USDA may withhold any easement payment, and cost-share payments owing to the participant at any time there is a material breach of the easement covenants, rental agreement, or any contract. Such withheld funds may be used to offset costs incurred by the United States in any remedial actions or retained as damages pursuant to court order or settlement agreement.

(e) Under an easement, the United States shall be entitled to recover any and all administrative and legal costs, including attorney's fees or expenses, associated with any enforcement or remedial action.

#### § 1415.15 Payments not subject to claims.

Any cost-share, rental payment, or easement payment or portion thereof due any person under this part shall be allowed without regard to any claim or lien in favor of any creditor, except agencies of the United States Government.

#### §1415.16 Assignments.

(a) Any person entitled to any cash payment under this program may assign the right to receive such cash payments,

in whole or in part.

(b) If a participant that is entitled to a payment dies, becomes incompetent, or is otherwise unable to receive the payment, or is succeeded by another person who renders or completes the required performance, others may be eligible to receive payment in such a manner as USDA determines is fair and reasonable in light of all the circumstances.

#### § 1415.17 Delegation to third parties.

(a) USDA may permit an approved private conservation or land trust organization, State or other Federal agency to administer an easement with the consent or written request of the landowner. Rental agreements will not be delegated to private organizations, State, or other Federal agencies.

(b) USDA will have the right to conduct periodic inspections and enforce the easement and associated restoration agreement for any easements administered pursuant to this section.

- (c) The private organization, State, or other Federal agency shall assume the costs incurred in administering and enforcing the easement, including the costs of restoration or rehabilitation of the land to the extent that such restoration or rehabilitation is above and beyond that required by the GRP conservation plan and restoration agreement. Any additional restoration must be consistent with the purposes of the easement.
- (d) A private organization, State, or other Federal agency that seeks to

- administer and enforce an easement shall apply to the NRCS State Conservationist for approval. The State Conservationist shall consult with FSA State Executive Director prior to approval.
- (e) For a private organization to administer and enforce an easement, the private organization must be organized as required by 28 U.S.C. 501(c)(3) of the Internal Revenue Code of 1986 or be controlled by an organization described in section 28 U.S.C. 509(a)(2) of that code. In addition, the private organization must provide evidence to USDA that it has:
- (1) Relevant experience necessary to administer grassland and shrubland easements;
- (2) A charter that describes the commitment of the private organization to conserving ranchland, agricultural land, or grassland for grazing and conservation purposes;
- (3) The human and financial resources necessary, as determined by the Chief, NRCS, to effectuate the purposes of the charter; and
- (4) Sufficient financial resources to carry out easement administrative and enforcement activities.
- (f) If a private organization is terminated, withdraws from the agreement to administer the easement, or the landowner submits a request in writing to terminate such agreement, the USDA will assume the responsibility upon receiving such formal notice from the organization or the landowner. Subsequent agreements for easement management with other approved private, nonprofit organizations could be entered into at the request of the landowner with approval from the NRCS State Conservationist. If the owner and the new organization fail to notify the NRCS State Conservationist of the reassignment within 30 days of termination, the easement shall revert to the control of NRCS.

#### §1415.18 Appeals.

- (a) Applicants or participants may appeal decisions regarding this program in accordance with 7 CFR parts 11, 614, and 780.
- (b) Before a person may seek judicial review of any action taken under this part, the person must exhaust all administrative appeal procedures set forth in paragraph (a) of this section.

#### §1415.19 Scheme or device.

(a) If it is determined by the Department that a participant has employed a scheme or device to defeat the purposes of this part, any part of any program payment otherwise due or paid such participant during the applicable

period may be withheld or be required to be refunded with interest thereon, as determined appropriate by the Department.

- (b) A scheme or device includes, but is not limited to, coercion, fraud, misrepresentation, depriving any other person of payments for cost-share practices or easements for the purpose of obtaining a payment to which a person would otherwise not be entitled.
- (c) A participant who succeeds to the responsibilities under this part shall report in writing to the Department any interest of any kind in enrolled land that is held by a predecessor or any lender. A failure of full disclosure will be considered a scheme or device under this section.

#### § 1415.20 Confidentiality.

Appraisals are considered confidential information and are not distributed. The regulations in this part provide that any appraisals, market analysis, or supporting documentation that may be used by USDA in determining property value are considered confidential information, and shall only be disclosed as determined at the sole discretion of FSA and NRCS in accordance with applicable law.

