

November 5, 2002

Thomas M. Sullivan, Chief Counsel
Office of Advocacy
Small Business Administration
Washington, DC

Dear Mr. Sullivan:

In accordance with Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," enclosed is the Nuclear Regulatory Commission's (NRC's) Procedures and Policies for complying with the Regulatory Flexibility Act, as amended (5 U.S.C. 601 et seq.). The NRC has been following these procedures since 1981 to ensure compliance with the requirements that an agency consider the impact of its rules on small entities. The NRC will make these policies and procedures available to the public on its website.

If you have any questions on this matter, please have a member of your staff contact Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration on (301) 415-7163 (mtl@nrc.gov).

Sincerely,

/RA/

William D. Travers
Executive Director
for Operations

Enclosure:
NRC Policies and Procedures

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NRC Procedures and Policies for Considering Small Entities Under the Regulatory Flexibility Act, as amended (5 U.S.C. 601 *et seq.*)

Background

The Regulatory Flexibility Act (RFA) of 1980, as amended, requires Federal agencies to review their regulations to ensure that they do not unduly inhibit the ability of small entities to compete. The RFA compels agencies to analyze the impact of their regulations on small entities and to communicate and explain their findings to the public. There are three specific RFA requirements applicable to NRC rulemaking:

- (1) analysis of the impact of each rulemaking on small entities and evaluation of alternatives that would accomplish regulatory objectives without unduly burdening small entities or erecting barriers to competition.
- (2) the periodic review of existing agency rules which have a significant economic impact on a substantial number of small entities.
- (3) preparation and publication of a semiannual agenda listing rules under development that may have a significant economic impact on a substantial number of small entities.

The NRC's procedures for complying with these RFA requirements are explained in the following sections. In addition, the NRC has developed guidance documents to assist its staff and the public in interpreting RFA requirements as applicable to NRC rulemaking

Analysis of NRC Rulemakings - Impact on Small Entities

Initial Determination

The RFA applies to each rule subject to notice and comment procedures under the Administrative Procedure Act (APA) (5 U.S.C. 553 (b)). Therefore, the requirements of the RFA apply to each proposed rule developed by the NRC, but not to final rules for which a proposed rule was not issued.

As part of the NRC rulemaking process, the agency has adopted procedures for constructing a rulemaking plan. Section 4(c) of NRC's Management Directive 6.3, "The Rulemaking Process" states that the NRC technical staff is to consider whether a rulemaking will be cost-effective and whether it will be a major rule. A "major rule" under the Small Business Regulatory Enforcement Fairness Act is one that is likely to result in an annual effect on the economy of \$100 million or more. In conjunction with this analysis, the staff makes a preliminary determination whether the rulemaking is likely to affect licensees qualifying as small entities.

In accordance with Small Business Administration's (SBA) regulation 13 CFR 121.902 (b)(4), the NRC has developed its own size standards for performing a Regulatory Flexibility Analysis pursuant to the RFA, and has verified with the SBA Office of Advocacy that its size standards are appropriate for NRC analyses. The NRC size standards at 10 CFR 2.810 currently define the following types of small entities:

- ▶ small business: a for-profit concern providing a service with average gross receipts of \$5 million or less over its last 3 completed fiscal years, or a manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.
- ▶ small organization: a not-for-profit organization which is independently owned and operated and has annual gross receipts of \$5 million or less.
- ▶ small governmental jurisdiction: government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.
- ▶ small educational institution: one that is supported by a qualifying small governmental jurisdiction or one that is not state or publicly supported and has 500 or fewer employees.

Apart from these size standards, the NRC closely follows other SBA provisions. In particular, the NRC defines annual receipts in accordance with the SBA regulations at 13 CFR 121.104. In addition, the NRC has applied SBA regulations regarding affiliation at 13 CFR 121.103 and has determined that an NRC licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of this determination.

Draft Regulatory Analysis

Because the NRC is committed to regulating in a cost-effective manner, it is the agency's policy to prepare for each rulemaking, and to make publicly available, a regulatory analysis calculating the costs and benefits, including alternative regulatory approaches. The NRC's Regulatory Analysis Guidelines require that the factors necessary to evaluate the economic impact of the regulatory action under consideration on small entities be addressed in the Regulatory Analysis.

