule.

Example:

ADDRESSES: Copies of the public record may be inspected at: NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C. A hearing concerning licensee requirements under this regulation will be held at: The NRC Auditorium, 11545 Rockville Pike, Rockville, Maryland.

(f) FOR FURTHER INFORMATION CONTACT. This caption identifies a person who can answer questions or provide additional information concerning the document. The name and telephone number of the designated individual must be presented. The NRC may include the person's title, mailing address, and e-mail address. Two or more persons may be listed as contacts concerning different aspects of a document.

Example: One contact person.

FURTHER INFORMATION CONTACT: (Name of contact person), Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-1234; e-mail XXX@NRC.GOV.

Example: Two contact persons.

FOR FURTHER INFORMATION CONTACT: (Name of contact person), Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-1111; e-mail XXX@NRC.GOV, or (Name of contact person), Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 415-2222; e-mail XXX@NRC.GOV.

5.9 Preambles: Supplementary Information.

The Supplementary Information section of the preamble serves as the published history of the document. The Supplementary Information section in a final rule contains the background information and specific details 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 to present an adequate explanation of the regulation. To provide an adequate basis for the rulemaking on the record in the event of a court challenge to the final rule, the Supplementary Information section should include a discussion of --

- (1) The purpose of the regulation;
- (2) The need for the regulation;
- (3) The laws or directives that authorize the regulatory action;
- (4) The relationship of the regulation to existing regulations;
- (5) The rulemaking history of the proceeding;
- (6) The alternatives considered in developing the regulation;
- (7) The economic impact of the selected alternative on those likely to be affected by the regulation;
- (8) Any noncompliance or penalty provisions;
- (9) The substantive provisions of the final regulation on a section-by-section basis;
- (10) The public comments received;
- (11) The views, concerns, and comments raised by Agreement States during development of the final rule; and

(12) How, if at all, the regulation was modified in response to public comment, Agreement State participation, 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 also can 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. Section-by-Section Analysis of Substantive Changes
- IX. Agreement State Compatibility
- X. Finding of No Significant Environmental Impact: Availability.
- XI. Paperwork Reduction Act Statement.
- XII. Regulatory Analysis.
- XIII. Regulatory Flexibility Certification.
- XIV. Backfit Analysis.
- XV. Small Business Regulatory Enforcement Fairness Act

I. 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 Parts 30 or 70, 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 the secondary metals industry from recycling smelted alloys containing these two radioactive materials as residual contamination.

II. Rulemaking Initiation

The Department of Energy has under way Cascade Improvement Programs and Cascade Upgrading Programs begun by the AEC at both U.S. uranium enrichment plants-- Portsmouth, Ohio, and Paducah, Kentucky. 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 may not simply list the changes made in the regulation. A substantive description of the changes made in the regulation must be included. This description should present a section-by-section analysis of the substantive provisions of the final regulatory text.

Example:

Section-by-Section Analysis

Section 170.11 Exemptions.

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

and if those commitments are included in the amendment application then there would be no technical review conducted by the NRC.
Section 170.20 Average cost per professional staff-hour.

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

* * * * *

(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 of the rule from the alternatives considered;

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

(iii) The magnitude of the changes; and

(iv) The factual reasons for the change.

(3) Generally, the most effective method of presenting comment analysis in the Supplementary Information section of the preamble is to present an issue-by-issue discussion. Substantive comments are presented by summarizing the issue addressed and the commenter's reasoning and then stating NRC's response and its reasons for accepting or rejecting the comment.

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

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

(iii) Each individual comment need not be addressed separately. If several comments raise the same issue, they may be treated 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 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, 2120 L Street NW. (Lower Level), 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 fulfill its mandate effectively, requires complete, factual, and current information concerning the regulated activities of its licensees. Employees are an important source of information and should be encouraged to come forth with any potential safety-related items without fear of retribution from their employers. The purpose of the final rule is to ensure that employees are aware that employment discrimination for engaging in a protected activity, for example, contacting the Commission, is illegal and that a remedy exists through the Department of Labor (DOL). The organizations subject to the rule should understand that the Commission will not permit any interference with communications between the Commission's representatives and employees. In addition to redress being available to the individual employee, the Commission may, upon learning of an adverse finding against an employer by the 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.