Signed at Washington, DC on May 13, 2004.

#### Bruce I. Knight,

Vice President, Commodity Credit Corporation and Chief, Natural Resources Conservation Service.

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# NUCLEAR REGULATORY COMMISSION

#### 10 CFR Chapter I

Regulatory Analysis Guidelines: Final Criteria for the Treatment of Individual Requirements in a Regulatory Analysis

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Regulatory analysis guidelines.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing its final criteria for the treatment of individual requirements in a regulatory analysis, because aggregating or "bundling" different requirements in a single regulatory analysis could potentially mask the inclusion of an individual requirement that is not cost-justified. As a result of these new criteria, the NRC will issue Revision 4 of its Regulatory Analysis Guidelines, NUREG/BR-0058 in the near future.

#### FOR FURTHER INFORMATION CONTACT:

Brian J. Richter, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone (301) 415– 1978; e-mail *bjr@nrc.gov*.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

The NRC usually performs a regulatory analysis for an entire rule in evaluating a proposed regulatory initiative to determine if the rule is costjustified. External stakeholders from the nuclear power industry raised concerns that bundling different requirements in a single regulatory analysis can potentially mask the inclusion of an individual requirement when the net benefit from one of the requirements supports a second requirement that is not cost-justified.

In order to address this concern, the NRC published proposed criteria for the treatment of individual requirements in a regulatory analysis for comment on April 18, 2003 (68 FR 19162).

#### II. Comments on the Proposed Criteria

After publishing its proposed criteria for the treatment of individual requirements in a regulatory analysis, the NRC received two sets of comments: one set from the Nuclear Energy Institute (NEI), an organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry and the second from the Nuclear Regulatory Services Group (NRSG), a consortium of power reactor licensees.

In general, NEI states that the NRC's proposed criteria do not adequately incorporate the relevant Commission guidance on this issue and that the public comments made at a public meeting on March 21, 2002, were not taken into account by the NRC staff. The two areas of concern to NEI were the NRC's criteria necessary to evaluate the bundling of individual requirements and the NRC's guidance on using subjective judgment in making bundling decisions.

The law firm of Ballard Spahr
Andrews & Ingersoll, LLP, also
submitted a set of comments on behalf
of the Nuclear Regulatory Services
Group (NRSG). NRSG calls the proposed
criteria "a positive step in providing
detailed guidance in this area for the
first time" and suggested some
refinements of the criteria so that "all
proposed new regulatory requirements
receive a proper analysis of their costs
and benefits."

Comment: NEI's initial comment was that on "\* \* \* rules that provide risk-informed voluntary alternatives to

current regulations, an individual requirement should have to be costjustified and integral to the purpose of the rule rather than [NRC's position that it be] cost-justified or integral to the purpose of the rule." NEI claims that the NRC's criteria "\* \* would be a significant disincentive to implementation of voluntary alternative requirements developed by industry groups because of the lack of scrutable guidance regarding the addition of individual requirements by the NRC staff."

Response: The NRC believes that its position is correct with respect to the need for each criterion to be considered as a basis for bundling. NRC's position may be clearer if one considers requirements that are not necessary to a rule as enhancements. Then, if one uses NEI's criteria of requiring both conditions, i.e., being both costbeneficial and necessary, no enhancements to a rule would be tolerated or should even be considered because an enhancement is not necessary to the purpose of the rule. But a fundamental principle of cost-benefit methodology is to select the alternative that achieves the largest net benefit, which could conceivably be an alternative with enhancements. Thus, NEI's position is tantamount to ignoring the cost-benefit implications of any requirement that is not necessary to meet the objective of the rule. Under NEI's approach, cost-beneficial relaxations could not be included in a rulemaking if they were not necessary to the purpose of the rule.

Alternatively, the NRC's position allows for the selection of the alternative with the largest net benefit. Also, the NRC does not believe that NEI has demonstrated how the proposed criteria would be a "significant disincentive" to the implementation of voluntary alternative requirements developed by industry groups. As long as the voluntary alternatives are shown to be cost-beneficial and result in no decrease in safety from the NRC's proposed requirement, there should not be a problem.

