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1 Purpose

The purpose of this Guidance Document is to identify the process for using risk-informed and performancebased (RIPB) approaches, as appropriate, when developing or revising American Nuclear Society (ANS) standards. This document also helps the consensus committees, subcommittees, and working groups (WGs) decide if and how RIPB approaches can be incorporated into their standards.

This document is intended to be used by all consensus committees during the development of new ANS standards and for revising existing ANS standards that chose to incorporate RIPB approaches.

2 Background

In 2013, the ANS Standards Board (SB) commissioned the Risk-Informed, Performance-Based Principles and Policy Committee (RP3C) to establish "approaches, priorities, responsibilities, and schedules for implementation of risk-informed and performance-based principles in ANS standards."

The RP3C was then tasked by the SB to develop a plan:

"which would provide the approaches and procedures to be used by ANS Standards Committee consensus committees (CCs), subcommittees (SCs), and Working Groups (WGs) to implement RIPB principles in a consistent manner."

This Guidance Document represents a primary deliverable of that plan.

3 Organization of the Guide

Section 4 identifies the process to be used to initiate or enhance the incorporation of RIPB approaches during the development of new or the revision of existing standards.

Section 5 defines objectives of RIPB standards.

Section 6 discusses RIPB attributes and approaches to help standard developers incorporate the key elements.

This Guidance Document also contains five appendices:

- Appendix A identifies the roles and responsibilities of the ANS RP3C.
- Appendix B provides background information on the development of RIPB attributes and how RIPB approaches have been successfully incorporated into the U.S. Nuclear Regulatory Commission (NRC) Maintenance Rule (10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" [1]).

- Appendix C provides a simple example of the application of the RIPB elements and attributes.
- Appendix D provides examples of RIPB attributes in ANS standards.
- Appendix E provides answers to a series of focused "Frequently Asked Questions (FAQs)" to help users with applying this Guidance Document.

4 **Process for Incorporating RIPB Approaches**

The following describes the process to be used to initiate or enhance the incorporation of RIPB approaches during the development of new or the revision of existing standards. Appendix A describes the roles and responsibilities of the RP3C for implementing this process.

4.1 WG Formation and Project Initiation Notification System Stage

4.1.1 WG Formation Stage

During the project initiation stage, or at any time during the development stage, if the WG Chair determines that a new or existing standard will involve RIPB approaches, then the WG Chair should include one or more professionals with some experience in RIPB approaches to be a part of the WG. Potential members are discussed further in the next section.

The WG Chair should also consider requiring attendance at a training session on this Guidance Document for all WG members during the early standards development stage.

4.1.2 **Project Initiation and Notification System (PINS) Development Stage**

The PINS form includes the following question for the WG Chair to address:

Will this standard use risk-informed insights, performance-based requirements, and/or a graded approach?

The PINS instructions state that it is strongly recommended that new and revised standards use RIPB requirements and/or a graded approach, where applicable.

The WG Chair should contact the RP3C Chair for guidance to incorporate these methods while preparing the PINS. If guidance is needed regarding performing a probabilistic risk assessment (PRA) or regarding using a PRA for risk-informed insights, the WG Chair should contact the Joint Committee on Nuclear Risk Management (JCNRM), one of the consensus committees under the ANS SB, and include the JCNRM Sub-Committee on Risk Applications (SCoRA).

Should incorporation of RIPB approach(es) to the standard being developed or revised be deemed to be not effective or applicable, then the remainder of this procedure is not applicable to that particular standard. The WG Chair should then develop a brief evaluation of the standard's RIPB non-applicability and share it with other stakeholders (e.g., people on the consensus committee). The evaluation should include assumptions and an overall assessment for consideration and reference by future WGs. This RIPB non-applicability statement should be submitted with the PINS.

4.2 Standards Development Stage

Once a standard has been deemed appropriate to incorporate RIPB approach(es), then the WG Chair should interface with the RP3C to obtain support from RP3C and/or JCNRM on how best to incorporate RIPB approaches consistent with the guidance provided below. It is strongly recommended that JCNRM should be consulted if PRA or other risk methods are involved.

4.2.1 Early Outline/Draft

The WG Chair should use this Guidance Document, particularly Sections 5 and 6, to support the WG determination as to whether RIPB approaches can be applied along with incorporation of RIPB approaches into the standard and should reach out to the RP3C and/or JCNRM (via <u>standards@ans.org</u>) to request the necessary assistance throughout the writing or review process.

