POLICY ISSUE
INFORMATION

September 1, 2000 SECY-00-0191

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: HIGH-LEVEL GUIDELINES FOR PERFORMANCE-BASED ACTIVITIES

PURPOSE:

This paper is to inform the Commission of the development of the high-level guidelines consistent with the direction in the Staff Requirements Memorandum (SRM) to SECY-99-176, "Plans for Pursuing Performance-Based Initiatives." The guidelines, their relationship to the risk-informed program, and the results of test applications of the guidelines are provided. These guidelines can be applied to regulatory activities to identify and assess the use of performance-based regulatory approaches instead of prescriptive criteria to assure safe performance, and as such, should help to increase reliance on performance-based regulatory approaches throughout the agency.

SUMMARY:

The staff has developed and tested high-level guidelines (Attachment 1) to identify and assess the viability of making elements of the regulatory framework performance-based. The guidelines are intended to promote the use of a performance-based regulatory framework throughout the agency. In general, a performance-based regulatory approach focuses on results as the primary basis for regulatory decision-making and as such allows licensee flexibility in meeting a regulatory requirement. This in turn, can result in a more efficient and effective regulatory process.

Internal and external stakeholders have commented on the guidelines and their comments have been addressed in the development of the guidelines. Specifically, the staff has addressed concerns among some stakeholders that a performance-based regulatory framework would focus only on reductions in regulatory burden and that public health and safety would lose

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emphasis. The staff notes that a performance-based approach is intended to focus the regulatory framework on desired outcomes and would be applied in conjunction with the agency's defense-in-depth principles as articulated in the Commission's White Paper, "Risk-Informed and Performance-Based Regulation," SRM to SECY-98-144 (White Paper).

Based on feasibility testing of the guidelines, the staff concludes that they can be used to effectively focus the regulatory framework to be more performance-based by:

(A) Identifying the elements of the regulatory framework which can be made more performance-based. Note, the regulatory framework may include the regulation and its supporting regulatory guides, standard review plans, technical specifications, NUREGs, and inspection guidance.

(B) Selecting or formulating performance parameters and associated performance criteria appropriate to the regulatory issue being addressed. For example, they facilitate identifying the level (i.e., component, train, system) at which performance criteria should be set.

Having established the feasibility of the guidelines, the staff plans to develop implementing guidance to incorporate the guidelines into internal NRC procedures, and to apply the guidelines to future regulatory initiatives, including those that are identified through risk-informed activities.

BACKGROUND:

In the SRM to SECY-99-176, issued on September 13, 1999, the Commission directed the staff to develop high-level guidelines to identify and assess the viability of candidate performance-based activities. The staff published a set of proposed guidelines in the Federal Register on January 24, 2000. The Commission was provided with a copy of the guidelines for information prior to the Federal Register publication.

In the SRM to SECY-99-176 the Commission directed that:

(A) The guidelines should be developed with input from stakeholders and the program offices.

(B) The guidelines should include discussion on how risk information might assist in the development of performance-based initiatives.

(C) The guidelines should be provided to the Commission for information.

(D) The staff should periodically update the Commission on its plans and progress in identifying and developing performance-based initiatives.

DISCUSSION:

The staff has used definitions from the White Paper for terminology such as "deterministic analyses," "risk insights," and "performance-based approach" in developing the guidelines. Consistent with the NRC's Strategic Plan and the White Paper, the guidelines are to be applied across the full spectrum of materials, processes, and facilities regulated by the NRC.

Program Office and Stakeholder Input

In response to the SRM, the staff took the following actions:

The staff established a Performance-Based Regulation Working Group (PBRWG) to ensure broad NRC program office participation in the development of the guidelines. The PBRWG has representation from RES, NRR, NMSS, and regional representation through Region III. The PBRWG was instrumental in developing consensus among the offices on this initiative. Once these guidelines are incorporated into internal NRC procedures, the PBRWG will cease to exist and line management will assume responsibility for applying the guidelines.

A facilitated workshop was held on March 1, 2000 with a number of internal and external stakeholders representing the reactor, materials, and waste areas. This workshop solicited comments on an initial draft of the proposed guidelines and on a set of specific questions which were posed in two Federal Register Notices. Revised guidelines were published on May 9, 2000, and an on-line workshop was held on June 8, 2000. Comments were received at the workshops and in response to the Federal Register Notices, and the guidelines contained herein have been modified in response to public comments. The majority of the comments were supportive of the guidelines and staff efforts to make NRC regulatory requirements more performance-based. The staff's response to all comments appears in Attachment 2.

In addition, the staff briefed the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW). The Advisory Committee on Medical Uses of Isotopes (ACMUI) was provided briefing material.

Interrelationships Among Regulatory Initiatives

Initiatives to change the regulatory framework arise from various sources such as Commission direction, operating experience, stakeholder suggestions and staff initiatives. These proposed initiatives are normally subjected to a screening process that include identification of the specific modification of the regulatory framework and an initial prioritization utilizing the NRC's performance goals to determine whether the proposed initiative should be pursued and with what priority. A determination will then be made as to whether to pursue a "Risk-Informed and Performance-Based," "Risk-Informed," "Performance-Based," or "Traditional" approach based on guidelines described in this paper and in the Risk-Informed Regulation Implementation Plan (RIRIP). The staff would use the guidelines to assess the viability (discussed below) to make this determination. When feasible, it is preferable to use a risk-informed and performance-based approach. The staff is coordinating the guidelines in both areas to assure that no inconsistencies exist between them. A separate paper on RIRIP will be presented to the Commission. Once a decision is made to pursue a performance-based approach, the staff will apply the guidelines to assess the change (as described below) to further develop the approach. If the staff finds that a performance-based approach is not feasible, then the staff will assess what other methods can be used.

Overview of Guidelines

The guidelines are structured under three main groupings:

(i) Guidelines to Assess Viability: These guidelines rely on the four attributes of a performance-based approach as discussed in the White Paper. These are: measurable or calculable parameters; objective performance criteria; flexibility; and a performance failure not resulting in an immediate safety concern. These guidelines assess whether a more performance-based approach is feasible for any given new regulatory initiative. This assessment would be applied on a case-by-case basis and would be based on an integrated consideration of the individual guidelines within this grouping. In applying the guidelines, the staff must be cognizant of circumstances when implementation of a performance-based approach, in a manner inconsistent with the intent or objective, may have a negative or unacceptable effect on safety. For example, postponing needed maintenance in order to meet an availability goal would not be an acceptable way to use flexibility. However, it would be appropriate to revise the availability goal, reflecting considerations of safety significance, and expand flexibility if a sound technical basis is demonstrated.

(ii) Guidelines to Assess Change: If a performance-based approach is deemed viable based on the guidelines in (i) above, then the regulatory activity would be evaluated against guidelines that assess whether a more performance-based approach results in opportunities for regulatory improvement (by which is meant a positive contribution to the NRC's performance goals and achieving a net societal benefit). The performance goals are: maintain safety; increase public confidence; increase effectiveness, efficiency and realism; and reduce unnecessary regulatory burden. Additional guidelines in this group include a net benefit test, the ability of the proposal to be incorporated in the regulatory framework, and the ability to accommodate new technology. This evaluation is to be based on an integrated assessment of the individual guidelines within this grouping.

(iii) Guidelines to Assure Consistency with Other Regulatory Principles: These guidelines assess consistency and coherence with overriding NRC goals and principles (e.g., the defense-in-depth principle). It only needs to be applied if the candidate activity passes the first two sets of guidelines.