Comment: NEI notes that the phrase "integral to the purpose of the rule," used both in a Staff Requirements Memorandum (SRM), dated January 19, 2001, and in the February 2002 preliminary criteria, was subsequently dropped from the proposed criteria. The phrase relates to whether a proposed requirement can be "integral to the purpose of the rule" if the individual requirement is not cost-beneficial, not required for compliance, and not required for adequate protection. NEI's

position is that the phrase should be included in the NRC's final criteria.

Response: The NRC replaced the phrase "integral to the purpose of the rule" as stated in the 2002 criteria, with "necessary to the purpose of the rule" because NRC believes that "necessary" conveys a clearer meaning. As discussed in both the proposed and final criteria papers, a requirement is necessary to the purpose of the rule if it is needed for the regulatory initiative to resolve the problems and concerns, and meet the stated objectives that are the focus of the regulatory initiative.

Comment: NEI believes that NRC analysts need more guidance on making bundling judgments. They claim that because NRC's guidance is confusing and provides no meaningful standard, it is easier for the NRC staff to aggregate requirements without explanation.

Response: The NRC's guidance is consistent with that provided in the Office of Management and Budget's (OMB) Circular A–4, "Regulatory Analysis" issued September 17, 2003, in which OMB recognizes the need to examine individual provisions separately and goes on to state:

Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

The OMB circular recognizes that judgment must be used for such analyses. The level of analysis needs to be tempered by many factors such as controversiality, complexity, magnitude of consequences, and the like. Also, each regulatory analysis could possibly have unique features that would likely affect the type of analysis that should be done. Further, NRC final guidance will include reference to the OMB circular and the NRC does not believe additional guidance is needed.

Comment: NEI claims that the use of an analyst's judgment as proposed by the NRC relies too much on NRC management review and public comment. They state: "The burden should be on the NRC to provide sufficient information to evaluate regulatory analysis decisions."

Response: Regulatory analyses are well founded and rely on sound judgments. This is done through peer review, management oversight, review of public comments, etc., and reliance on the analyst's judgment which is central to the regulatory analysis process. The NRC believes that its guidance ensures that its regulatory

analyses will provide sufficient information for the public to evaluate regulatory decisions and makes the process both "meaningful and scrutable."

Comment: NEI quotes the SRM calling for regulatory analyses to be "meaningful and scrutable" and claims that the analysis cannot meet this requirement unless there is some documented basis for disaggregation.

Response: The NRC believes that regulatory analyses prepared under the revised guidelines are "meaningful and scrutable," especially given that the guidance is consistent with that provided by OMB on this issue. The reason for disaggregation would be discussed in each regulatory analysis on a case-by-case basis.

Comment: NEI states that the proposed criteria are inconsistent with the other detailed guidance on the treatment of values and impacts contained in NUREG/BR/0058, as currently written.

Response: The NRC disagrees with this comment and believes this final guidance clarifies and supports existing guidance in NUREG/BR-0058. Further, the NRC believes this new guidance is directly relevant to the current discussion on the identification of alternatives. This guidance considers the scope of requirements and the variability in physical and technical requirements as bases for defining alternatives. This bundling issue should be viewed as an extension or clarification of that discussion.

Comment: NEI states with respect to bundling that the "proposed criteria do not establish a common understanding of new requirements, do not establish a scrutable process for making regulatory decisions about voluntary initiatives, and do not provide sufficient documentation to inform future decisions."

Response: The NRC reiterates its position that "bundling" guidance sets forth in detail how an analyst should handle the "bundling" issue and is also consistent with the cited OMB guidance. The NRC also believes that regulatory analyses and supporting documentation prepared under the revised guidance will be sufficient to provide documentation which may be reviewed to inform future decisions. The NRC notes that regulatory analyses are prepared as tools to support reasoned decision making and public understanding of the NRC's decisions; in this regard, the NRC believes that the revised guidelines achieve these objectives.

*Comment:* NEI requests that the NRC defer its final decision on these criteria

until previous comments are "properly addressed."

Response: Sufficient information was not provided to defer a final decision. The NRC maintains that it has properly addressed all public comments. Also, the Advisory Committee on Reactor Safeguards has stated in a July 17, 2003, letter from its Chairman, Mario V. Bonaca, to the Chairman of the Commission, that the NRC staff's criteria "are appropriate and responsive to the Commission's direction."