The RP3C Chair should identify a RP3C member and/or JCNRM identify a JCNRM member(s) as the primary point(s) of contact from those respective groups to support the WG, especially during the early stages of the standard development.

If a RIPB approach is applied, one of the approaches discussed in Sections 5 and 6 below should be applied when developing a new or revising the existing standard. This process involves defining the outcomes or results of the standard that will be developed using a risk-informed and/or performance-based approach, as well as the proposed attributes associated with each approach.

4.2.2 Pre-Subcommittee Draft

The WG Chair should send the pre-subcommittee draft of the standard to the RP3C for review using his/her judgment as to when the draft is sufficiently mature enough to materially benefit from the review. If PRA approaches are part of the standard, the WG Chair should also send the draft document to the JCNRM for review. Details of the standard do not necessarily have to be completed at this time.

The RP3C or JCNRM should schedule and perform the review within a reasonable time period to minimize any impact to the standard development schedule. The review and comments should be confined as to how the standard might better employ RIPB approaches.

To benefit future work, WG decisions on the standard should be maintained in the ANS online Standards Workspace (currently "ANS Collaborate") with a link that can be found on the ANS website under "Standards Workspace."

After the pre-subcommittee draft standard development phase, it might be too late to implement any or all of the RP3C or JCNRM recommendations. Implementation decisions should be based upon the value added (technical and economical) versus the difficulty in implementing the recommendations. However, the upfront schedule should attempt to forecast the time needed to implement recommendations based on the simplicity or complexity of the standard. The WG Chair should consult with the subcommittee and consensus committee chairs to address questions of schedule, volunteer resources (total and appropriate skill sets), extensiveness of standard rework, etc., so as to chart the best path forward.

The WG Chair maintains the authority to adopt, reject, or adapt any of the RP3C or JCNRM recommendations resulting from the review. However, the reasons for such decisions should be documented in the record of the standard (i.e., in the "Standards Workspace") and a copy sent to the RP3C and/or JCNRM (depending on which committee(s) is supporting the standard development and review).



5 **Objectives of RIPB Standards**

The following discusses the high-level objectives for standards that incorporate RIPB insights.

5.1 Outcome(s) Statement

The goal of a standard is to establish requirements ("shall" statements) that, taken together, accomplish one or more outcomes (perhaps involving multiple products or outputs). Always implicit (but only sometimes explicit) is that the user of a standard will have a high level of confidence that the outcomes will be accomplished if the "shall" requirements are met.

Accordingly, a clear understanding of the "big picture" and declaration of the ultimate outcomes called for in a standard (perhaps involving multiple products or outputs), or others that may be associated with it, is a critical step in the early stage of any standard development effort. This latter objective applies to all standards including those standards that incorporate risk-informed and performance-based attributes.

When a standard is newly developed or updated using both risk-informed and performance-based approaches, the outcomes called for in the standard can be defined such that specific results can either be performance-based or risk-informed or both; where the final outcome is a mix of attributes and approaches. A good example of a standard that uses RIPB insights is NFPA-805, *Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Station* [2], where some previously designated outcomes (e.g., amount of fire water storage) were replaced with performance-based requirements and where PRA methods can be used to determine the acceptability to the plant fire safe shutdown analysis. *ANS-2.26, Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design*, [3] is another good example of a standard that uses RIPB attributes.

5.2 **Objectives for Risk-Informed Standards**

Risk-informed insights can be used to support decisions on the scope, focus, level of rigor, and/or complexity of the standard. The method for analyzing "risk" is often done by using PRA methods. ANS/ASME PRA standards provide requirements to ensure that a PRA has sufficient technical acceptability to support a risk-informed application.

A "risk-informed" approach to design represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus attention on design and operational issues commensurate with specific design and safety objectives.

A risk-informed process sets up an integrated decision-making structure that allows for the consideration of a broad range of technical and stakeholder input uncertainties, uncertainties in analysis and decision criteria, and knowledge constraints. Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," [4] and guideline NEI 18-04 (Rev. 1), "Risk-Informed Performance-Based Technology Guidance for Non-Light Water Reactors," [5] are examples of effective risk-informed processes.

5.2.1 Using Risk Insights to Define the Scope of the Standard

Risk insights can be used to define or even narrow the scope of a outcomes called for in a standard, e.g., to identify only those program elements or structures, systems, and components (SSCs) that are the more important (from a risk perspective) to achieve the desired outcome(s). Facilities with risk models may be able to consider quantitative measures, such as risk importance measures, as part of the scoping decision.