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 who knowingly supplies false information or that compensation be provided to an employer to defray the cost of defending against the allegations. The Commission has rejected these comments since the statutory authority of the Commission under Section 210 neither provides for penalties against individuals or for any reimbursement to an employer. 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) The Supplementary Information section of the preamble to each final rule that affects facilities licensed under 10 CFR Parts 30, 34, 35, 40, 61, and 70, or their State equivalent, must contain a discussion of the opportunities afforded to the public and Agreement States for their early and substantive participation in the rulemaking process. This discussion must present the views, concerns, and comments raised by the public and Agreement States during the development of the final rule. This discussion should contain sufficient detail to provide the public and Agreement States with an additional opportunity to review NRC's rationale in response to their comments during the public comment period. The discussion should be presented as part of the general discussion concerning any substantive comments received in the Supplementary Information section of the preamble to the final rule (See paragraph (d) of this section).

(f) If a final rule references an NRC publication (NUREG), the NRC shall include a statement in the Supplementary Information section of the preamble to the final rule that indicates how an interested person may obtain a copy of the referenced material. The statement is inserted as a single-spaced footnote following the first reference to a NUREG in the final rule.

(1) If the referenced NUREG is in draft form, the NRC shall use the following statement of availability.

Example:

¹Those considering public comment may request a free single copy of draft NUREG-XXXX by writing to the U.S. Nuclear Regulatory Commission, Printing and Graphics Branch, Washington, DC 20555-0001. A copy is also available for inspection and/or copying in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C.

(2) If the referenced NUREG is in final form, the NRC shall use the following statement of availability.

Example:

¹Copies of NUREGS may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection and/or copying in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C.

(g) The Administrative Procedure Act (APA) generally requires that an agency publish a notice of proposed rulemaking to provide an interested person with notice of the proceeding and afford him or her with an opportunity to comment on the contemplated action before the agency issues the rule in final form (5 U.S.C. 553(b)). The APA also generally requires that a final rule become effective at least 30 days after the final rule is published in the Federal Register (5 U.S.C. 553(d)). An agency may waive either or both of these requirements for a rulemaking action that meets the exceptions to the requirements specified in the APA.

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

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

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

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

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

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

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

(A) A final rule for which the notice and comment requirements are waived under the good cause exception if the basis of the waiver is that the notice and comment procedure is impractical or contrary to the public interest; and

(B) An interpretative rule or general statement of policy adopted without notice and comment unless the NRC determines that notice and comment procedures serve no useful purpose or would be so burdensome that any foreseeable gain would be outweighed.

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

Example:

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

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

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

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

(B) For an interpretative rule;

(C) For a statement of policy; or

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

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

Example:

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

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

Example:

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

5.11 Procedural requirements for rulemaking.

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

(1) An assessment of the environmental impact of the final rule under the National Environmental Policy Act and 10 CFR Part 51 (see Section 5.13 of this handbook);

(2) OMB approval for each new or amended information collection requirement under the Paperwork Reduction Act (see Section 5.15 of this handbook);

(3) A regulatory analysis prepared in accordance with the Regulatory Analysis Guidelines approved by the Commission in a Staff Requirements Memorandum issued June 30, 1995 (SECY-95-028), and issued as NUREG/BR-0058, Rev. 2. A regulatory analysis examines the economic impact, in terms of costs and benefits, of alternatives considered in developing the final rule (see Section 5.17 of this handbook);

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

(5) A backfit analysis prepared in accordance with 10 CFR 50.109, 72.62, or 76.76 (see Section 5.21 of this handbook); and

(6) Compliance with the congressional review procedures established by the Small Business Regulatory Enforcement Fairness Act (see Section 5.23 of this handbook.

(b) The environmental assessment and economic analyses should precede, or be prepared concurrently with, the development of the final 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 is similar. The Act permits a regulatory flexibility analysis to be combined with any other analysis as long as it meets the requirements of the Act (see Section 5.19 of this handbook). Section 5.2 of the Regulatory Analysis Guidelines requires that factors necessary to evaluate the economic impact on small entities be addressed in the regulatory analysis (see Section 5.17 of this handbook).