Comment: NRSG stated that the NRC should require separate analysis of individual requirements to the extent practicable. They went on to state "that disaggregation of requirements should be the preferred approach, with the burden on the NRC to justify why separate analysis of individual requirements is not appropriate in a given case."

Response: The NRC acknowledges that, for the purposes of developing an overall cost estimate of a regulatory initiative, the analyst should obtain separate cost estimates for each individual requirement to the extent practical. This is because it is the most logical model for developing an overall cost estimate, namely a bottom up approach. Further, the NRC agrees that cost-benefit analyses of individual requirements that are related (but not necessary) to the overall regulatory initiative need to be considered in reaching a sound regulatory decision. However, it is important to remember that the underlying purpose of a regulatory analysis is to provide decision makers with a tool for choosing between options or alternatives. When a regulatory initiative has a number of discreet, yet necessary requirements, the decision maker's choice is not whether to include or exclude necessary individual requirements but, rather, whether or not to enact the initiative as a whole. Therefore, the separate analyses of necessary individual requirements cannot contribute to this decision.

Further, as stated in the proposed criteria, published for public comment in the Federal Register on April 18, 2003 (68 FR 19162): "Specifically, this guidance states that a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality, and that a more detailed disaggregation would only be appropriate if it produces substantially different alternatives with potentially meaningful results." This implies that the analyst must be able to demonstrate that any aggregation in the analysis would not result in different conclusions of the analysis. Therefore,

the NRC still does not believe that disaggregation in all cases should be the preferred approach and stands by the position stated in the proposed criteria. As stated in the guidance, "the NRC does not believe that there should be a general requirement for a separate analysis of each individual requirement of a rule. This could lead to unnecessary complexities." Also, NRC believes that its guidance is consistent with OMB Circular A–4, cited above.

Comment: NRSG states that if, according to the criteria, an individual requirement must be both "related" to the stated objective of the regulatory initiative and be "cost-beneficial," then the NRC should clarify what it means by "cost-beneficial." The commenter also states that the criteria for the treatment of any individual requirement must be consistent with the standards of the backfitting rule. Under the backfit rule, any new requirement that is a backfit must be shown to be cost-justified and produce a "substantial increase" in overall safety. Lastly, their final two points in this section are in agreement with the NRC criteria. First, the commenter agrees with the NRC that in "cases where a new backfit requirement is being considered for inclusion in a voluntary alternative, to current regulations \* \* \* NRC should consider imposing such a new requirement, if justified under the standards of Section 50.109, through the normal disciplined backfitting process, \* \* rather than merely including it in a voluntaryalternative rule." Second, NRSG "agree(s) with the NRC position that if an individual backfit requirement is not related to the objective of the regulatory initiative \* \* \*, the "requirement must be addressed and justified as a backfit separately."

Response: For the most part, the NRC agrees with these comments. With respect to the NRC's meaning of "costbeneficial" in the situation discussed by the commenter, the NRC means that the regulatory initiative results in a larger net benefit than would accrue to an action without that requirement. Further, with respect to the backfit rule, the NRC position is that when an individual requirement is related to the stated regulatory objective, the individual requirement should be costjustified, and the overall regulatory initiative should constitute a substantial increase in the public health and safety.

Comment: NRSG stated that there should be further guidance on backfitting issues related to the American Society of Mechanical Engineers (ASME) Code. Specifically, they state:

NRC's guidance should allow the NRC discretion to perform a cost-benefit analysis of individual new requirements contained in later editions of Section XI before they are incorporated wholesale into Section 50.55a. If the NRC finds that individual new requirements of later Code editions are not cost-beneficial for some or all plants, the NRC should screen out those new individual requirements in accordance with the standards of the backfitting rule.

Response: The Commission's policy regarding Inservice Inspection (ISI) requirements is to assure the integrity of the reactor coolant system (RCS) boundary and containment as they relate to defense-in-depth considerations, that do not lend themselves to cost-benefit analyses. Further, in this specific instance, cost-benefit analyses are not well suited to determine if new requirements that address aging of components are appropriate because of the many uncertainties associated with the effects of aging.