If the analysis used to support outcomes called for in a standard is a PRA or uses PRA methods, then the JCNRM should be consulted.

5.2.2 Using Risk Metrics as Part of the Standards Outcome Statement

The outcome of the standard can be stated in terms of risk metrics such as the "consequence at a given frequency." If the analysis used to support outcomes called for in a standard is a PRA or uses PRA methods, then the JCNRM should be consulted.

5.2.3 Using Risk Insights to Define How to Meet the Standard's Outcome

Risk insights can be used in defining the rigor or level of effort to be used in meeting the outcomes called for in a standard. Risk insights can help to set requirements for testing, surveilling, or inspecting SSCs. For example, a standard that tests a number of similar components subject to wear could require more frequent tests for wear in the high-risk SSC category, somewhat less frequent tests for the medium-risk SSC category, and long-term monitoring for the low-risk SSC category.

Using this type of graded approach, the nuclear industry has been successful in implementing risk-informed, in-service testing and inspection programs that reduce the technical rigor and periodicity of tests/inspections, which ultimately translates to both cost and radiological exposure savings. The NRC has issued the following regulatory guides that employ this principle:

- Regulatory Guide 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," [6]; and,
- Regulatory Guide 1.178, "An Approach for Plant-Specific Risk-Informed Decisionmaking Inservice Inspection of Piping" [7]).

Similar to the categorization and focus applications observed above, the increase in level of rigor or specificity of the standard's outcomes can be applied on a graded scale based on risk insights. The programmatic or design requirements can be different and focused based on the specific risk contribution. For example, an SSC may have different functions during different modes of reactor operation, and the categorization and the suggested treatment may differ for the different functions. Similarly, the level or rigor and sophistication of an analysis called for in a standard or in the elements of a nuclear safety program can be tailored based upon risk insights.

Furthermore, the standard can specify the use of probabilistic or statistical methods for achieving the outcome. If these methods employ PRA methods, or alternative risk assessment tools concepts, the JCNRM should be consulted. The nuclear industry has been successful in identifying safety-related SSCs that have little or no safety significance and convincing the regulators to reduce the regulatory treatment requirements typically placed on safety-related SSC (10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems and Components" [8]).

Finally, while the standard can allow for different risk-informing approaches to be used to achieve outcomes, the approaches should be described and context or limitations or use in order to provide an appropriate level of confidence on the accuracy or repeatability of achieving the outcome.

5.3 **Objectives for Performance-Based Standards**

Performance-based standards uses an approach that focuses on desired, measurable outcomes, rather than prescriptive processes, techniques, or procedures. Performance-based standards can achieve desired



outcomes without specific direction regarding \underline{how} those outcomes are to be obtained. This is the key element to offering flexibility to the user of a standard.

All standards specify <u>what</u> is to be done by the standard's user. This is described in general terms under the "Purpose" and "Scope" sections in a standard. Sometimes, the standard may also indicate what it takes to obtain the ultimate outcome from the actions taken. A standard may address the "<u>how</u>" of achieving the "Purpose" and indicate the ultimate outcome such that ambiguity of interpretation is minimized. Ideally, the "Purpose" statement in a standard addresses the "why" aspect of the series of questions that generally apply to any standard, namely "Why," "What," and "How" the objectives of the standard are to be accomplished.

Depending upon the specific outcome to be achieved, different levels of prescription on how to achieve that outcome may be appropriate. For example, in calculating reactor decay heat, it is necessary to use scientific principles, representative data, and applicable equations. Therefore, defining the exact steps to perform a calculation may be the best means for achieving the outcome of specifying an appropriate heat load for the design basis.

Alternatively, a standard's outcome may be of a type where it is more appropriate to provide flexibility (i.e., less prescriptiveness) in how to achieve the outcome. For example, a standard might have "not exceeding a radiological exposure limit" as an outcome. The user of the standard can be provided flexibility on how to achieve this outcome., The standard may constrain this flexibility by the specification of certain high-level expectations, such as minimum margin and/or reliability.