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

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 51.20(a)(1)); or

(2) Involves a matter that the Commission has determined should be covered by an environmental impact statement (See 10 CFR 51.20(a)(2) and (b)).

(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. This statement must indicate that either --

(1) An environmental impact statement has been prepared for the final rule;

(2) An environmental assessment and finding of no significant impact have been prepared for the final rule; or

(3) The final rule is one of the types of actions included in the list of categorical exclusions set out in 10 CFR 51.22(c).

(c) In order to fulfill a commitment made to the Council on Environmental Quality, the NRC shall consult with the States on environmental issues before issuing an environmental assessment and shall document the consultation in the environmental assessment. The Executive Director for

Operations has approved an NRC procedure for consultation with the States during the preparation of an environmental assessment for a rulemaking action (See the Memorandum from David L. Morrison to multiple addressees dated May 18, 1995). These procedures are presented in Appendix E to this handbook.

(d) In a letter dated March 31, 1994, from the Chairman to the President, the NRC voluntarily agreed to carry out the measures set forth in Executive Order 12898 mandating that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, or activities on minority populations and low-income populations. The NRC stated that these requirements applied primarily to its efforts to comply with NEPA and that it would address environmental justice aspects as part of its considerations under NEPA. The EDO signed the NRC's environmental justice procedures on October 24, 1995.

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

Environmental Impact Statement: Availability

As required by the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, the NRC has prepared a final environmental impact statement for this regulation.

The NRC requested public comments on environmental justice issues for this rule. (Indicate whether public comments have been addressed and whether the environmental impact statement has changed as a result of public comment).

The NRC requested the views of the States on the environmental impact statement for this rule. (Indicate whether the States' comments

have been addressed and whether the environmental impact statement has changed as a result of the States' comments).

The final environmental impact statement is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), 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 also must be indicated under the ADDRESSES caption of the preamble.

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

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

Finding of No Significant Environmental
Impact: Environmental Assessment

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

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

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

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

Finding of No Significant Environmental Impact: Availability

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

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

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

The environmental assessment is available for inspection at the NRC Public Document Room, 2100 L Street NW. (Lower Level), Washington, D.C. Single copies of the environmental assessment are available from (insert name, address, and telephone number of contact person).

Note: Availability of the environmental assessment also must be listed under the ADDRESSES caption of the preamble.

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

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

(i) Amendments to Parts 0, 1, 2, 4, 7, 8, 9, 10, 11, 14, 19, 21, 25, 55, 75, 95, 110, 140, 150, 170, or 171 of this chapter (10 CFR 51.22(c)(1)).

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

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

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

(B) Recordkeeping requirements; or

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

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

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

Environmental Impact: Categorical Exclusion

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

5.15 Paperwork Reduction Act.

(a) General. The Paperwork Reduction Act (44 U.S.C. 3501 et seq.) is intended to minimize the burden on regulated parties resulting from the collection of information by and for the Federal Government. The Act also is intended to maximize the public benefit and practical utility of information created, collected, disclosed, maintained, used, shared, and disseminated by or for the Federal Government. The Act requires each Federal agency to obtain approval from OMB for each information collection activity that affects 10 or more persons. The factors necessary to obtain OMB approval must be addressed in the regulatory analysis (see Section 5.17 of this handbook). The NRC complies with the Act in a manner consistent with its responsibilities to ensure that public health and safety is adequately protected. An approved information collection request must display the OMB clearance number, a public protection notification, and, where appropriate, the expiration date. The Information and Records Management Branch is responsible for coordinating NRC activities necessary to comply with the Paperwork Reduction Act.

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

(1) An information collection request that is submitted to nine or fewer people must contain a statement that the request is not subject to the Paperwork Reduction Act.

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

(c) NRC regulations. Each new information collection requirement appearing in an added or amended regulation must be approved by OMB before it becomes effective. In addition, each existing information collection requirement, including recordkeeping, application, reporting, and third-party disclosure requirements, that appears in 10 CFR Chapter I must be reapproved by OMB when the current OMB clearance expires. An information collection requirement appearing in NRC regulations is invalid and nonenforceable unless --

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

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

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

- (i) Was not first issued as a proposed rule; and
- (ii) Contains an information collection requirement.