When the Commission formulated its policy, the then Chairman stated that: "Both the ASME and the ACRS have strongly urged that the Commission maintain the current updating requirement" and that—

ASME asserts that the failure of the NRC to incorporate later editions of the Code in the requirements, absent justification under a backfit analysis, would serve to undermine ASME because of the disincentive of volunteers to engage themselves in an ASME process that will not necessarily affect operating plants. Moreover, because some states routinely establish requirements based on current ASME codes, the acceptance of the staff's approach would create the anomaly that non-nuclear facilities might be required to conform to more modern codes than nuclear facilities.

The Chairman also indicated he was aware "that industry participates in the development of the ASME codes and that costs are considered in the amendment process. Thus, although the revisions may not be analyzed with the rigor required by our backfit analysis, the costs and benefits are implicitly weighed."

Another Commissioner commented:

10 CFR 50.109 has served the NRC, our licensees, and our stakeholders well, and thus, my decision to not subject ASME Code updates to its backfit provisions was made only after I carefully considered how the staff's recommended option should exacerbate the complexity, inconsistency, and program divergence associated with our current update process. My decision also came after considering the diverse makeup of the ASME members that produce Code changes and the consensus process they use.

\* \* I believe that considerations of increased safety versus cost are implicit in the ASME consensus process.

In sum, NRSG's suggested approach is inconsistent with the Commission's previous guidance to the staff.

#### III. Final Criteria

In evaluating a proposed regulatory initiative, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is costjustified. However, aggregating or "bundling" different requirements in a single analysis could potentially mask the inclusion of an unnecessary individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of one requirement could potentially support a second unnecessary requirement that is not cost-justified. Similarly, in the case of other types of rules, including those subject to backfit analysis, the net benefit from one requirement could potentially support another requirement that is not cost-justified.2

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine if it is appropriate to include each individual requirement. Clearly, in certain instances, the inclusion of an individual requirement is necessary. This would be the case, for example, when the individual requirement is needed for the regulatory initiative to resolve the problems and concerns and meet the stated objectives 3 that are the focus of the regulatory initiative. Even though inclusion of individual requirements is necessary in this case, the analyst should obtain separate cost estimates for each requirement, to the extent practical, in deriving the total cost estimate presented for the aggregated requirements.

However, there will also be instances in which the individual requirement is not a necessary component of the regulatory initiative, and thus the NRC will have some discretion regarding its inclusion. In these circumstances, the NRC should adhere to the following guideline:

If the individual requirement is related (*i.e.*, supportive but not necessary) to the stated objective of the regulatory initiative, it should be included only if its overall effect is to make the bundled regulatory requirement more cost-beneficial. This would involve a quantitative and/or qualitative evaluation of the costs and benefits of the regulatory initiative with and without the individual requirement included, and a direct comparison of those results.<sup>4</sup>

In applying this guideline, the NRC will need to separate out the discrete requirements in order to evaluate their effect on the cost-benefit results. In theory, each regulatory initiative could include several discretionary individual requirements and each of those discretionary requirements could be comprised of many discrete steps, in which each discrete step could be viewed as a distinct individual requirement. This raises the potential for a large number of iterative costbenefit comparisons, with attendant analytical complexities. Thus, considerable care needs to be given to the level of disaggregation that one attaches to a discretionary requirement.

In general, a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality. For example, more detailed disaggregation is only appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. Alternatively, individual elements that contribute little to the overall costs and benefits and are noncontroversial may not warrant much, if any, consideration. In general, it will not be necessary to provide additional documentation or analysis to explain how this determination is made, although such a finding can certainly be challenged at the public comment stage. 5 For further guidance, the analyst is referred to principles regarding the appropriate level of detail to be included in a

<sup>&</sup>lt;sup>1</sup> The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (NUREG/BR–0058) have been developed so that a regulatory analysis that conforms to these Guidelines will meet the requirements of the backfit rule and the provisions of the CRGR Charter.

<sup>&</sup>lt;sup>2</sup> This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (though costs may be considered in determining how to achieve a certain level of protection).

<sup>&</sup>lt;sup>3</sup> The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule.