Note that a standard needs to provide some level of direction/prescription on what needs to be done to achieve the outcome. This is frequently called "Level of Detail." If it did not provide this detail, then the standard would have no "shall" statements and would not be a standard. This is frequently provided as a process that is acceptable to achieve the desired outcome. A process generally defines a series of action steps where each action involves input of information, performance of an activity, output products and a decision on acceptability. Information from the process is fed into the next action step or fed back to a previous action step. However, a performance-based standard would keep the direction provided at a high level and would allow flexibility in the specific steps that could be taken to achieve the outcome. The degree of flexibility can be a function of what is needed to ensure success (i.e., achieve the desired outcome and any associated performance-based metrics). The degrees of "how" would be up to the standard writer to determine, along with any constraints that would need to be placed on the standard's user when determining performance-based metrics. This thought process is part of what is explained for determining performance-based outcomes in "Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors," [9] which was a document developed by the Licensing Modernization Project.

This process is outlined in a step-by-step manner in the following subsections. Examples of clear and effective RIPB outcome statements in ANS standards are provided in Appendix D.

5.3.1 Define the Approach (Major Steps) to Obtaining the Outcome

The goal of a standard is to define an acceptable approach in the development of products or analysis such that there is a high level of confidence that the desired outcome identified in the standard will be achieved. In general, standards offer and provide requirements to use a structured approach for achieving an outcome. This can be done at a high level or in a more detailed prescriptive manner depending upon the nature of the standard, the preference of the standard writers, and the needs of the standard users. In general, requiring a higher level-of-detail leads to less flexibility for the standard's user, which is frequently the reason level-of-detail becomes a significant consideration.



5.3.2 Determine Whether There Are Alternative Approaches for Achieving the Outcome

For some situations, standard writers might agree that there is only one approach that will result in achieving the outcome (e.g., calculation of decay heat load). In that case, the standard is generally not considered suitable to being written in a performance-based manner.

In other situations, there may be various means to establish the outcome (e.g., achieving an appropriate fire protection program or radiation protection program). In these situations, the level of specificity in the definition of the process for achieving the outcome, or sub-outcomes, should be determined. A key consideration is that auditable assurance be provided based on validated principles.

Table 1 provides the key elements of the RIPB approaches that can support the development of new standards or revision of existing standards. Examples are provided in Appendix C on how these approaches have been used, and where their use could be enhanced in three current ANS standards.

For more detailed background and process steps in determining performance-based outcomes, refer to "Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors." [9]

Table 1 – Key RIPB Objectives

Risk-Informed Objectives

- R1. Use risk insights to define the scope of the standard.
- R2. Use risk insights (quantitative or qualitative) to define the level of prescription or rigor needed to achieve the outcome.
- R3. Define the desired outcome in terms of quantitative or qualitative risk metrics.

Performance-Based Objectives

- P1. Define the outcome in terms of performance parameters that are observable and measurable.
- P2. Provide the appropriate level of prescription and flexibility (due to consideration of physical and temporal margins) to achieve the outcome (what to do; not detailed how to do it).

6. Attributes of a RIPB Standard

6.1 **Risk-Informed Attributes**

The following are attributes of a standard that meet objective R3 (Define the desired outcome in terms of quantitative or qualitative risk metrics):

1. The standard needs to identify the <u>risk end point</u> at hand – this is the undesired outcome that will occur if the standard's requirements are not met. Perhaps the "risk end point" is a reactor core damage accident, or perhaps it is that an operating equipment item will be unavailable when it should be capable of running, which could lead to or contribute to an accident. Or perhaps a calibration procedure will be done incorrectly, which again could lead to or contribute to an accident.

- 2. Then, the standard needs to <u>identify the metric used for measuring or analyzing</u> that risk end point. Three examples would include core damage frequency, or the number of hours per year that an operating equipment item is unavailable, or the probability that a calibration procedure is performed incorrectly.
- 3. Then, the standard needs to identify a <u>threshold</u> or <u>criterion</u> separating an "acceptable" from an "unacceptable" outcome. An example of a threshold or criterion might be when the mean core damage frequency exceeds 1.0 x 10⁻⁴ per year, or when the operating equipment is unavailable more than 7 hours per year, or when the calibration is done incorrectly more than 1 time in 200. Below that threshold, the outcome is acceptable, and above it, the outcome is unacceptable.
- 4. Then, the standard needs to identify <u>how to measure</u> (or analyze) the relevant parameter to determine if the outcome is above or below the threshold considering the associated performance uncertainties.