Impact on Small Entities: Initial Regulatory Flexibility Analysis

If the NRC believes that a proposed rule will have a significant economic impact on a substantial number of small entities, the staff prepares an initial regulatory flexibility analysis.

Procedurally, since the factors necessary to evaluate the economic impact of the proposed rule on small entities are addressed in the regulatory analysis that considers the costs and benefits of the proposed rule, the regulatory flexibility analysis is normally included as an appendix to the regulatory analysis. The draft regulatory flexibility analysis, or a summary of the analysis, is published in the *Federal Register* for public comment as an appendix to the proposed rule. In brief, such analysis provides:

- ▶ a description of why the NRC is considering regulatory action, and the legal basis for the proposed rule.

- ▶ an estimate, including the justification or assumptions used, of the annual economic impact on small entities that would be caused by the proposed regulation by changes such as hardware modifications, procedural changes for testing or maintenance, or hiring of additional personnel.
- ▶ a description and estimate of the number of small entities to which the rule would apply.
- ▶ projected reporting, recordkeeping, or other compliance requirements and the type of professional skills necessary for the preparation of the reports or records.
- ▶ alternatives considered, and justification that the proposed regulation is the least costly alternative that will provide adequate protection to the public and the licensees.
- ▶ economic impact in terms of the total annual cost that would result from the proposed regulation.

When the final rule is published in the *Federal Register*, it contains a final flexibility analysis. This includes a summary of the issues raised by public comments in response to the initial regulatory flexibility analysis, the NRC's assessment of these issues, and any changes made in the proposed rule as a result of the comments.

No Impact on Small Entities: Certification

If the NRC determines that a proposed rule is not likely to have significant economic impact on a substantial number of small entities, the Commission provides certification to this effect in accordance with section 605(b) of the RFA. In these circumstances, the NRC does not prepare an initial regulatory flexibility analysis. The draft regulatory analysis which contains sufficient information to support the certification is made an enclosure to the Commission paper or the memorandum requesting issuance by the Executive Director for Operations (EDO). The Commission's certification statement contains sufficient information to support the conclusion of no significant impact, and provides information on the number and type of small entities involved and the potential effect the rule will have upon them.

The Commission's certification and accompanying rationale is published in the *Federal Register* in the preamble for the proposed rule along with a request for public comment on the Commission's decision to dispense with a regulatory flexibility analysis.

This certification statement is repeated in final rules unless, based on comments received or other information, there is a reason to change this conclusion, in which case a final regulatory flexibility analysis is prepared. The NRC staff reviews and addresses all public comments regarding the Commission's certification in the statement of considerations for the final rule. In the event of adverse comments, the statement of considerations will contain clear justification for the Commission's decision to reaffirm its initial certification; alternatively, the Commission directs the staff to conduct a regulatory flexibility analysis, which is published along with the final rule.

Need for More Information

In some instances, the NRC staff may find, after preparing an initial regulatory flexibility analysis or conducting a preliminary examination of the anticipated impacts of the proposed rule on small entities, that the NRC needs more information on how or whether the proposed rule will actually affect small entities or on how a rule may be modified to alleviate significant economic impact upon them. In such cases, the NRC may include in the preamble of the proposed rule a request for public comment on the potential impact of the proposed rule on small entities. Typically, small entities are invited to 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.

Comments received on regulatory flexibility issues are addressed in the statement of considerations for the final rule.

Emergency Situations

The RFA permits the NRC to delay the completion of a regulatory flexibility analysis for a rule issued in response to an emergency, when compliance with the RFA would obviously be impractical. The NRC publishes in the *Federal Register*, concurrent with the final rule, a written finding detailing need for and cause of the delay of the analysis. The NRC then shall prepare its flexibility analysis within 180 days of completion of the final rule or the rule will lapse and have no effect. The NRC's policy is to limit its interpretation of "emergency situations" as to those that could have an immediate and significant impact on public health and safety.