<sup>&</sup>lt;sup>4</sup> There may be circumstances in which the analyst considers including an individual requirement that is unrelated to the overall regulatory initiative. For example, an analyst may consider combining certain unrelated requirements as a way to eliminate duplicative rulemaking costs to the NRC and increase regulatory efficiency. Under these circumstances, it would be appropriate to combine these discrete individual requirements if the overall effect is to make the regulatory initiative more cost-beneficial. In those instances in which the individual requirement is a backfit, the requirement must be addressed and justified as a backfit separately. These backfits are not to be included in the overall regulatory analysis of the remainder of the regulatory initiative.

<sup>&</sup>lt;sup>5</sup> See NUREG/BR-0053, Revision 5, March 2001, "U.S. Nuclear Regulatory Commission Regulations Handbook," Section 7.9, for discussion of how to treat comments.

regulatory analysis, as discussed in Chapter 4 of the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

In some cases, an individual requirement that is being considered for inclusion in a voluntary alternative to current regulations may be justifiable under the backfit criteria. In these cases the individual requirement is both costjustified and provides a substantial increase in the overall protection of the public health and safety or the common defense and security. If so, the NRC should consider imposing the individual requirement as a backfit affecting all plants to which it applies, rather than merely including it in a voluntary-alternative rule affecting only those plants where the voluntary alternative is adopted.

A special case involves the NRC's periodic review and endorsement of consensus standards, such as new versions of the American Society of Mechanical Engineers (ASME) codes. These NRC endorsements can typically involve hundreds, if not thousands, of individual provisions. Thus, evaluating the benefits and costs of each individual provision in a regulatory analysis can be a monumental task. Further, the value gained by performing such an exercise appears limited. These consensus standards tend to be noncontroversial and have already undergone extensive external review and been endorsed by industry. Although regulatory actions endorsing these consensus standards must be addressed in a regulatory analysis, it is usually not necessary for the regulatory analysis to address the individual provisions of the consensus standards.

The NRC believes this is appropriate for several reasons:

- (1) It has been longstanding NRC policy to incorporate later versions of the ASME Code into its regulations; and thus, licensees know when receiving their operating licenses that updating the ASME Code is part of the regulatory process;
- (2) Endorsement of the ASME Code is consistent with the National Technology Transfer and Advancement Act, inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, inservice inspection and inservice testing by rulemaking; and
- (3) These consensus standards undergo significant external review and discussion before being endorsed by the NRC.

Some aspects of these regulatory actions endorsing consensus standards are backfits which must be addressed

and justified individually. For example, NRC endorsement (incorporation by reference) of the ASME Boiler and Pressure Vessel Code (BPV) provisions on inservice inspection and inservice testing, and the ASME Operations and Maintenance (OM) Code, are not ordinarily considered backfits, because it has been the NRC's longstanding policy to incorporate later versions of the ASME codes into its regulations. However, under some circumstances the NRC's endorsement of a later ASME BPV or OM Code is treated as a backfit. The application of the backfit rule to ASME code endorsements is discussed in the Appendix below. Aside from these backfits, these regulatory analyses should include consideration of the major features (e.g., process changes, recordkeeping requirements) of the regulatory action which should then be aggregated to produce qualitative or quantitative estimates of the overall burdens and benefits in order to determine if the remainder of the action is justified.

Dated in Rockville, Maryland, this 17th day of May, 2004.

For the Nuclear Regulatory Commission. **Annette Vietti-Cook**,

Secretary of the Commission.

**Note:** The following appendix will not appear in the Code of Federal Regulations.

#### Appendix

## Guidance on Backfitting Related to ASME

10 CFR 50.55a requires nuclear power plant licensees to construct ASME Boiler and Pressure Vessel Code (BPV Code) Class 1, 2, and 3 components under the rules provided in Section III, Division 1, of the ASME BPV Code; inspect Class 1, 2, 3, Class MC, and Class CC components under the rules provided in Section XI, Division 1, of the ASME BPV Code; and test Class 1, 2, and 3 pumps and valves under the rules provided in the ASME Code for Operation and Maintenance of Nuclear Power Plants (OM Code). From time to time, the NRC amends 10 CFR 50.55a to incorporate by reference later editions and addenda of: Section III, Division 1, of the ASME BPV Code; Section XI, Division 1, of the ASME BPV Code; and the ASME OM Code.