Use of Risk Information Relative to Performance-Based Initiatives

Consistent with the definition of a "risk-informed, performance-based approach" provided in the White Paper, risk information will be used to assist in the development of performance-based initiatives so that the staff will accomplish the following:

- Focus attention on the most important activities;
- Establish objective criteria for evaluating performance;
- Develop measurable or calculable parameters for monitoring system and licensee performance;
- Provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes; and

- Focus on the results as the primary basis for regulatory decision-making.

The staff has identified risk information to be relevant with respect to performance-based initiatives in three ways:

(1) A Basis for Establishing Appropriate Level of Performance:

A performance-based approach will assist in ensuring that important systems, functions, and other elements of regulated activity provide the requisite level of performance. In effect, the high level performance-based guidelines, and specifically the viability guidelines, provide a framework to search for the appropriate performance parameter and the level of performance necessary to achieve the safety objective. For example, for a given activity, the guidelines can help determine if performance goals should be set at the component, system or function level.

(2) To Provide Metrics, Thresholds and/or Regulatory Response:

The staff is using risk considerations to select performance metrics in several contexts. The reactor oversight program uses performance indicators which rely on risk information such as reliability and availability of certain systems, trains and components. The risk significance of performance changes can be evaluated directly where performance indicators are based on risk information. Performance thresholds and appropriate regulatory responses could then be determined in a straightforward manner. The guidelines are useful to characterize the appropriate performance attributes that might be monitored using risk insights. For example, risk information can be used to set reliability and availability goals for critical safety equipment.

(3) Unavailability of Quantitative Risk Evaluation Models:

On February 11, 1999, the Commission issued the SRM to SECY-98-132 in which the staff was directed to pursue performance-based initiatives that are not amenable to probabilistic risk assessment. Although many regulated activities may not be easily related to a quantitative risk model, they should not be precluded from being made more performance-based. Therefore, the staff is planning to apply the guidelines to suitable candidates in this category. In these instances, risk information of a less quantitative or non-quantitative nature, such as that available from an integrated safety assessment, should be relied upon. In some or all of these areas, a performance-based approach may present opportunities for regulatory improvements.

Testing of the High-Level Guidelines

Application of the guidelines requires that the nature of the regulated activity and the safety issues be defined with specificity. To explore how such challenges can be met in practice, the staff selected two issues to test the guidelines. For each issue, an NRC panel was formed consisting of experts on the specific regulatory issue. The first issue is related to the ongoing effort to risk-inform 10 CFR 50.44 (Standards for Combustible Gas Control System in Light-Water-Cooled Power Reactors). Although the hypothetical regulatory change is thought to be plausible, it must be considered purely illustrative at this time while the alternatives that will be proposed for revisions to 10 CFR 50.44 are still under consideration. The second issue involves a recent change that was made to Subpart H (Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas) of 10 CFR Part 20. In this case, the guidelines were applied retrospectively for illustrative purposes. The results of tests clearly support the utility of the high-level guidelines. A detailed description of these tests and the results appears in Attachment 3.

On the basis of the two test cases, the staff identified two issues concerning generic application of the guidelines. First, for a given regulatory activity, it appears that, in order to maximize the performance-based potential, one must apply the guidelines to the entire regulatory framework as it relates to that activity. This is because there typically exists a hierarchy of information pertaining to a regulated activity which encompass the more general provisions of the rule language to the relatively detailed supporting documents. Thus, opportunities to make an activity more performance-based could occur anywhere along the hierarchy. Further, an assessment that fails to apply the guidelines to the full regulatory framework could result in partial or ineffectual results, where, for example, a rule is made more performance-based but remains supported by unnecessarily prescriptive regulatory guidance.

Second, in most instances, performance will not be dependent on a single parameter. Rather, the guidelines will have to be applied to a combination of performance parameters each of which contributes to attaining the performance goals. For example, the first case study in Attachment 3 uses the combination of capability, reliability, and availability to provide the basis for setting performance criteria.

PLANS FOR PERFORMANCE-BASED INITIATIVE:

The staff plans to:

- Apply the guidelines in ongoing or future approved rulemakings, as appropriate.

- Apply the guidelines to ongoing regulatory efforts under Option 3 of SECY-98-300, “Options for Risk-Informed Revisions to 10 CFR Part 50.”

- Apply the guidelines to suitable candidates identified as being not appropriate to be risk-informed pursuant to the “Risk-Informed Regulation Implementation Plan” (SECY-00-0062, March 15, 2000).

- Develop a management directive to support agency-wide implementation of the guidelines in ongoing or future approved rulemakings and other regulatory activities, as appropriate (e.g., the inspection process). Supporting guidance at the office level will occur through office letters.

- Develop a communications plan to promote broader awareness of performance-based approaches on the part of external stakeholders. Wider acceptance of the guidelines should lead to efficiencies and an overall increased level of performance-based activities.

- Provide a report to the Commission on the above activities at the end of FY-2001.

RESOURCES:

For FY 2001, RES currently has 1 FTE to: (1) apply the guidelines to a candidate regulation identified as not appropriate to be risk-informed; (2) develop a management directive; and (3) develop a communication plan. Resources requirements for developing specific performance-based changes to the regulatory framework as a result of implementing the high-level guidelines will be addressed, as appropriate, by the performing office(s). Future requirements will be addressed through the Planning, Budgeting, and Performance Management process.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objection. The Office of the Chief Information Officer has reviewed this Commission Paper for information technology and information management implications and concurs in it.

/RA/

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Attachments: 1. High-Level Guidelines for Performance-Based Activities
2. NRC Response to Public Comments
3. Process and Case Studies Applying High-Level Guidelines

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High-Level Guidelines for Performance-Based Activities

The proposed guidelines to identify and assess performance-based activities are shown below. They are substantially the same as those published in the Federal Register on May 9, 2000, with modifications based on internal and external stakeholder input. These guidelines are based on the four attributes in the Commission's White Paper, "Risk-Informed and Performance-Based Regulation," SRM to SECY-98-144. The nature of the regulated activity and the safety issues for which regulatory requirements are to be developed need to be defined with specificity before the guidelines are applied. Generally, an integrated assessment from a set of guidelines will provide the basis for any conclusion.

I. Guidelines to Assess Viability

The staff will apply the following guidelines to assess whether a more performance-based approach is viable for any given new regulatory initiative. This assessment would be applied on a case-by-case basis and would be based on an integrated consideration of the individual guidelines. Risk information provides the basis for identifying systems, functions or other elements of regulated activity which should be targeted for application of these guidelines so that the appropriate performance parameters are chosen and the level of performance is set to achieve the safety objective. The assessment for viability will ensure that sufficient information (data) and analytical methods exist or can be developed. The guidelines are listed below:

A. Measurable (or calculable) parameters to monitor acceptable plant and licensee performance exist or can be developed.

   (1) Directly measured parameter related to safety objective will typically satisfy this guideline.

   (2) A calculated parameter may also be acceptable if there is a clear relationship to the safety objective.

   (3) Parameters which licensees can readily access, or are currently accessing, in real time will typically satisfy this guideline. Parameters monitored periodically to address postulated or design basis conditions may also be acceptable.

   (4) Acceptable parameters should be consistent with defense-in-depth and uncertainty considerations.