(2) A revised clearance package must be developed and submitted for OMB approval if a final rule contains an information collection requirement that has been added or amended since the clearance package for the proposed rule was submitted for OMB approval.

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

(e) Standard statements. One of the following statements must be included in the Supplementary Information section of the preamble to each final rule concerning information collection requirements. Information

collection requirements include any reporting, recordkeeping, third-party disclosure, or application requirement.

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

Paperwork Reduction Act Statement

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

The public reporting burden for this information collection is estimated to average ___ hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs NEOB-10202, (3150-), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

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

Paperwork Reduction Act Statement

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

Because the rule will reduce existing information collection requirements, the public burden for this information collection is expected to be decreased by _____ hours per licensee. This reduction includes the time required for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of this information collection, including suggestions for further reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-_____), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

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

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

(ii) These information collection requirements are not amended in the final rule.

Paperwork Reduction Act Statement

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

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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

Paperwork Reduction Act Statement

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

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

Paperwork Reduction Act Statement

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

(6) Information collection requirements of limited applicability. If a final rule of limited applicability contains an information collection requirement that affects fewer than 10 respondents, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Paperwork Reduction Act Statement

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

(f) Guidance. Questions concerning the procedures and requirements of the Paperwork Reduction Act may be directed to Brenda Jo. Shelton, Chief, Information and Records Management Branch (415-7233).

5.17 Regulatory analysis.

(a) Introduction. The Commission approved the issuance of NRC's revised Regulatory Analysis Guidelines on June 30, 1995 (SECY-95-028). The Regulatory Analysis Guidelines are printed in NUREG/BR-0058, Rev. 2, August 1995. These guidelines establish a framework for --

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

(b) Purpose. (1) The regulatory analysis is intended to ensure that NRC decisions that impose regulatory burdens on licensees are based on adequate information concerning the extent of these burdens and the resulting benefits. The regulatory analysis also ensures that decisions are made through a systematic and disciplined process that is clear to all participants and affected parties. Ultimately, the regulatory analysis ensures that the regulatory burdens imposed are needed, justified, and the minimum necessary to achieve regulatory objectives.

- (2) Each regulatory analysis must assess the following impacts:
 - (i) Direct costs or savings to licensees, the NRC, and State and local government agencies;
 - (ii) Nonradiation risk-related costs or savings to the general public;
 - (iii) Averted onsite impacts;
 - (iv) Changes in regulatory efficiency or scientific knowledge needed for regulatory purposes; and
 - (v) Conformance with formal positions adopted by national and international standards organizations.

(c) Coverage. (1) A regulatory analysis must accompany each mechanism used by the NRC staff to establish or communicate generic requirements, guidance, requests, or NRC staff positions that place a burden on licensees.

(2) Regulatory analysis requirements for a given action may be eliminated at the discretion of the Commission, the EDO, a Deputy EDO, or the responsible NRC Office Director.

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

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

(1) If the final rule imposes collection requirements that require obtaining OMB approval under the Paperwork Reduction Act (see Section 5.15 of this handbook), the OMB clearance package must be included as a stand-alone appendix to the regulatory analysis.

(2) The regulatory analysis must contain information sufficient to address requirements mandated by the Regulatory Flexibility Act (see Section 5.19 of this handbook).

(i) If the final rule is likely to have a significant economic impact on a substantial number of small entities a final regulatory flexibility analysis must be prepared. The regulatory flexibility analysis is included as an appendix to the regulatory analysis and as part of the final rule. The

regulatory flexibility analysis may reference information discussed in the body of the regulatory analysis.

(ii) If the NRC certifies that the final rule does not have a significant economic impact on a substantial number of small entities, the regulatory analysis must contain sufficient information concerning the potential impact of the final rule on small entities to support this certification.

(3) If an environmental impact statement has been prepared and forms the basis for the final rule, a summary of the environmental impact statement is an appropriate substitute for the information and analysis requirements identified in NUREG/BR-0058, Rev. 2, Sections 4.1-4.3.

(e) Required statement. The following 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 obtain a copy of it.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C. Single copies of the analysis may be obtained from (insert name, address, and telephone number of staff contact).