6.2 **Performance-Based Attributes**

The following are attributes of a standard that meet objectives P1, and P2, i.e., have an outcome in terms of performance parameters that are observable and that can be made measurable; and provide the appropriate level of prescription and flexibility to achieve the outcome:

- 1. The standard needs to identify the <u>performance end point</u> at hand, which will achieve the performance objective. Perhaps the "performance end point" is that an operating pump should not stop when it should continue running to provide a cooling function, or that a vibration-monitoring procedure for a motor should support measurements adequate for preventing vibration-induced failure. Such a "performance end point" may be called a limit state indicating an acceptable limit. The end point represents one end of a range of acceptable values. This range is used to assess physical and temporal margins as provided in NUREG/BR-0303, "Guidance for Performance-Based Regulation" [10].
- 2. Then, the standard needs to <u>identify the metric used for measuring</u> the expected operational state and performance end point. The difference between the operational state and the limit state is the margin. Reference [10] should be used to appropriately assess the margin as well as distinguish between physical and temporal margins. As a temporal example, for an operating pump that provides flow during an accident, this could be that it should not fail to provide required flow capability until it operates for more than X hours in the defined environment. The number X hours is under the control of the designer to offer this minimum acceptable level of service capability. A physical example is a vibration monitoring procedure that directs corrective action to take place well short of pump failure based on the results of the vibration inspection. The degree of physical and temporal margins available can be used to determine the level of prescriptions that should be applied in the standard.
- 3. Then, the standard needs to determine a <u>threshold</u> or <u>criterion</u> separating an "acceptable" from an "unacceptable" outcome. An example of a threshold might be when the physical and/or temporal margins are so large in comparison with the demanded functional capability that there is high confidence for a monitoring program to detect and correct significant erosion of margins. The monitoring may be done more prescriptively or less prescriptively depending on the consequence associated with failure to detect erosion of margins.

4. Then, the standard needs to identify <u>how to measure</u> (or analyze) the performance to determine if it is above or below the threshold of acceptable margins. Reference [11] can be used to deal with performance uncertainty in a way that assesses the likelihood that the pump will operate for the needed duration but the estimate of the duration turns out to be wrong.

7 References

- [1] 10 Code of Federal Regulations 50.65 "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," U.S. Nuclear Regulatory Commission.
- [2] NFPA-805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Station."
- [3] ANS-2.26, "Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design."
- [4] Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."
- [5] NEI 18-04 (Rev. 1), "Risk-Informed Performance-Based Technology Guidance for Non-Light Water Reactors."
- [6] Regulatory Guide 1.175, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Testing," U.S. Nuclear Regulatory Commission.
- [7] Regulatory Guide 1.178, "An Approach for Plant-Specific Risk-Informed Decisionmaking Inservice Inspection of Piping," U.S. Nuclear Regulatory Commission.
- [8] 10 Code of Federal Regulations 50.69, "Risk-informed Categorization and Treatment of Structures, Systems and Components," U.S. Nuclear Regulatory Commission.
- [9] "Introduction to Implementation and Assessment of Safety for Risk-Informed and Performance-Based Technical Requirements in Non-Light Water Reactors."
- [10] NUREG/BR-0303, "Guidance for Performance-Based Regulation," U.S. Nuclear Regulatory Commission (2002).
- [11] NUREG/CR-6833, "Formal Methods of Decision Analysis Applied to Prioritization of Research and Other Topics," U.S. Nuclear Regulatory Commission (2003).

APPENDIX A

Roles and Responsibilities

The following describes the roles and responsibilities assigned by the ANS SB to support implementation of this Guidance Document.

A.1 ANS Standards Board

(a) Approve this Guidance Document and promote its use within all consensus committees.

A. 2 RP3C Chair

- (a) Assign responsibilities to maintain this Guidance Document (e.g., developing a schedule for its review and update).
- (b) Assign responsibilities for developing training on this Guidance Document.
- (c) Assign responsibilities of members for review of new and revised standards.
- (d) Assign RP3C members to provide guidance to WG chairs during all stages of standards development.

A.3 **RP3C Members**

- (a) Provide guidance to WG chairs during all stages of standards development.
- (b) Support reviews of new and revised standards as assigned by the RP3C Chair.
- (c) Develop training on this Guidance Document as assigned by the RP3C Chair.
- (d) Take training on this Guidance Document as specified by the RP3C Chair.