B. Objective criteria to assess performance exist or can be developed.

   (1) Objective criteria consistent with the desired outcome are established based on risk insights, deterministic analyses and/or performance history.

C. Licensee flexibility in meeting the established performance criteria exists or can be developed.

   (1) Programs and processes used to achieve the established performance criteria would be at the licensee's discretion.

(2) A consideration in incorporating flexibility to meet established performance criteria will be to encourage and reward improved outcomes provided inappropriate incentives can be avoided.

D. A framework exists or can be developed such that performance criteria, if not met, will not result in an immediate safety concern.

(1) An adequate safety margin exists.

(2) Time is available for taking corrective action to avoid the safety concern.

(3) The licensee is capable of detecting and correcting performance degradation.

II. Guidelines to Assess Performance-Based Regulatory Change

If a more performance-based approach is deemed to be viable based on the guidelines in I. Guidelines to Assess Viability above, then the consequences of adopting a more performance-based approach would be evaluated based on an integrated consideration of this second group of guidelines. This assessment would compare the start up and implementation costs of the regulatory change relative to the NRC's performance goals and other desirable outcomes. The outcomes would be considered applicable to the public, the applicant or licensee, and the NRC staff. The guidelines are listed below:

A. Maintain safety, protect the environment and the common defense and security.

(1) Safety considerations play a primary role in assessing any change arising from the use of performance-based approaches.

(2) Adequate safety margins are maintained using realistic safety analyses, including explicit consideration of uncertainties.

B. Increase public confidence.

(1) An emphasis on results and objective criteria (characteristics of a performance-based approach) can help NRC to be viewed as an independent, open, efficient, clear, and reliable regulator.

(2) A performance-based approach helps with providing the public clear and accurate information about, and a meaningful role in the regulatory programs.

(3) A performance-based approach helps explain NRC's roles and responsibilities and how public concerns are considered.

C. Increase effectiveness, efficiency and realism of the NRC activities and decision-making.

(1) An assessment would be made of the level of conservatism existing in the currently applicable regulatory requirements considering analysis methodology and the applicable

assumptions. Any proposal to use realistic analysis would take into account uncertainty factors and defense-in-depth relative to the scenario under consideration.

(2) An assessment would be made of the performance criteria and the level in the performance hierarchy where they have been set. In general, performance criteria should be set at a level commensurate with the function being performed. In most cases, performance criteria would be expected to be set at the system level or higher.

D. Reduce unnecessary regulatory burden.

(1) A performance-based approach enables NRC to impose regulatory burden which is commensurate with the safety benefit, and which effectively focuses resources on safety issues.

(2) A performance-based approach will enable the costs associated with NRC activities to States, the public, applicants and licensees to be focused on areas of highest safety priority and avoid burden imposed by overly prescriptive regulatory requirements.

E. The expected result of using a performance-based approach shows an overall net benefit.

(1) A reasonable net benefit test would begin with a qualitative approach to evaluate whether there is merit in changing the existing regulatory framework. When the net benefit test is approached from the perspective of existing practices, stakeholder input may be sought.

(2) Unless imposition of a safety improvement or other societal outcome is contemplated, expending resources for a change in regulatory practice would be justified in most cases only if NRC or licensee operations benefit from such a change. The primary source of initial information and feedback regarding potential benefits to licensees would be the licensees themselves.

(3) For the limited purpose of screening potential performance-based changes, consideration of a specific result (such as net reduction in worker radiation exposure) may be sufficient for weighing the immediate implications of a proposed change.

F. The performance-based approach can be incorporated into the regulatory framework.

(1) The regulatory framework may include the regulation in the Code of Federal Regulations, the associated Regulatory Guide, NUREG, Standard Review Plan, Technical Specification, and/or inspection guidance.

(2) A feasible performance-based approach would be one which can be directed specifically at changing one, some, or all of these elements.

(3) The proponent of the change to the elements of the regulatory framework would have the responsibility to provide sufficient justification for the proposed change; all stakeholders would have the opportunity to provide feedback on the proposal, typically in a public meeting.

(4) Inspection and enforcement considerations would be addressed during the formulation of regulatory changes rather than afterwards. Such considerations could include reduced NRC scrutiny if performance so warrants.

G. The performance-based approach would accommodate new technology.

(1) The incentive to consider a performance-based approach may arise from development of new technologies as well as difficulty stemming from technological changes in finding spare components and parts.

(2) Advanced proven technologies may provide more economical solutions to a regulatory issue without compromising safety, hence justifying consideration of a performance-based approach.

III. Guidelines to Assure Consistency with Other Regulatory Principles

A. A proposed change to a more performance-based approach is consistent and coherent with other overriding goals, principles and approaches involving the NRC's regulatory process.

(1) These principles are provided in the Principles of Good Regulation, the Probabilistic Risk Assessment (PRA) Policy Statement, the Regulatory Guide 1.174, "An Approach for Using PRA in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," and the NRC's Strategic Plan.

(2) Consistent with the high-level at which the guidance described above has been articulated, specific factors which need to be addressed in each case (such as defense-in-depth and treatment of uncertainties) would depend on the particular regulatory issues involved.

NRC Response to Public Comments:

The Federal Register Notice (FRN), 65 FR 3615 on January 24, 2000, requested comments on the proposed high-level guidelines with particular interest in a set of specific questions. Comments were provided at the March 1, 2000 workshop and in writing. The workshop was conducted as a facilitated discussion among stakeholders representing a wide variety of interests, including NRC representatives from the program offices. Revised guidelines were published in the Federal Register on May 9, 2000 (65 FR 26772), reflecting comments to that point. In addition, an on-line workshop, held on June 8, 2000, provided another opportunity for public comment. Limited comments were received as a result of this workshop.

In the January 24, 2000, FRN, the NRC specifically requested comments on a number of key questions concerning the proposed guidelines. The NRC's response to comments has been structured within the framework of the questions published in the January FRN. Comments not associated directly with any of the questions are shown under the heading "Other Comments."

The NRC's response to the comments and any indication as to how the guidelines have changed in response to the comments follows:

A. <u>Clarity and Specificity of the Guidelines</u>

1. Are the proposed guidelines appropriate and clear?

   Comment: Overall, favorable opinions were expressed regarding appropriateness and clarity of the guidelines. However, two commenters who were generally opposed to any shift to a more performance-based approach provided unfavorable responses. Specifically, those clearly opposed to the performance-based regulatory approach are concerned that its primary purpose is to reduce regulatory requirements and licensee burden thereby compromising the safety standard for overseeing regulated activity. Additionally, there is concern that under a performance-based approach, one would not be able to prevent accidental releases of radioactive material.

   Response: In the NRC's view, the performance-based approach has the potential of making the regulatory decisions more effective and efficient by reducing unnecessary regulatory burden, and do so without compromising overall safety. Further, the guidelines require that in order for an activity to be a viable performance-based candidate, failure to meet its performance criteria will not result in an immediate safety concern. Amplifying guidelines specify that a sufficient safety margin exists, time is available to take corrective action, and the licensee is capable of detecting and correcting performance degradation. Active consideration of all these factors can lead to superior safety standards while avoiding unnecessary regulatory burden. At the same time, the guidelines focus attention on the factors which prevent release of unsafe amounts of radioactive materials.

2. Are there additional guidelines that would improve clarity and specificity?

   Comment: One comment proposed a guideline to increase safety and another comment proposed a guideline to prevent incentives to "perverse" outcomes.