5.19 Regulatory Flexibility Act.

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

(b) Applicability. The Act applies to each rule subject to notice and comment rulemaking under the Administrative Procedure Act (5 U.S.C. 553 (b)). Therefore, the requirements of the Act apply to each proposed rule developed by the NRC. The Act does not apply if a rule is first issued in final form without notice of proposed rulemaking.

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

(1) If the NRC believes that a final rule will have a "significant economic impact on a substantial number of small entities," the Act requires that the NRC prepare a regulatory flexibility analysis. The Act also requires that this analysis, or a summary of the analysis, be published in the Federal Register for public comment. The regulatory flexibility analysis may be

combined with other analyses as long as it meets the requirements of the Act. The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 2) require that factors necessary to evaluate the economic impact of the proposed rule on small entities be addressed in the regulatory analysis that considers the costs and benefits of the proposed rule (see Section 5.17 of this handbook).

(2) The Act permits the NRC to dispense with the preparation of a regulatory flexibility analysis if --

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

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

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

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

§ 2.810 NRC Size Standards.

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

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

(1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$5 million or less over its last 3 completed fiscal years; or

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

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

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

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

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

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

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

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

(1) If a final regulatory flexibility analysis has been prepared, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Regulatory Flexibility Analysis

The NRC has prepared a final regulatory analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis indicates that although the final rule has an economic impact of \$1,500-1,750 annually on medical licensees, of which 18 percent are small entities, the selected alternative is the least costly alternative that provides adequate protection from radiation exposure to patients and workers. A copy of the analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), 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 provide the factual basis for this conclusion. The statement must include detailed information on the number and type of small entities involved and why the rule will have no or minimal effect on them. A simple unsubstantiated conclusion is insufficient.

Regulatory Flexibility Certification

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

(f) 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 regulatory flexibility analysis contain --

(1) A succinct statement of the need for, and the objectives of, the rule;

(2) A summary of the issues raised by public comment on the initial regulatory flexibility analysis, a summary of NRC's assessment of those issues, and a statement of any changes made in the rule as a result of public comment;

(3) A description of the type of small entities and an estimate of the number of small entities to which the rule applies or an explanation of why no such estimate is available;

(4) A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that are subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) A description of the steps the NRC has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule that affect the impact on small entities was considered by the NRC and rejected.

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

(1) The NRC may not delay the preparation of a regulatory flexibility analysis for more than 180 days after completion of the final rule. If an analysis is not prepared within 180 days, the rule lapses and has no effect.

(2) The delay must be supported by a written finding that is published in the Federal Register no later than the publication date of the final rule.

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

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

5.21 Backfit analysis.

(a) The NRC has established standards for the management of backfitting requirements imposed on power reactors (10 CFR 50.109). Backfitting is a process that can include both plant-specific changes and generic changes applied to one or more classes of power reactors. Essentially identical provisions were established to manage backfitting requirements imposed on gaseous diffusion plants (10 CFR 76.76). Provisions also were established to manage backfitting requirements imposed on an independent spent fuel storage installation or a monitored retrievable storage installation (10 CFR 72.62).

(b) The definition of backfitting has three components.

(1) The first component is the modification of or addition to --

(i) Systems, structures, components, or design of a facility;

(ii) The design approval or manufacturing license for a facility; or

(iii) The procedures or organization required to design, construct, or operate a facility.

(2) The second component is that the modification or addition is the result of either --

(i) A new or amended provision of the Commission's regulations; or

(ii) A regulatory NRC staff position interpreting these regulations that is either new or different from a previously applicable NRC staff position.

(3) The third component is that the modification or addition is considered a backfit only if it results from a new or amended regulation or staff position issued after --

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;

(ii) Six months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

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

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

(c) Except as indicated in paragraph (e) of this section, the NRC shall prepare a systematic and documented backfit analysis for each backfit that it seeks to impose by rulemaking action. The Commission may impose a backfit on a facility that already provides adequate protection of public health and safety and common defense and security only if the backfit analysis indicates that --

(1) There would be a substantial increase in the overall protection to the public health and safety or the common defense and security derived from the backfit; and

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

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

(1) A statement of the specific objectives that the backfit is designed to achieve;

(2) A general description of the activity that would be required of the licensee or the applicant to complete the backfit;

(3) The potential change in the risk to the public from the accidental offsite release of radioactive material;

(4) The potential impact on the radiological exposure of facility employees;

(5) The installation and continuing costs associated with the backfit including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the backfit and the availability of NRC resources;

(8) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the backfit; and

(9) Whether the backfit is interim or final and, if interim, the justification for imposing the backfit on an interim basis.

