April 27, 2005

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and Investigations
United States House of Representatives
Washington, DC 20515-0515

Dear Mr. Chairman:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am pleased to respond to your letter dated April 5, 2005, requesting documents and information relating to NRC's compliance with Section 610 of the Regulatory Flexibility Act. The agency's regulatory activity is directed to NRC licensees, most of which are not small entities. NRC's responses to your specific questions are enclosed.

Sincerely,

/RA/

Nils J. Diaz

Enclosure: As stated

cc: The Honorable Bart Stupak, Ranking Member,
Committee on Oversight and Investigations

Identical letter sent to:

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and
Investigations
United States House of Representatives
Washington, D.C. 20515
cc: Honorable Bart Stupak

The Honorable Joe Barton, Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515
cc: Honorable John Dingell

Response to Letter Dated April 5, 2005
from Joe Barton, Chairman,
Committee on Energy and Commerce
relating to
NRC's Compliance with Section 610 of the Regulatory Flexibility Act

1. Please provide a copy of your agency's plans and related guidance documents, for the review of rules, pursuant to Section 610 of the Regulatory Flexibility Act.

   Response

   The NRC has not developed a specific plan or guidance documents for the periodic review of rules under Section 610 because so few of our rules are subject to this review. Rules that are subject to this review are routinely revised within the 10-year window.

2. Provide a detailed narrative explanation of (a) the steps your agency takes to identify rules and regulations for review under Section 610, (b) how your agency tracks rules that may be subject to Section 610 review, and (c) the analytical process your agency follows to perform Section 610 reviews.

   Response

   (a) The NRC analyzes each rulemaking to determine the potential impact of the contemplated regulatory action on small entities. If the NRC determines that it is unable to certify that a rule does not have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis is performed for the rule. These rules are identified as subject to review under Section 610.

   (b) The NRC tracks rules that may be subject to Section 610 review through preparation of its semi-annual Regulatory Flexibility Agenda included as part of the Unified Agenda of Federal Regulatory and Deregulatory Actions.

   (c) Upon identification of a rule subject to Section 610 review, the NRC follows the general analytical process for performing a regulatory flexibility analysis outlined in the implementation guidance for Federal agencies developed by the Small Business Administration.

3. Provide a list of all rules that have been reviewed by your agency under Section 610, including the dates upon which notice was provided that the rules were subject to review, when the reviews were completed, the results of those reviews, the specific factors considered (pursuant to Section 610), and the reasons for making review decisions.

   Response

   It has not been necessary for the NRC to perform or complete any Section 610 reviews since January 1, 1995, because the regulations that would have been subject to Section 610 review have been revised within the 10-year window.

Enclosure

4. What rules has your agency identified as having "a significant economic impact on a substantial number of small entities," and will those rules be subject to Section 610 review, and if not, why not?

   Response

   The specific regulations that have been determined to have a significant economic impact on a substantial number of small entities are as follows:

   10 CFR Parts 170/171 - Each year, the NRC revises its regulations that assess license, inspection, and annual fees to recover most of its operating budget as required by the Omnibus Budget Reconciliation Act of 1990, as amended. As part of each annual revision, the NRC considers the impact of the fees on small entities. The FY 2004 final fee rule was published on April 26, 2004 (69 FR 22664). A proposed rule that would revise fee provisions for FY 2005 was published on February 22, 2005 (70 FR 8678). Because this rule is revised annually, a Section 610 review is not contemplated.

   10 CFR Part 35 - The NRC's regulations governing the medical use of byproduct material were revised by a final rule published on April 24, 2002 (67 FR 20250). This final rule significantly reduced the regulatory burden imposed on small entities. This regulation was amended on March 30, 2005 (70 FR 16336). If not revised in the interim, the regulations in 10 CFR Part 35 will be subject to a Section 610 review in 2015.

5. What percentage of proposed rules and final rules has your agency certified as not having "a significant economic impact on a substantial number of small entities," pursuant to the Regulatory Flexibility Act?

   Response

   Approximately 93 percent of the proposed and final rules have been certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act.

6. Provide guidance documents used by your agency to assess whether proposed rules could be certified as not having a "significant economic impact on a substantial number of small entities."

   Response

   The NRC uses the following guidance documents to comply with all provisions of the Regulatory Flexibility Act, including the assessment of whether proposed rules could be certified as not having a significant economic impact on a substantial number of small entities:

   - *A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act*, Office of Advocacy, Small Business Administration, 2003, http://www.sbaonline.sba.gov/advo/laws/rfaguide.pdf

- *The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission*, NUREG/BR-0058, September 2004, http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/
- *Procedures and the Regulatory Flexibility Act*, http://www.nrc.gov/what-we-do/regulatory/rulemaking/flexibility-act.html
- Sections 5.21 and 7.21, *NRC Regulations Handbook*, NUREG/BR-0053, Rev. 5, March 2001 (attached)

7. Identify the offices, job titles, and names of individuals responsible for devising, implementing, and ensuring adherence to procedures for conducting periodic review of rules pursuant to Section 610.