Response: As discussed below, a framework and process to increase safety by adding to regulatory requirements (subject to 10 CFR 50.109, the Backfit Rule) exists and it would not be efficient to duplicate this through additional guidelines. No changes were made in the main guidelines because safety and beneficial outcomes are generally desirable goals which form parts of normal staff considerations. However, the amplifying guidelines under "Maintain Safety" have been modified to emphasize that safety considerations will play the primary role in NRC's assessments. Since the Commission addressed the matter of encouraging and rewarding improved outcomes in the White Paper (SRM to SECY-98-144, "White paper on Risk-Informed and Performance-Based Regulation)," an amplifying guideline to this effect has been added. This amplifying guideline under overall net benefit generated a comment indicating a misunderstanding that cost would be given a greater emphasis than safety. A revision has been made regarding the considerations related to a simplified net benefit test.

3. How does the "high-level" nature of the guidelines affect the clarity and specificity of the guidelines?

   Comment: The comments provided did not indicate any need to change any of the guidelines due to this factor. One commenter specifically endorsed the "high-level" approach to the guidelines, while also suggesting a graded approach incorporating a minimum acceptable risk.

   Response: The NRC interpreted "minimum acceptable risk" to mean a level of risk consistent with adequate protection considerations. The NRC agrees that a graded approach is appropriate for regulatory changes above and beyond adequate protection. The NRC maintains that the guidelines, as currently formulated, allow for this; thus, no changes were made to address this comment.

B. <u>Implementation of the Guidelines</u>

1. What guidelines, if any, are mandatory for an activity to qualify as a performance-based initiative?

   Comment: Commenters stated that none of the guidelines should be mandatory.

   Response: The viability guidelines must be satisfied for an activity to qualify as a performance-based initiative. In this sense, they may be considered mandatory. For example, a sufficient safety margin must exist. Also, the "Guidelines to Assure Consistency with Other Regulatory Principles" could be considered mandatory because they cover principles which the NRC would not knowingly violate.

2. What is the best way to implement these guidelines?

   Comment: An issue of considerable interest was whether a performance-based approach should be voluntary or not. Certain commenters believed that voluntary changes negatively affect the NRC's inspection and enforcement role whereas others maintained that changes must be voluntary to ensure flexibility on the part of licensees.

Response: It is anticipated that voluntary implementation will often be proposed, and where mandatory implementation is proposed, such a change would be subject to the Backfit Rule. Additionally, the NRC has decided to implement the guidelines to new initiatives. Initiatives proposed by stakeholders, such as in petitions for rulemaking, would thus be considered as potential candidates.

3. How should the Backfit Rule apply to the implementation of performance-based approaches?

   Comment: Most commenters indicated that reliance on a performance-based approach would have no bearing on whether or not the Backfit Rule applied. One commenter expressed the view that the Backfit Rule should apply to reductions in regulatory burden.

   Response: The NRC concurs that increased reliance on a performance-based approach poses no unique considerations relative to the Backfit Rule. The NRC fully expects that all new requirements, including those made performance-based, will be subject to existing NRC procedures which include backfit considerations as well as formal regulatory analysis requirements. This comment goes well beyond the scope of these guidelines as currently envisaged.

4. Should these guidelines be applied to all types of activity, e.g., should they be applied to petitions for rulemaking?

   Comment: To the extent that commenters favored application of the guidelines, they also supported application to all activities directed at improving the effectiveness of regulations. One commenter acknowledged that it may not be appropriate for some regulations, such as the Fitness for Duty Rule.

   Response: The NRC intends to apply the guidelines to all activities including responding to and resolving petitions for rulemaking. The commenter who indicated that they were not appropriate for all regulations did not provide a rationale for that position.

5. Should these guidelines only be applied to new regulatory initiatives?

   Comment: A number of commenters from industry preferred wider implementation. For example, one suggestion was to use the guidelines as a screen against existing regulations and to propose changes to the rules based on the potential for significant benefit.

   Response: NRC's current plans are to only implement the guidelines for new initiatives primarily because of NRC resource constraints. However, it should be noted that other mechanisms would continue to exist to identify potential changes to the regulatory framework.

6. Will these guidelines be effective in determining whether we can make a regulatory initiative more performance-based?

   Comment: In general, to the extent that any comments were offered in this regard, the response was in the affirmative.

C. Establishment of Objective Performance Criteria

1. In moving to performance-based requirements, should the current level of conservatism be maintained or should introduction of more realism be attempted?

   Comments: Commenters expressed the view that the appropriate level of conservatism depends on the analysis methodology and the applicable assumptions. Defense-in-depth and uncertainty factors also need to be considered. One commenter stated that it should not be assumed that the level of defense-in-depth remain the same in a performance-based approach.

   Response: The NRC agrees with the commenters and amplifying guidelines have been modified or added under main guidelines associated with "Measurable (or calculable) parameters to monitor acceptable plant and licensee performance exist or can be developed" and "Increase effectiveness, efficiency and realism of the NRC activities and decision-making."

2 What level of conservatism (safety margin) needs to be built into a performance criterion to avoid facing an immediate safety concern if the criterion is not met?

   The comments and response from (C.1) above are also applicable here.

3. Recognizing that performance criteria can be set at different levels in a hierarchy (e.g., component, train, system, release, dose), on what basis is an appropriate level in the hierarchy selected for setting performance-based requirements, and what is the appropriate level of conservatism for each tier in the hierarchy?

   Comment: Oral and written comments expressed the view that performance criteria are best set at the function or system level.

   Response: Some amplifying guidelines which address this issue have been added under the main guideline of "Increase effectiveness, efficiency and realism of the NRC activities and decision-making".

4. Who would be responsible for proposing and justifying the acceptance limits and adequacy of objective criteria?

   Comment: A commenter suggested that the proponent of a change should bear the responsibility for justifying the criteria and the adequacy of acceptance limits.

   Response: The NRC agrees with the commenter. Some amplifying guidelines have been added under the main guideline of "The performance-based approach can be incorporated into the regulatory framework".

5. What are examples of performance-based objectives that are not amenable to risk analyses such as PRA or Integrated Safety Assessment?

   Comment: Examples offered were cross-cutting issues, including fitness-for-duty, safety conscious work environment and management effectiveness.

Response: The NRC agrees with the commenter's examples and they are included in the Commission Paper.

6. In the context of risk-informed regulation, to what extent should performance criteria account for potential risk from beyond-design-basis accidents (i.e., severe accidents)?

   Comment: A commenter stated that risk-informed regulation reaches beyond design basis events by its nature.

   Response: The NRC agrees that risk-informed regulation needs to consider beyond-design-basis accidents.

D. <u>Identification and use of measurable (or calculable) parameters</u>

1. How and by whom are performance parameters to be determined?

   Comment: Comments were presented expressing concern that the NRC would be entirely dependent on licensees' own reports regarding performance. One commenter has stated that information collection at nuclear facilities may require changes to better measure performance. Another commenter raised concerns about licensee honesty and full disclosure.

   Response: The NRC would be responsible for setting the performance parameters with input from stakeholders. Further, the NRC would always maintain vigilance over performance observations. If information collection requirements need to be changed to implement a performance-based approach, such proposals will be addressed in the context of the specific regulatory requirement under consideration. No changes were made in the guidelines based on these comments.