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

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

(ii) A backfit is necessary to bring a facility into compliance with a license, a licensee's written commitments, or the rules and orders of the Commission; or

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

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

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

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

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

Backfit Analysis

As required by 10 CFR 50.109 (or 72.62 or 76.75, as appropriate), the Commission has completed a backfit analysis for the final rule. The Commission has determined, on the basis of this analysis, that backfitting to comply with the requirements of this final rule provides a substantial increase in protection to public health and safety or the common defense and security at a cost that is justified by the substantial increase. The basis for this determination is based reads as follows. (Insert the text of the backfit analysis).

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

Backfit Analysis

The Commission has concluded, on the basis of the documented evaluation required by 10 CFR 50.109(a)(4) (or 72.62 or 76.76, as appropriate), that the backfit requirements contained in this final rule (Insert one of the following three options: Option 1 - "are necessary to bring the facilities described into compliance with licensees or the rules and orders of the Commission or into conformance with written commitments by the licensees, and therefore," Option 2 - "are necessary to ensure that the facilities described in the rule provide adequate

protection to the health and safety of the public and are in accord with the common defense and security, and therefore," Option 3 - "involve defining or redefining what level of protection to the public health and safety or the common defense and security should be regarded as adequate, and therefore,") that a backfit analysis is not required and the cost-benefit standards of 10 CFR 50.109(a)(3) (or 72.62 or 76.76, as appropriate) do not apply. The documented evaluation includes a statement of the objectives of and reasons for the backfits that are required by the final rule and sets forth the basis for the Commission's conclusions that these backfits are not subject to the cost-benefit standards of 10 CFR 50.109(a)(3) (or 72.62 or 76.76, as appropriate). (Insert the text of the documented evaluation).

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

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule; and therefore, a backfit analysis is not required for this final rule because (Insert one of the following three options: Option 1 - "these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I." Option 2 - "these amendments do not impose more stringent safety requirements on 10 CFR Part 50 (or Part 72 or Part 76, as appropriate) licensees." Option 3 - "these amendments are mandated by (cite the appropriate act of Congress)").

5.23 Small Business Regulatory Enforcement Fairness Act.

(a) Among other requirements, the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires Federal agencies to provide Congress with an opportunity to review agency rules. For each final rule, an agency is required to submit to Congress a report containing a copy of the final rule, a concise general statement of the final rule (including a statement indicating whether the action is a "major" rule) and the effective date of the final rule. The report must be submitted to each House of Congress and the Comptroller General before the rule takes effect. The report must be accompanied by any other relevant information required by another act or by an Executive order. This would include any cost-benefit analyses, regulatory flexibility analyses, Paperwork Reduction Act statements, and any environmental assessments or impact statements.

(b) The effective date for all "major" rules may be no earlier than 60 days after the date of congressional receipt of the required material or publication of the final rule in the Federal Register, whichever is later. The legislation also establishes special congressional procedures for the disapproval of agency rules. The requirements concerning major rules are applicable to all major final rules promulgated after March 1, 1996. A "major rule" is defined in 5 U.S.C. 804 (2) as a final action has resulted or is likely to result in--

- (1) An annual effect on the economy of \$100,000,000 or more;
- (2) A major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

(c) Under the Act, the Office of Management and Budget (OMB) is responsible for the determination of whether a rule is "major." Therefore, the NRC must submit a description of its final rules to OMB and OMB must verify the NRC's determination as to whether the final rule is considered a major rule under this Act before the final rule may be submitted for signature and publication.

(d) The following statement must be inserted in the Supplementary Information section of the preamble to the final rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

(e) On June 25, 1996, the EDO issued a memorandum to office directors that established a simple process for assuring compliance with SBREFA. These procedures are presented in Appendix F to this handbook. Questions concerning SBREFA may be directed to Michael T. Lesar (415-7163).

5.25 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, in a standard fashion, the major topics of the final rule and the categories of persons affected by it.