A.4 Consensus Committee Chairs

- (a) Support awareness of and implementation of this Guidance Document throughout the various stages of development of new and revised standards to WG Chairs.
- (b) Take training on this Guidance Document.
- (c) Provide experience-based feedback to improve this Guidance Document.

A.5 Subcommittee Chairs

- (a) Support awareness of and implementation of this Guidance Document throughout the various stages of development of new and revised standards to WG Chairs.
- (b) Take training on this Guidance Document.
- (c) Provide experience-based feedback to improve this Guidance Document.

A.6 Working Group Chairs

- (a) Take training on the Guidance Document.
- (b) Use this Guidance Document throughout the development of any new or revised standards for which they are leading.
- (c) Use consultation and guidance available from JCNRM for matters related to PRAs.
- (d) Provide experience-based feedback to improve this Guidance Document.

A.7 JCNRM/SCoRA

(a) Be available for consultation and advice when a WG is using PRA methods or other riskinformed approaches. JCNRM/SCoRA can support A.2 (d), A.3 (a), and A.3 (b).

APPENDIX B

Background on Risk-Informed and Performance-Based Approaches

B.1 General Background

The NRC has defined the RIPB approach as:

An approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for safety decision-making [B.1].¹

In SRM-SECY-98-0144 [B.1] the NRC (at the Commission level) provided characteristic attributes and expected outcomes of applying RIPB approaches in regulations. The importance of this document for ANS lies in the fact that it can be invoked to request endorsement of a standard by the NRC staff. The following is largely taken from the NRC document [B.1].

Outcome Attributes of Risk-Informed Safety

A "risk-informed" approach to safety decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety. A "risk-informed" approach enhances the traditional engineering approach (sometimes called a deterministic approach) by: (1) allowing explicit consideration of a broader set of potential challenges to safety, (2) providing a logical means for prioritizing these challenges based on risk significance, operating experience, and/or engineering judgment, (3) facilitating consideration of a broader set of resources to defend against these challenges, (4) explicitly identifying and quantifying sources of uncertainty in the analysis (although such analyses do not necessarily reflect all important sources of uncertainty), and (5) leading to better decision-making by providing a means to test the sensitivity of the results to key assumptions. Here, "prioritization" is key; while "risk-informed" means, in part, "not relying purely on the probabilistic risk assessment (PRA)," it also means being able to say that some scenarios or systems are more important than others and understanding how sure we are about the statements we are making. If PRA or PRA methods are used or contemplated, the JCNRM should be consulted.

Outcome Attributes of Performance-Based Safety

A performance-based safety approach is one that establishes performance and results as the primary basis for safety decision-making, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee performance, (2) objective criteria to assess performance are established based on risk insights, traditional

¹ Indented text in italics recognizes a direct quote from another document.

engineering analyses and/or performance history, (3) users of the standard have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern. A performance-based approach offers two categories of benefits: (1) the focus is on actual performance rather than satisfaction of prescriptive process requirements, and (2) the burden of demonstrating actual performance can be substantially less than the burden of demonstrating compliance with prescriptive process requirements.

Outcome Attributes of RIPB Safety

A RIPB approach to safety decision-making combines the "risk-informed" and "performance-based" elements. Stated succinctly, RIPB safety is an approach in which risk insights, engineering analysis and judgment including the principle of defense-in-depth and the incorporation of safety margins, and performance history are used to (1) focus attention on the most important activities to achieve the desired results, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for decision-making. By "results," we mean actual safety performance, not demonstrations of adherence to mandated processes or prescriptions.

An ANS standard that can validate and verify that the above Commission approved outcomes can be and have been accomplished should have substantially more confidence that it will be endorsed by the NRC.

B.2 Example of Regulatory Application: Maintenance Rule

The nuclear industry has had many successes in implementing RIPB approaches. One area that the nuclear industry has been particularly successful in has been in establishing maintenance programs to meet the NRC Maintenance Rule (10 *CFR* 50.65) [B.2], which is a RIPB rule.

The following provides examples of RIPB <u>attributes</u> in the NRC's Maintenance Rule. Although there are significant differences between what is put in a regulation versus a standard, the identification and discussion of some of the key attributes in the Maintenance Rule can be beneficial in understanding what is meant to use RIPB attributes/approaches.

B.2.1 Outcome

The rule states in (a)(1):

[licensees] shall monitor the performance or condition of structures, systems, or components, against licensee-established goals, in a manner sufficient to provide reasonable assurance that these structures, systems, and components, as defined in paragraph (b) of this section, are capable of fulfilling their intended functions.