2. How do you decide what a relevant performance parameter is?

   Comment: Some commenters expressed reservations with the use of performance parameters such as core damage frequency as a calculable parameter. Other comments cautioned against drawing broader conclusions (such as overall level of safety or lack thereof) from performance measures than may be justified.

   Response: As these considerations are context specific, and the merits of specific performance parameters are explicitly considered by the guidelines, no changes are proposed in the guidelines. However, on the basis of the experience gained from the limited testing of the guidelines, the scope of what is meant by "performance parameter" has been expanded. It was found that a number of relevant parameters may be required to address the guidelines relative to a given regulatory issue.

3. How much uncertainty can be tolerated in the measurable or calculated parameters?

   Comment: Comments indicate a strong connection between consideration of uncertainty and the level of conservatism in establishing the performance parameters and acceptance criteria.

Response: Changes made in response to (C.1) above are also applicable to this issue.

E. Pilot projects

1. Would undertaking pilot projects in the reactor, materials, and waste arenas provide beneficial experience before finalizing the guidelines?

   Comment: Some commenters stated that pilot projects would be useful, and others stated that they were not needed. One commenter suggested that it was important to learn appropriate lessons from implementation of the maintenance rule. Another commented that Option B of 10 CFR 50, Appendix J has already appropriately demonstrated the favorable results from a performance-based regulation.

   Response: The NRC plans to apply the guidelines to specific regulations as part of the implementation process and does not currently plan to conduct pilot projects. Based on testing, as reported in Attachment 3, the NRC believes the guidelines are sufficiently developed such that pilots are not needed.

2. What should be the relationship between any such pilot projects and those being implemented to risk-inform the regulations?

   Comment: Commenters generally stated that the ongoing pilot projects related to risk-informing the regulations need not be perturbed by including consideration of the guidelines, but appropriate coordination should be maintained. Any screening of regulations should be done one time as opposed to subjecting each regulation to various screenings at different times under different processes.

   Response: The NRC proposes to integrate the interfaces between performance-based and risk-informed activities so as to help ensure a more integrated approach and avoid duplication.

F. Other Comments

1. Eliminate all high-level guidelines used to evaluate opportunities for regulatory improvement (II. Guidelines to Assess Performance-Based Regulatory Change):

   Comment: One commenter at the public workshop suggested that the set of guidelines to assess performance-based regulatory improvement be eliminated.

   Response: The NRC continues to believe that this set of guidelines constitutes an integral part of a structure and logic to consider explicitly the values important to any regulatory improvement program. No changes were made based on this comment.

2. Inclusion of the Advisory Committee on Medical Uses of Isotopes (ACMUI):

   Comment: One commenter at the public workshop suggested that ACMUI should be included among the advisory committees which would have an opportunity to review the high-level guidelines.

Response: ACMUI has been included with ACRS and ACNW as committees whose feedback will be sought before the guidelines are submitted to the Commission.

3. Inclusion of perspective from the NRC regions in the work of the Performance-Based Regulations Working Group (PBRWG):

   Comment: One commenter at the public workshop suggested that a representative from the NRC regional offices should be included in the PBRWG, which will play an instrumental role in developing and applying the guidelines.

   Response: Regional representation has been added to the PBRWG.

4. Inspection and enforcement considerations:

   Comment: Comments from within and outside the NRC expressed the need for inspection and enforcement aspects to be front-end considerations. A commenter also suggested that performance above a threshold should result in reduced NRC scrutiny, as long as future departures from good performance would be detectable. Similarly, another commenter supported the notion that past performance could be used to determine the level of flexibility, thereby rewarding or penalizing licensees based on performance history.

   Response: An amplifying guideline has been added under the guideline “The performance-based approach can be incorporated into the regulatory framework” to address this comment.

5. Consideration of a significantly different regulatory paradigm:

   Comment: One commenter offered suggestions to significantly modify the regulatory framework so that any changes undertaken by the NRC would have as a pre-requisite an improvement in the level of safety.

   Response: The NRC notes that current NRC procedures fully allow for identification and implementation of safety enhancements subject to the Backfit Rule. The proposals presented would have wide ranging impacts, and consideration of performance-based initiatives would be only tangentially related to most of them. No specific changes to the guidelines were made in consideration of these comments.

Process and Case Studies Applying High-Level Guidelines

The purpose of this attachment is to present case studies in which the high-level guidelines are applied to specific regulatory provisions. The guidelines to assess viability are emphasized because they represent what is distinctive regarding identifying and assessing performance-based activities. The guidelines were applied to two areas. The first was based on a postulated set of regulatory requirements which the staff hypothesized may be identified as performance-based candidates. The second was a retrospective evaluation of a regulation recently promulgated to assess whether the changes could be seen as having made the existing regulation more performance-based.

Process, Concepts and Definitions

The high-level guidelines to assess viability center on selection or formulation of performance parameters and associated performance criteria. Application of these guidelines depend on certain definitions, which are developed below.

Kinds of "Performance"

In formulating a concept for performance, the staff has drawn on ideas used in the Revised Reactor Oversight Process, in which “performance” refers to those activities in design, procurement, construction, maintenance, and operation that support achievement of the objectives of the cornerstones of safety in the Reactor Oversight Process. In an analogous manner, other applications would entail identification of key aspects of performance and focus on activities which are important to safety.

Risk-significant performance changes generally affect system characteristics such as frequency of events and reliability, availability, or capability of systems, structures, and components (SSCs). Here, “capability” refers to the physical capacity of the system to accomplish a given function, such as “deliver required flow at a given pressure,” “successfully bear a given load,” or “effectively filter air taken into a breathing apparatus.” Availability refers to the fraction of time that the SSC is capable of performing its function. Reliability refers to the probability that a given SSC will function on demand and during the required mission time, given that it was available.

Many kinds of performance affect the system characteristics including such factors as human performance, and the condition in which equipment is left after preventive or corrective maintenance (recognizing that the conduct of testing and maintenance itself affects availability). Ultimately, licensee corrective action programs also affect reliability and availability. Even spare parts management can affect availability.

Characteristics of Functional Safety Requirements

A complete functional safety requirement includes the following:

(1) A definition of the safety mission to be carried out.

This entails at least an implicit specification of the physical challenge that needs to be met. Meeting the challenge will require a level of performance characterized in terms of one or more physical parameters such as flowrate at a particular pressure, or heat removal rate. The system performance specification may be made implicitly, as when a functional outcome is mandated, conditional on a specific challenge (such as maximum peak clad temperature following a specific LOCA, or "no containment failure due to hydrogen combustion" following major core damage).

(2) An indication of the required degree of assurance (functional reliability) that the mission will be carried out successfully.

Assurance of successful performance has previously been approached using concepts such as redundancy (single-failure proof design), special treatment requirements (in procurement, installation, and surveillance), and limiting conditions of operation (so that individual trains or channels of the system cannot be out of service longer than allowed outage times). Surveillance testing or inspection may be mandated at specified intervals so that the probability of undetected faults is limited. System reliability can be promoted by requirements on redundancy, QA, surveillance testing, and allowed outage times.

Implementation Phases of Functional Safety Requirements

There are two distinct kinds of activities involved in implementation of functional safety requirements involving performance parameters. The first kind of activity is associated with design and construction (includes design, procurement, installation and gaining assurance that system design is capable of achieving the desired reliability). The second kind of activity is operational and aimed at maintaining the required reliability and availability. It includes such things as surveillance testing, preventive maintenance, corrective maintenance, and corrective action programs. In the regulatory sphere the first kind of activity is generally associated with licensing. Later plant modifications may also be included. The first kind of activity includes formulation, initial achievement, and subsequent modification of a safety case; the second kind of activity is aimed at keeping the current safety case valid.