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

Example: Format for a document citing a single CFR Part.

List of Subjects in 10 CFR Part 20

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

Example: Format of a document citing two or more CFR Parts.

List of Subjects

10 CFR Part 30

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

10 CFR Part 40.

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

10 CFR Part 70

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

(b) The NRC shall use the list of subject index terms developed by the RDB and approved by the OFR in the list of subject index terms provided for each part. These terms are contained in the "Federal Register Thesaurus of Indexing Terms." The terms provide a common vocabulary for indexing the rulemaking documents of all agencies and form the basis for the CFR Index. A 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 RDB (415-7158).

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

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

5.27 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 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 Section 5.31 of this handbook for information on authority citations). 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. 552 and 553, the NRC is adopting the following amendments to 10 CFR Parts 30, 50, and 73.

5.29 Amendatory language.

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

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

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

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

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

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

(1) Added.

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

Examples:

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

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

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

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

Example:

§19.3 [Amended]

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

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

Examples:

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

2. 10 CFR Chapter I is amended by revising Part 100 to read as follows:

3. Section 73.97 is amended by removing paragraph (e).

(3) Corrected. "Corrected" means that a clerical or typographical error in a published document is fixed. The error must be corrected before the next annual revision of 10 CFR Chapter I. Once the error is codified, a formal amendment is necessary to make the change. A correction is not an amendment and may not be used to write in second thoughts. Any "fine tuning" of a published regulation must be in the form of a formal clarifying amendment.

Examples:

1. In the issue of March 15, 1996 (61 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, 1996 (61 FR 98765), the delegation of authority is corrected in the first paragraph of the second column by changing "Director" to read "Administrator "

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

Examples

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

2. Part 33 is redesignated as Part 75.

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

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

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

Examples:

1. Part 110 is amended by removing §110.70.

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

(6) Republished. "Republished" means that an unchanged unit of CFR text is set out for the convenience of the reader, often to provide the context for an amendment. This term is mostly used with the introductory text of a

section or paragraph. Because all regulatory text that is published or republished in a final rule document is used to update the CFR, the NRC shall present any republished text it chooses to use accurately.

Example

1. In §2.1, the introductory text of paragraph (a) is republished and paragraphs (a)(1) and (2) are revised to read as follows:

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

Examples:

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

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

Example:

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

(9) Suspended. "Suspended" means that the effectiveness of a CFR unit is stayed temporarily or indefinitely. Suspended is not a true amendatory term because it does not actually change the content of the CFR; it simply reflects the changed status of a particular CFR unit. During the suspension, the CFR unit is not in effect or enforceable. The NRC should avoid an open-ended suspension whenever possible by stating the duration of the suspension in the document announcing the action. The suspended provision continues to appear in the CFR; however, the OFR will insert an editorial note explaining the status of the provision. The NRC is responsible for issuing the 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, 1995, to October 1, 1996.

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

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

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

(d) If an amendment makes several changes within a section, the amendatory language must clearly identify each change. All changes to the section must be described in one amendatory instruction.

Examples:

1. In §73.3, paragraphs (d) and (f) are revised, 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 Section 5.31 (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. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 33.

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

1. The authority citation for Part 33 continues to read as follows:
AUTHORITY: 42 U.S.C. 2111, 2201, 2232, 2233, 42 U.S.C. 5841.

2. Section 33.13 is revised to read as follows:

§33.13 Applications for specific licenses of broad scope.

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

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

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

* * * * *

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

(Note: The use of asterisks in amending CFR text is discussed in 5.35 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.

5.31 Authority citations.

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

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

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

Example:

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

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

(b) Content. The RDB maintains a complete list of the currently effective authority citations for each part in 10 CFR Chapter I. The drafter may contact RDB to obtain the current authority citation for insertion into his or her document (415-6864).

(c) Placing authority citations: When amending an entire CFR part. If a document sets out a whole CFR part, the authority citation must be placed directly after the table of contents and before the regulatory text.

Example:

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

Sec.

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

AUTHORITY: 42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 5841.

(d) Placing authority citations: When amending a portion of a CFR part.

If a document amends only certain sections within a CFR part, a complete citation of authority must be presented.