#### Section A. Incorporation by Reference of Later Editions and Addenda of Section III, Division 1 of ASME BPV Code

Incorporation by reference of later editions and addenda of Section III, Division 1, of the ASME BPV Code is prospective in nature. The later editions and addenda do not affect a plant that has received a construction permit or an operating license, or a design that has been approved because the edition and addenda to be used in constructing a plant are, by rule, determined on the basis of the date of the construction permit and are not changed, except voluntarily by the

licensee. Thus, incorporation by reference of a later edition and addenda of Section III, Division 1, does not constitute a "backfitting" as defined in § 50.109(a)(1).

#### Section B. Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV and OM Codes

Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV Code and the ASME OM Code affect the ISI and IST programs of operating reactors. However, the backfit rule generally does not apply to incorporation by reference of later editions and addenda of the ASME BPV (Section XI) and OM codes for the following reasons—

- (1) The NRC's longstanding policy has been to incorporate later versions of the ASME codes into its regulations; thus, licensees know when receiving their operating licenses that such updating is part of the regulatory process. This is reflected in § 50.55a which requires licensees to revise their in-service inspection (ISI) and inservice-testing (IST) programs every 120 months to the latest edition and addenda of Section XI of the ASME BPV Code and the ASME OM Code incorporated by reference into § 50.55a that is in effect 12 months before the start of a new 120-month ISI and IST interval. Thus, when the NRC endorses a later version of a code, it is implementing this longstanding policy.
- (2) ASME BPV and OM codes are national consensus standards developed by participants with broad and varied interests, in which all interested parties (including the NRC and utilities) participate. This consideration is consistent with both the intent and spirit of the backfit rule (*i.e.*, the NRC provides for the protection of the public health and safety, and does not unilaterally imposed undue burden on applicants or licensees).
- (3) Endorsement of these ASME codes is consistent with the National Technology Transfer and Advancement Act, inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, inservice inspection and inservice testing by rulemaking.

# Section C. Other Circumstances Where the NRC Does Not Apply the Backfit Rule to the Endorsement of a Later Code

Other circumstances where the NRC does not apply the backfit rule to the endorsement of a later code are as follows—

- (1) When the NRC takes exception to a later ASME BPV or OM code provision, and merely retains the current existing requirement, prohibits the use of the later code provision, or limits the use of the later code provision, the backfit rule does not apply because the NRC is not imposing new requirements. However, the NRC provides the technical and/or policy bases for taking exceptions to the code in the Statement of Considerations for the rule.
- (2) When an NRC exception relaxes an existing ASME BPV or OM code provision but does not prohibit a licensee from using the existing code provision.

## Section D. Endorsement of Later ASME BPV or OM Codes That Are Considered Backfits

There are some circumstances when the NRC considers it appropriate to treat as a backfit the endorsement of a later ASME BPV or OM code—

(1) When the NRC endorses a later provision of the ASME BPV or OM code that takes a substantially different direction from the currently existing requirements, the action is treated as a backfit. An example was the NRC's initial endorsement of Subsections IWE and IWL of Section XI, which imposed containment inspection requirements on operating reactors for the first time. The final rule dated August 8, 1996 (61 FR 41303), incorporated by reference in § 50.55a the 1992 Edition with the 1992 Addenda of IWE and IWL of Section XI to require that containments be routinely inspected to detect defects that could compromise a containment's structural integrity. This action expanded the scope of § 50.55a to include components that were not considered by the existing regulations to be within the scope of ISI. Because those requirements involved a substantially different direction, they were treated as backfits, and justified under the standards of 10 CFR 50.109.

(2) When the NRC requires implementation of later ASME BPV or OM code provision on an expedited basis, the action is treated as a backfit. This applies when implementation is required sooner than it would be required if the NRC simply endorsed the Code without any expedited language. An example was the final rule dated September 22, 1999 (64 FR 51370), which incorporated by reference the 1989 Addenda through the 1996 Addenda of Section III and Section XI of the ASME BPV Code, and the 1995 Edition with the 1996 Addenda of the ASME OM Code. The final rule expedited the implementation of the 1995 Edition with the 1996 Addenda of Appendix VIII of Section XI of the ASME BPV Code for qualification of personnel and procedures for performing ultrasonic (UT) examinations. The expedited implementation of Appendix VIII was considered a backfit because licensees were required to implement the new requirements in Appendix VIII before the next 120-month ISI program inspection interval update. Another example was the final rule dated August 6, 1992 (57 FR 34666), which incorporated by reference in § 50.55a the 1986 Addenda through the 1989 Edition of Section III and Section XI of the ASME BPV Code. The final rule added a requirement to expedite the implementation of the revised reactor vessel shell weld examinations in the 1989 Edition of Section XI. Imposing these examinations was considered a backfit because licensees were required to implement the examinations before the next 120-month ISI program inspection interval update.