Hierarchy of Regulatory Framework

Current regulatory requirements are formulated at several distinct levels which are termed as the hierarchical structure within the regulatory framework. Rules generally state high-level requirements, while lower-level guidance documents provide more specific guidance, including examples of acceptable ways to meet requirements. Technical Specifications and other license conditions also play a role in imposing requirements on licensees. It is found that assessment of the viability of performance-based approaches in a given area is best discussed in light of a comprehensive picture of requirements existing at all of these levels.

Rule Level

The rule states the mission, including the challenges to be addressed and the definition of successful performance. Some existing rules explicitly quantify physical success criteria, such as peak clad temperature, or percentage of metal assumed to react with water to produce hydrogen in certain scenarios.

Evaluation Guidance Level

At this level, which includes both regulatory guides and standard review plans, numerical success criteria are given if they were not stated as part of the rule. These may relate to capability requirements or reliability requirements. Guidance at this level does not have the standing of rules, but it may articulate standards that are considered to be a way to satisfy the intent of rules.

Guidance on acceptable evaluation methods is also provided, including conservative analysis assumptions that may be required in order to assure that conclusions based on the evaluations are robust.

Operational Level (Technical Specifications, Commitments, other elements of the Licensing Basis, etc.)

At this level, requirements are aimed at assuring that assumptions related to safety are upheld. Requirements may be imposed on surveillance test interval and/or test protocol. Technical Specifications may limit the amount of time that the plant is allowed to operate with certain equipment trains out of service. Consensus standards cited by rules are also effectively operational level guidance.

Case Study 1: Combustible Gas Control

This case study applies the viability guidelines to a hypothetical new requirement concerning combustible gas control. The purpose of this hypothetical requirement is to control the probability of containment failure from uncontrolled burns of combustible gas which can occur under certain scenarios in certain containment designs. If the requirement satisfies the viability guidelines concerning measurable performance parameters, objective performance criteria, licensee flexibility, and safety margin, this is an indication that the requirement can be made performance-based.

The case study assumes the following:

- For plants with certain containment designs, some risk-significant scenarios lead to the burning of combustible gas at levels that can threaten containment integrity.

- A technical basis exists for identifying and quantifying risk-significant scenarios and their elements on a plant-specific basis.

- A technical basis exists for quantifying the amounts and rates of generation of combustible gases, and modeling the phenomenology of burns (including the resulting loads).

- A technical basis exists for analysis of containment response to loads caused by combustion of gas.

- A technical basis exists for establishing a needed functional reliability. This could be derived from an argument based on the Quantitative Health Objectives (QHOs), the frequency at which this function is challenged, and the expected radiological consequences of functional failure of combustible gas control, given that it is challenged.

Formulation of a Requirement on Combustible Gas Control

For purposes of this illustration, a hypothetical requirement on combustible gas control has been formulated that would be applicable to specific classes of plants. This hypothetical requirement on combustible gas control is characterized as follows in terms of the concepts discussed above.

The Safety Issue:

The safety issue is prevention of failure of containment due to loads caused by burning of combustible gases in conjunction with other loads (e.g., steam pressurization, HPME) during risk-significant core damage scenarios that produce significant amounts of combustible gas. The emphasis on “risk-significant” core damage scenarios means that station blackout sequences need to be addressed (including the availability of power for ignition systems) and the phenomenology of core damage scenarios needs to be allowed for, including the amounts and rates of hydrogen generation and the severity of the environments that result. It is also necessary to include methodology for evaluation of containment loads resulting from burns, and specification of required margin on containment performance, if this is warranted.

Physical Definition of Success:

A possible definition of success is “Prevention of containment failure from burning of combustible gas concurrent with other containment loadings, given severe core damage with accompanying evolution of gas.”

This is to be assessed using evaluation methods and assumptions mandated in specification of the safety issue (above), and depends on technology. For igniters, it will be necessary to specify physical ignition capability: surface temperature, number, and distribution.

Depending on implementation of technology selected, Technical Specifications on capability may be warranted (specification of the physical ignition capability required to be confirmed by test).

Specification of Functional Reliability Needed To Meet Requirement:

As discussed earlier, the desired functional reliability can be determined from such considerations as the QHOs, the consequences of functional failure, and the frequency of challenges to this function (the frequency of severe core damage). In the discussion that follows, it is assumed that such a determination has been carried out, and that for plants in the class subject to this requirement, the overall functional failure probability is to be maintained well below 0.1. This probability is conditional on the scenario ingredients called out previously, such as station blackout. This assumption bears on licensee flexibility and on the feasibility of detecting performance changes within a reasonable time.

As formulated, this hypothetical requirement specifies evaluation methodologies with respect to the challenge and definition of success. These evaluations could be carried out on a plant-specific basis, or for classes of plants; for purposes of the present case study, it is tacitly assumed that each plant carries out the evaluations according to the acceptable methodologies. The performance parameters thus derived will take credit for aspects of containment performance that are themselves the subject of other requirements, which may be prescriptive. The hypothetical requirement does not force a choice of technology.

Application of the Viability Guidelines

The following aspects of the overall requirement, as hypothesized, warrant consideration as areas that could be performance-based: igniter capability, functional reliability, division reliability, and division availability. (For this case study, the choice of igniter technology is presumed, although this choice might not be made in all cases.) Atmospheric mixing is a related area that could be performance-based, but it is not treated here. The following discussion applies the four viability guidelines to each potential performance-based area in turn.

Igniter Capability:

In order to succeed, the igniter function must provide sufficient physical capability (e.g., enough surface area at a sufficiently high temperature). The functional reliability associated is discussed separately.

> Guideline IA: Several capability parameters exist: surface temperature, number, and distribution.
>
> Guideline 1B: Criteria for each of these parameters can be developed based on ignition phenomenology.
>
> Guideline IC: Within igniter technology, relatively little flexibility in achieving these parameters may exist, but choice of technology itself may be allowed.
>
> Guideline ID: Provided that performance is actually monitored periodically, so that the failure is detected in test and not in an actual accident scenario, not meeting the criterion does not immediately cause a safety concern. This is based on the fact that the frequency of severe core damage is itself limited.

Functional Reliability:

Here, the phrase “functional reliability” refers to the probability that the ignition function will be carried out successfully, given that a need for the function arises. Since the function may be performed by a collection of SSCs, which may be designed to allow for some failures, the functional reliability depends on lower-level figures of merit such as division-level, train-level, or component-level reliability and availability.

> Guideline IA: This guideline is met. At the functional level, for this case, it would be calculated from division and component level performance and availability data.

Guideline IB: This guideline is met. Functional reliability criterion is derivable as indicated above from QHO arguments, or could be formulated based on other lines of reasoning.

Guideline IC: Choice of technology is one level of flexibility. Within igniter technology, there is flexibility in system redundancy and in licensee management of division availability.

Guideline ID: Declining reliability is not an immediate safety concern. This is based on the fact that the frequency of severe core damage is itself limited.

Division Reliability:

Here, the phrase “division reliability” refers to the reliability of a functional subset of the igniter function. In fact, divisional redundancy may not be required for this function – it is possible that a single division might meet the requirement. The present discussion tacitly assumes that some redundancy would be incorporated into the design. Depending on the design, the functional reliability requirement would then be decomposed into division reliability requirements and division availability requirements.