Response

Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, is responsible for ensuring adherence to procedures for conducting periodic reviews under Section 610. Mr. Lesar may be contacted on (301) 415-7163 or e-mail: mtl@nrc.gov.

5.21 Regulatory Flexibility Act.

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

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

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

(1) If the NRC believes that the proposed rule will have a "significant economic impact on a substantial number of small entities," the act requires that the NRC prepare an initial regulatory flexibility analysis (See paragraph (d) of this section for NRC’s definition of “small entities”). The act also requires that this analysis, or a summary of the analysis, be published in the *Federal Register* for public comment. The regulatory flexibility analysis may be combined

with other analyses as long as it meets the requirements of the act. The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, Revision 3) require that factors necessary to evaluate the economic impact of the proposed rule on small entities be addressed in the regulatory analysis that considers the costs and benefits of the proposed rule (see Section 5.19 of this handbook).

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

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

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

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

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

§ 2.810 NRC Size Standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

Regulatory Flexibility Analysis

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

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

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

Regulatory Flexibility Analysis

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

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

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

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

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

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

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

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

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

Regulatory Flexibility Certification

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

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

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

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

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

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

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

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

(ii) If a proposed rule would affect nuclear power plant licensees, use the following statement.

Regulatory Flexibility Certification

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

(f) **Initial Regulatory Flexibility Analysis**. The act requires that the initial regulatory flexibility analysis, or a summary of the analysis, be published in the *Federal Register* with the proposed rule. The analysis or summary is presented as an appendix to the document. If a summary is published, it must contain sufficient detail concerning the cost and benefits of the

proposed rule to enable a small entity to determine how the proposed rule will affect it, and whether it requires the more detailed information contained in the analysis. An initial regulatory flexibility analysis must contain the following information:

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

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

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

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

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

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

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

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

(ii) Indicate the type of small entity subject to each requirement, for example, field radiographers, private physicians, manufacturers of certain equipment. Indicate the type of professional skill needed to prepare the report, for example, that of a radiographer, a lab technician, a production manager, a general administrative expert.

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

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

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

7.21 Regulatory Flexibility Act.

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

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

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

(1) If the NRC believes that a final rule will have a "significant economic impact on a substantial number of small entities," the act requires that the NRC prepare a regulatory flexibility analysis (See paragraph (d) of this section for NRC’s definition of “small entities”). The act also requires that this analysis, or a summary of the analysis, be published in the

Federal Register for public comment. The regulatory flexibility analysis may be combined with other analyses as long as it meets the requirements of the act. The NRC's Regulatory Analysis Guidelines (NUREG/BR-0058, Revision 3) require that factors necessary to evaluate the economic impact of the proposed rule on small entities be addressed in the regulatory analysis that considers the costs and benefits of the proposed rule (see Section 7.19 of this handbook).

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

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

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

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

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

§ 2.810 NRC Size Standards.

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

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

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

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

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

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

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

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

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

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

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

(1) If a final regulatory flexibility analysis has been prepared, the NRC shall insert the following statement in the Supplementary Information section of the preamble to the final rule.

Regulatory Flexibility Analysis

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

(2) If a final regulatory flexibility analysis is not required, the NRC shall include the necessary certification statement in the Supplementary Information section of the preamble to the final rule. This statement must certify that the regulation does not have a significant economic impact on a substantial number of small entities and include a succinct statement of the reasons for this certification. This statement must contain sufficient information to provide the factual basis for this conclusion. The statement must include detailed information on the

number and type of small entities involved and why the rule will have no or minimal effect on them. A simple unsubstantiated conclusion is insufficient.

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

Regulatory Flexibility Certification

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

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

Regulatory Flexibility Certification

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

(f) **Final Regulatory Flexibility Analysis: Content**. The final regulatory flexibility analysis is an updated version of the initial analysis. The final analysis must be revised to reflect new information received through public comment or any other source. The act requires that the final regulatory flexibility analysis contain --

(1) A succinct statement of the need for, and the objectives of, the rule;

(2) A summary of the issues raised by public comment on the initial regulatory flexibility analysis, a summary of NRC's assessment of those issues, and a statement of any changes made in the rule as a result of public comment;

(3) A description of the type of small entities and an estimate of the number of small entities to which the rule applies or an explanation of why no such estimate is available;

(4) A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that are subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) A description of the steps the NRC has taken to minimize the significant economic impact on small entities consistent with the stated objectives of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule that affect the impact on small entities was considered by the NRC and rejected.

(g) **Emergency provisions**. The act permits the NRC to delay the completion of a regulatory flexibility analysis for a rule issued in response to an emergency that makes timely compliance with the requirement to prepare an analysis impractical.

(1) The NRC may not delay the preparation of a regulatory flexibility analysis for more than 180 days after completion of the final rule. If an analysis is not prepared within 180 days, the rule lapses and has no effect.

(2) The delay must be supported by a written finding that is published in the *Federal Register* no later than the publication date of the final rule.

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

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