(3) When the NRC takes an exception to an ASME BPV or OM code provision and imposes a requirement that is substantially different from the current existing requirement as well as substantially different than the later code. An example of this is presented in the portion of the final rule dated September 19, 2002, in which the NRC adopted dissimilar metal piping weld UT

examination coverage requirements from those in the ASME code.

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### SMALL BUSINESS ADMINISTRATION 13 CFR Parts 121, 124, 125, and 134

RIN 3245-AE92

#### Small Business Size Regulations; Rules of Procedure Governing Cases Before the Office of Hearings and Appeals

**AGENCY:** Small Business Administration. **ACTION:** Final rule.

**SUMMARY:** This final rule amends the U.S. Small Business Administration's (SBA's) small business size regulations and the regulations applying to appeals of size determinations. In particular, this rule amends the definitions of affiliation and employees. It also makes procedural and technical changes to cover programs such as the SBA's HUBZone Program and the governmentwide Small Disadvantaged Business Program. Further, the rule codifies several long-standing precedents of the SBA's Office of Hearings and Appeals and clarifies the jurisdiction of that office.

**DATES:** Effective Date: The rule is effective on June 21, 2004. Applicability Date: These amendments apply to all solicitations issued on or after the effective date, as well as all applications for financial or other assistance pending as of or submitted to the SBA on or after the effective date.

FOR FURTHER INFORMATION CONTACT: Gary Jackson, Assistant Administrator, Office of Size Standards, (202) 205–6464 or *Gary.Jackson@sba.gov*.

SUPPLEMENTARY INFORMATION: On November 22, 2002, the U.S. Small Business Administration (SBA or Agency) published in the Federal Register, 67 FR 70339, a proposed rule to amend its regulations governing size. The SBA's size regulations (13 CFR part 121) are used to determine eligibility for all SBA and Federal programs that require an entity to be a small business concern (SBC).

In general, the SBA's size standards are based on either average annual receipts or number of employees, depending on the industry. When measuring a concern's size, the receipts or employees of affiliated concerns are included. This final rule modifies the definitions of affiliation and number of employees. In addition, the rule amends

13 CFR part 134 and clarifies the jurisdiction of the SBA's Office of Hearings and Appeals (OHA).

## **Section-by-Section Analysis of Comments**

The SBA received two comments on its proposal to amend § 121.102 and add a new paragraph (d) that would recognize that there currently exists an internal Size Policy Board at the SBA responsible for making recommendations to the Administrator on size standards, other size eligibility requirements, and size protest procedures. One commenter concurred with the proposal to recognize the size policy board, while another commenter noted a typographical error in the paragraph numbering. Upon further deliberation, the SBA has decided not to adopt this rule as proposed. The SBA believes that the make-up and utilization of a Size Policy Board or other means to effect size policy is an internal matter, and need not be spelled out in the regulations. The SBA's current organizational structure ensures that size standard issues are considered by all appropriate officials in the Agency.

The SBA also proposed amending the definition of affiliation set forth at § 121.103. The proposed rule provided that control may be affirmative or negative, set forth an example of negative control, stated that control may be exercised indirectly through a third party, and stated that affiliation may be found under the totality of circumstances even though no single factor is sufficient to constitute affiliation. The SBA received several comments on these proposed changes, including comments supporting the incorporation of certain provisions previously contained in the regulations to provide clearer guidance regarding the application of the affiliation rules.

The SBA received one comment regarding § 121.103(a)(6), which provides that when determining the concern's size, the SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates, regardless of whether the affiliates are organized for profit. The commenter stated that this regulation, along with § 121.104(d), does not explain how to aggregate and then average the receipts or employees of a concern's affiliates. The commenter explained that there are three different ways to calculate an average and with each, a different answer is obtained.

In response to this comment, the SBA has amended § 121.104 (receipts) and § 121.106 (employees) to explain how to