Guideline IA: Division reliability would be calculated from component level performance data.

Guideline IB: An objective criterion can be developed based on the functional reliability criterion discussed above.

Guideline IC: There is flexibility in design and in operational practices to meet this requirement.

Guideline ID: Declining reliability is not an immediate safety concern. This is based on the fact that the frequency of severe core damage is itself limited.

Division Availability:

Here, the phrase “division availability” refers to the availability of a functional subset of the igniter function. In fact, divisional redundancy may not be required for this function - it is possible that a single division might meet the requirement. The present discussion tacitly assumes that some redundancy would be incorporated into the design.

Guideline IA: Division availability would be evaluated directly from test and maintenance records.

Guideline IB: An objective criterion would be developed, based on system redundancy, the functional reliability criterion and the division reliability criterion discussed above.

Guideline IC: Flexibility exists in licensee management of maintenance.

Guideline ID: Not meeting the availability criterion would not be an immediate safety concern. In addition to factors cited above for other parameters, the availability criterion

has the property of being relatively easily observable, in that changes in performance are not masked by statistical fluctuations.

Summary

For active ignition technology, several capability parameters were identified. These satisfy some of the remaining guidelines in that they are measurable, criteria exist, and failure to meet performance criteria does not result in an immediate safety concern. However, within igniter technology, there may not be very much flexibility in meeting these criteria. Other technologies could be considered. Inquiry needed to establish the practicality or necessity of monitoring the efficacy of atmospheric mixing was not carried out.

Reliability parameters satisfy three of the four guidelines and might satisfy the fourth. Criteria can be derived, flexibility is afforded, and failure to satisfy reliability requirements is not an immediate safety concern. However, whether it is practical to confirm reliability through monitoring is a plant-specific evaluation. Viability requires that unacceptable performance cause enough failure events within a reasonable monitoring time to manifest the current (degraded) performance level. For this system, it is expected that quantitative evaluation would lead to a satisfactory finding for this guideline as well.

Therefore, the viability guidelines are substantially satisfied by several key elements of this requirement. A substantially performance-based version of this requirement would be viable. However, as noted previously, the evaluations carried out for this area will take credit for passive containment performance under severe conditions including high temperatures. Performance-basing of requirements on these less-testable aspects of containment integrity may not be viable. Moreover, this hypothetical requirement mandates evaluation of the frequency of this particular functional challenge (i.e., the frequency of severe core damage events that challenge this function). This frequency itself reflects credit for satisfaction of requirements that may not be performance-based. Nevertheless, the utility of the guidelines has been demonstrated to identify elements of the regulatory framework which can be made substantially performance-based.

Case Study 2: Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

This case study applies all three groups of guidelines to examine the recent changes to 10 CFR 20, Subpart H, Respiratory Protection and Controls to Restrict Internal Exposures. The stated goals of the revision were to revise the requirements to reflect current guidance (ANSI and OSHA) and to make the requirements for radiological protection less prescriptive while reducing unnecessary regulatory burden without reducing worker protection. A review of the changes made to the requirements indicates three generic types of changes:

1. Administrative changes that clarify the requirements,

2. Regulatory framework changes to the structure of the requirements resulting in a more logical order (e.g., moving Appendix A footnotes to the regulatory text), and

3. Regulatory changes that actually change the requirements explicitly identified in the rule and thus may impact the licensees' regulatory burden.

The purpose of this case study is to apply the three groups of guidelines to specific regulatory requirements and determine whether the revised rule can be judged to be more performance-based than the prior version of the rule. Hence, the guidelines are being applied as an assessment tool to the changes made to the rule by the recent revision, and not to the rule as a whole. The assessment was performed using a sampling approach. To assess the impact of the change to Subpart H, three of the changes to the rule were analyzed. The three changes selected were of the third type above. One change reflected an increased regulatory burden, one a reduction in regulatory burden, and one an overall neutral impact on the regulatory burden.

Application of the Viability Guidelines

The sample of three rule changes are examined below:

(i) A provision to reduce regulatory burden was contained in §20.1702(b), which added text to permit licensees to consider safety factors other than radiological factors when performing an ALARA analysis to determine whether or not respirators should be used. Applying the viability guidelines to assess this change results in the following:

Guideline I.A.: The parameters should reflect licensee performance of the ALARA program as well as consider non-radiological factors that affect worker safety. Under the original rule requirements, the non-radiological factors had to be considered, but were divorced from the radiological ALARA determination. This could have resulted in reduced worker protection from non-radiological factors while licensees sought to meet ALARA requirements. Measurable or calculable parameters would be available from performance history associated with the non-radiological and ALARA factors. When compared to the prior version of the Subpart H requirements, the revised requirement would only require identification of parameters associated with non-radiological safety factors, such as trending of occupational health and safety incidents, in addition to parameters associated with radiological factors.

Guideline I.B.: Objective criteria to assess performance of a licensee's ALARA program exist in the form of past performance. Objective criteria on performance of a licensee's ALARA program could be based on trending of worker doses.

Guideline I.C.: The prior version of the requirement allowed licensee flexibility by the definition of ALARA. The revised requirement provides another degree of freedom for the ALARA analysis by including non-radiological safety factors. Under the revised requirement, it is possible for the ALARA analysis to result in higher doses to workers but lower overall risk to the workers once non-radiological safety factors are included. By allowing slightly higher worker doses in this scenario, the NRC has provided the licensee increased flexibility. Thus, flexibility is increased with the revised requirement.

Guideline I.D.: By definition, the ALARA program operates in a dose regime that does not correspond to an immediate safety concern. Generally, the airborne concentrations of

radioactive material are such that failure of performance criteria will not result in an immediate safety concern. By including non-radiological safety factors, the revised requirement should result in lower total risk. Thus, the revised requirement should generally increase the safety margin. On occasion, hazards may be such that a failure of equipment might result in a relatively small safety margin. These rare cases result in more prescriptive requirements for equipment that will be discussed in further detail in the next requirement change example.

Summary – This change expands the scope of the ALARA analysis by including non-radiological safety factors. This introduces greater flexibility by not requiring respirator use in some circumstances in which it would previously have been required. The licensee may, however, expend some extra effort in justification. The net effect may be to decrease overall licensee burden. In summary, this change satisfies the viability guidelines, making the revised rule more performance based than the prior version.

(ii) A provision that increased regulatory burden was contained in §20.1703(c)(6) which added text to require fit testing before first field use of tight-fitting, face sealing respirators and at least annual testing thereafter. The quantitative criteria for successful fit testing are also codified. The prior version of the rule only included a requirement that the licensee's respiratory protection program include written procedures for fitting. The revised rule does not alter these requirements, but includes specific requirements for fit testing frequency and quantitative criteria for test fit factors that must be achieved during testing in order to use the Appendix A APFs. These new specific requirements explicitly provide lower-level (less outcome-oriented) objective criteria for assessing fit testing. Both the prior version of the rule and the revised rule included a requirement that the licensee include surveys and bioassays, as necessary, to evaluate actual intakes in the respiratory protection program. Applying the viability guidelines to assess this change results in the following:

Guideline I.A.: The parameters that measure desired outcomes associated with this requirement, dose due to internal exposure, are not affected by this change. The revised requirement explicitly mentions lower-level parameters for monitoring performance, but these parameters do not measure outcomes and were implicit in the prior version of the rule.