(1) If the authority for issuing an amendment is the same as the authority listed for the whole CFR part, simply restate the entire authority. The restated authority citation is placed before the first item in the list of amendments to the part.

Example:

PART 160 - TRESPASSING ON COMMISSION PROPERTY

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

AUTHORITY: 42 U.S.C. 2201, 2278a, 5841).

2. Section 160.3 is revised to read as follows:

§160.3 Trespass.

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

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

Example:

PART 71 - PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

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

2. Section 71.2 is revised to read as follows:

§71.2 Scope.

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

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

Example: A part authority that includes section specific citations. The second paragraph sets out the section specific authorities.

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

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

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

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

5.33 Regulatory text: CFR codification.

(a) Amending the CFR. The regulatory text of a final rule document is codified in the CFR. NRC regulations are codified in 10 CFR Chapter I. The regulatory text of each NRC final rule document must be presented as an amendment to 10 CFR Chapter 1. Regulatory text must --

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

(b) CFR structure. (1) The basic structure of the CFR consists of a hierarchy of designated CFR units. The major components of this structure are illustrated in the following table.

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

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

(3) The section is the basic CFR unit. Most amendments are expressed in terms of how they affect a section or a group of sections. The content of a section is limited to a short simple presentation of a single regulatory

proposition. Each section number includes the number of the part followed by a period and a sequential number. For example, the first section in Part 25 is expressed as "§25.1." Sections in a new or revised part need not be numbered consecutively. Using all odd or even sequential numbers in designating sections within a new or revised part leaves room for future expansion.

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

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

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

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

(i) The level of designation is the number of paragraph symbols necessary to identify a subdivision within a section. For CFR purposes, each subdivision within a paragraph also is considered a paragraph. The term

"subparagraph" may not be used when referencing a subdivided paragraph within the regulatory text of a Federal Register document.

Example:

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

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

Example:

§30.63 Violations.

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

- (1) The Atomic Energy Act of 1954, as amended;
- (2) Title II of the Energy Reorganization Act of 1974, as amended;

or

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

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

(1) For violations of --

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

(ii) Section 206 of the Energy Reorganization Act;

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

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

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

(iii) The NRC shall avoid overly detailed subdivision within a section by dividing a long, complex section into a series of smaller, more compact sections. Divisions below the third level of designation generally indicate that the drafter is attempting to include too much material within the section. As a result, the user will have more difficulty locating the important material that is buried within a section. A user finds information within a regulation primarily through the section heading. If sections are too long, there are fewer headings, and those headings cannot adequately reflect the material contained in the section. (See Section 13.7 of this handbook; Arranging material for ease of use.)

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

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

Example:

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

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

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

(1) To manufacture, make, 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 does not permit the use of hyphenated numbers (§117-2.1 or §11-7.201) or numbers with alpha characters (Part 115a, §115a.1, or §115.1a) in designating units within the CFR system.

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

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

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

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

(d) Full text amendment. The NRC shall present each amendment in a final rule document as a full text amendment to the CFR. Full text means that the complete text of the designated CFR unit being amended is presented in the document. The CFR unit is any block of text that can be identified by its number or letter designation. The unit of text presented may be as small as a

paragraph. Nomenclature changes or amendments to a table are the only exceptions to this rule.

(e) Footnotes. The NRC shall avoid the use of footnotes in the text of a regulatory document. Explanatory notes and references should be presented within document text. If a footnote is essential, care must be taken in the manner and form in which it is designated and presented in regulatory text. Incorrectly designated footnotes cause errors when a document is printed in the Federal Register and again when regulatory text is codified in the CFR. The NRC shall follow these guidelines when presenting footnotes in the text of a regulatory document.

(1) Material in text to which a footnote is keyed must be numbered with Arabic numerals presented in the fashion ^{1, 2, 3}, or in superscript. Asterisks or other symbols may not be used to designate footnotes within regulatory text.

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

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

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

(iii) Footnotes in the CFR are numbered consecutively throughout the part. An amendment to existing text that adds or removes a footnote may affect the numbering of any other footnotes contained in the amended part. It may not be necessary to redesignate existing footnotes to reflect added or

removed footnotes. Contact RDB on 415-7163 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 also must be set out in presenting the amendment.