Routine Notification to SBA

In addition to requesting public comment for proposed rules and their accompanying draft regulatory flexibility analyses, the NRC routinely informs the Small Business Administration (SBA) of each proposed and final rule that includes a regulatory flexibility certification statement

or for which a regulatory flexibility analysis has been performed. This notification occurs at the time the NRC transmits the rulemaking for publication in the *Federal Register*. Any SBA comments on a draft rule that may have a significant economic impact on a substantial number of small entities are addressed in the statements of consideration when the NRC publishes its final rule in the *Federal Register*, unless the Commission certifies that doing so does not serve the public interest.

Periodic Review of Existing Rules

Section 610 of the RFA requires the NRC to review all regulations that have a significant economic impact on a substantial number of small entities within 10 years of their adoption as final rules.

Much of the NRC's regulatory effort is directed to licensees who are not small entities; consequently, a significant number of the agency's regulations do not require Section 610 review. The few NRC regulations which have been found to have a significant impact on a substantial number of small entities concern byproduct, source, and special nuclear material licensees. The specific regulations that have been determined to have a significant economic impact on small entities have been revised recently, and are identified below:

10 CFR 170 and 10 CFR 171 - Annually, the NRC revises its regulations that assess license, inspection, and annual fees to recover most of its operating budget as required to implement the Omnibus Budget Reconciliation Act of 1990, as amended. As part of each annual revision, the NRC considers the impact of its fees on small entities.

10 CFR 35 - A final rule containing a complete revision of the NRC's regulations governing the medical use of byproduct material was published in the *Federal Register* on April 24, 2002. This substantial rulemaking took a number of years to complete, and resulted in a reduction in the regulatory burden imposed on small entities.

Because these regulations have been amended within the 10-year window, it has not been necessary for the NRC to develop a schedule for Section 610 review of its standing rules.

Semi-Annual Regulatory Agenda

The RFA requires the NRC to publish a regulatory agenda twice a year in the *Federal Register* listing all rules under development that are expected to have a significant economic impact on a substantial number of small entities. The agenda is required to state the objectives and legal basis of each such rule, discuss its expected impact on small entities, and provide a schedule for completion of each action.

The NRC complies with this regulatory flexibility agenda requirement by submitting data for inclusion in the *Unified Agenda of Federal Regulatory and Deregulatory Actions* (Unified Agenda), published in the Spring and Fall of each year by the Office of Management and Budget (OMB). Since all NRC rulemakings approved for development by the Commission, the EDO, or the Chief Financial Officer are assigned a Regulation Identifier Number (RIN), readers can easily cross-reference Unified Agenda entries to *Federal Register* notices and track a rulemaking from its planning to promulgation.

For more information on the NRC's Unified Agenda Listings contact: Betty Golden, Regulations Specialist, Rules and Directives Branch, (301) 415-6863 or email: BKG2@nrc.gov.

References

NRC Management Directive (MD) 6.3, "The Rulemaking Process."

NUREG/BR-0053, "NRC Regulations Handbook," Rev. 5, March 2001. (ADAMS Accession No. ML011010202)

NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Rev. 3, July 2000. (ADAMS Accession No. ML003738939)

NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," January 1997.

Regulatory Guide 10.12 - "Preparation of Petition for Rulemaking under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents."

These documents are available to interested persons electronically at the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. For more information, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, or 301-415-4737, or by email to pdrr@nrc.gov. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR.

In addition, copies of NUREGS may be purchased from The Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328; www.access.gpo.gov/gov/su_docs; (202) 512-1800. Copies are also available from the National Technical Information Service, Springfield, VA 22161-0002; www.ntis.gov; 1-800-533-6847 or, locally, (703) 805-6000.

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The NRC has also established a toll-free telephone number to answer inquiries from small entities about compliance with the statutes and regulations that affect them: 1-800-368-5642.

For further information concerning the Regulatory Flexibility Act contact Michael T. Lesar, Chief, Rules and Directives Branch, (301) 415-7163 or email: mtl@nrc.gov.