Guideline I.B.: Objective criteria to assess performance of a licensee's fit testing exist. The revision simply explicitly stated some of the objective criteria for fit testing.

Guideline I.C.:The prior version of the rule allowed licensee flexibility by only specifying that a written procedure for fitting be included in the respiratory protection program. The revision adds requirements at a lower level: it increases the specificity of requirements imposed by the rule. Thus, application of the third viability guideline would indicate that the revised rule may be less performance-based.

Guideline I.D.: For performance in the area of respirator equipment fitting, sufficient safety margin may not exist when performance criteria are not met. As discussed above in the analysis of the ALARA program, hazards may be such that a failure of the respirator fitting properly may result in a relatively small safety margin. In addition, time is not available for taking corrective action due to the nature of the hazards, such as internally deposited radioactive material or non-radioactive airborne materials, and the typical

frequency of surveys and bioassays. These scenarios require prescriptive requirements for fit testing. In addition, since proper fit is assumed when making dose calculations for legal records, prescriptive requirements are necessary to provide the proper assurance of accuracy. This guideline therefore corresponds to the motivation for the rule change.

Summary – This revision to the rule does not make the rule more performance-based. However, the reason for this is that sufficient safety margin and time for taking corrective action do not exist in the event the performance criteria are not met. The viability guidelines indicate that this area of the rule is not suitable for performance-based activities and support the motivation for the rule change.

(iii) A provision considered neutral relative to regulatory burden was included in the rulemaking relative to §20.1703(a)(6) [which becomes §20.1703(e) in the revised rule] such that text was added to require consideration of low temperature freezing of exhaust valves on negative pressure respirators, and removed text that specified protection against skin contamination. The only difference between the prior version of the rule and the revised rule for this particular change is the list of requirements explicitly mentioned by the rule that need to be considered when selecting respiratory protection equipment. Adding the requirement for consideration of low temperature work environments increases the analysis effort explicitly required. Removing the requirement for consideration of skin contamination requires the licensee to address skin contamination using means other than respiratory equipment. Applying the viability guidelines to assess this change results in the following:

Guideline I.A.: The parameters would be equivalent for the prior version of the rule and the revised rule.

Guideline I.B.: The objective criteria may be based on performance history.

Guideline I.C.: Although the list of requirements explicitly mentioned changes, the net affect on licensee flexibility is negligible. The level of specificity of the explicit requirements does not change. Since the objective criteria remain equivalent, the flexibility is unchanged by the change to the Subpart H requirements.

Guideline I.D.: Failure to meet the performance criteria of either the prior version of the rule or the revised rule could lead to situations that do not provide sufficient safety margin or time for taking corrective actions. For example, failure to consider low temperature work environments could result in exhalation valves on negative pressure respirators to freeze in the open position due to moisture from exhaled air when temperatures are below freezing. This situation would provide a pathway for airborne hazards, such as radioactive material, to bypass the respirator filter without the users knowledge. Thus, requirements are necessary to provide worker protection while in radioactive areas. This guideline therefore corresponds to the motivation for the rule change.

Summary – The revised rule is neither more or less performance-based than the prior version of the rule. The specific requirements changed in this example are prescriptive due to the fact that sufficient safety margin and time for taking corrective action do not exist in the event the performance criteria are not met. This example does demonstrate the validity of using the viability guidelines to assess performance-based activities and support the motivation for the rule change.

Conclusion: Application of the guidelines to the three selected changes to the rule indicates that the changes appear to comport with the guidelines. A premise in the testing of the guidelines was that the process of testing may indicate a need to change one or more of the guidelines. The guidelines worked well as they are and no changes are proposed as a result of the testing.

Application of the Guidelines to Assess Performance-Based Regulatory Change

For completeness, the changes to the requirements of Subpart H were evaluated against the remaining performance-based guidelines to verify that the changes resulted in a net regulatory benefit. For this evaluation, the composite of all the changes must be evaluated to provide the integrated consideration required, rather than evaluating each change individually. Thus, the results of the sampling approach above are extrapolated to include all changes to the rule when necessary. However, this evaluation is based primarily on the existing results contained in the staff's Statement of Considerations and the Regulatory Analysis for the amendment of Subpart H requirements.

Guideline II.A.: The following factors were noted:

- Allowing the consideration of non-radiological safety factors when performing an ALARA analysis results in an overall reduction in the worker's risk from all hazards;
- Explicitly identifying fit test criteria, intended to ensure that sufficient margin of safety (specifically, proper fit) is maintained under field and work conditions, increases assurance that respiratory equipment will perform as expected during use;
- Explicitly identifying environmental factors, such as low temperatures, for consideration in determining respiratory protection increases assurance that the proper operation of respiratory equipment will not be adversely affected during use.

Guideline II.B.: The following factors were noted:

- Identifying regulatory requirements in the amended rule text and removing guidance from the rule, such as moving some of the Appendix A footnotes to the regulatory text and deleting some that are addressed in the Regulatory Guide, clarifies the requirements and reduces confusion;
- Recognizing new devices and new technologies updates the rule to reflect current practices by licensees;
- Allowing use of single-use disposable masks when ALARA analysis indicates that respiratory protection is not necessary, provides a means for addressing respiratory protection equipment when requested by the worker.

Guideline II.C.: The following factors were noted:

- Including decontamination to reduce resuspension of radioactive material in the work place provides an effective and efficient means of controlling internal dose instead of using respirators;

- Adopting the existing guidance of ANSI, such as reduced equipment assigned protection factors (APFs) provides consistency;

- Adopting the existing requirements of OSHA, such as fit testing frequency and fit factors for positive pressure, continuous flow, and positive-demand devices, provides consistency.

Guideline II.D: The following was noted:

- Each amendment to the rule was reviewed by the staff to determine the impact on licensee burden and the conclusion was that 13 amendments reduced burden, 3 amendments increased burden, and 36 amendments had no impact on burden; with the net result being a reduction in licensee burden.

Guideline II.E: The following was noted:

The backfit analysis performed by the staff for the amendments concluded that the changes constitute not only a burden reduction, but also a substantial increase in the overall protection of public (worker) health and safety. Based on a review of public comments, public confidence is not significantly affected by the rule amendments. However, it is assumed that the substantial increase in the overall protection of worker health and safety would result in an associated increase in public confidence. The Regulatory Analysis estimated a net benefit of $1.5 million per year, including the cost to revise licensee procedures. Finally, since this is an amendment to an existing rule, the regulatory framework can inherently incorporate the approach into the existing regulatory framework. Thus, the existing Regulatory Analysis adequately addresses the regulatory improvement guidelines, demonstrating that the amendments to the rule result in a net regulatory benefit.

Application of the Guidelines to Assure Consistency with Other Regulatory Principles

The revision is inherently consistent with other regulatory principles. However, use of the guideline will support the assertion that the guideline is valid for evaluating future performance-based activities. The revised rule is consistent with 1992 American National Standards Institute (ANSI) guidance for respiratory protection and respiratory protection regulations published by Occupational Safety and Health Administration (OSHA). The findings of the environmental assessment analysis state that the revised rule is expected to result in a decrease in the use of respiratory protection and an increase in engineering and other controls to reduce airborne contaminants while maintaining total occupational dose as low as reasonably achievable. Thus, subject to the limitations of the sampling approach used, the revision to the rule is consistent with other regulatory principles.