This is, in essence, the required "outcome" which places responsibility on licensees to clearly define intended functions. It is clear (Attribute P1 from Table 1 of this Guidance Document) and supports performance-based implementation because it establishes a high-level goal. The goal is reasonable assurance of capability such that functional failure is unlikely relative to the design objectives. It is also risk informed because it includes a qualitative risk metric as part of the outcome (Attribute R2). Note that there are other ways for a rule (or standard) to be risk informed, so one should not think that a numerical risk metric must be included in the outcome(s) as the only way for a standard to be risk informed.

B.2.2 Method for Achieving Outcome

Several parts of the rule provide instructions for achieving the outcome. Examples include:

Example 1: *These goals shall be established commensurate with safety and, where practical, take into account industry-wide operating experience.*

This is a high-level instruction for how to meet part of the Maintenance Rule's outcome and flexibility is provided on how best to perform this (Attribute P2).

Example 2: Performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle provided the interval between evaluations does not exceed 24 months.

This is another example of a high-level instruction for how to meet part of the Maintenance Rule's outcome (Attribute P2), but it does also include some prescriptive elements.

Example 3: [t]he licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.

This is an example of a high-level instruction for meeting an element of the Maintenance Rule as well as a requirement of develop risk insights and to use risk insights in meeting the Maintenance Rule outcome (Attributes P2, R1, and R2). It implies a PRA by indicating the acceptable process to conduct an evaluation.

B.3 References

- [B.1] Staff Requirements Memorandum SECY-98-0144, "White Paper on Risk-Informed and Performance-Based Regulation," March 1, 1999, U.S. Nuclear Regulatory Commission.
- [B.2] 10 Code of Federal Regulations 50.65 "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," U.S. Nuclear Regulatory Commission.

APPENDIX C

Simplistic Example of Application of RIPB Approach

As a simple and stylized example, the following paragraphs elucidate how prescription in a standard may detract from the fitness for purpose of a standard. Modernization of ANS standards includes the goal to make standards more fit-for-purpose (accomplish the "why") and be more useful to industry by reducing unnecessary requirements.

Suppose ANS had a standard whose objective was cutting a long piece of aluminum bar, and then measuring its length using a household tape measure. Further suppose that this is accomplished by a sequence of prescriptive "shall" requirements, with "how to do it" specification for each cutting and each measuring step. Assume for the moment that the authors of the standard had in mind that, if the requirements are followed, the length of each piece would be measured to be, at a target length, within a tolerance of $\pm 1/16^{\text{th}}$ of an inch. (If accuracy to within one-thousandth of an inch was what the standard's authors had in mind, then they would not be specifying the use of a tape measure!) While such a standard might be important, nothing in such a standard would seem to involve risk concepts, and there would also be nothing in the standard that would be "performance-based." Hence, such a standard is labelled "prescriptive."

The pros and cons of a "prescriptive" approach are evident in the above example. The principal "pro" is that the standard is simple and easily implemented. From a risk-informed perspective, the assumptions involved offer no basis for assessing the accuracy and precision (i.e., uncertainty) of the resulting product. Employing the product in an application represents the outcome of the standard. Hence, the "con" of the standard is that the outcome is unknowable by the user of the standard without more information. The desired performance-based outcome attribute of incentivizing improved outcomes cannot be realized.

Alternatively, suppose that the objectives of the standard were explicitly to assure (i) that the cutting and measurement of each piece of aluminum was at least as precise as $\pm 1/16^{\text{th}}$ inch compared to the target, and (ii) that no more than one in each 100 of the aluminum pieces is to be out-of-tolerance due to cutting and/or measurement process factors.

This second objective, if cited in the standard, would be a "performance requirement" for the cutting process and the measurement system and hence for the standard. Suppose that the authors of the standard, using knowledge obtained in their profession, might assess that, based on experience, meeting the standard's prescriptive "shall" requirements would surely deliver an out-of-tolerance error rate at least that low, and that this is noted in the standard. This prescriptive standard would in this case have an explicit "performance target" in mind. However, the standard is still not performance-based because success is subject to the assumption of validity of expert knowledge and individual capability of the operator. To be performancebased in a formal way, there needs to be flexibility available to the operator (no matter how much an expert) in the cutting and measurement processes.

Its prescriptive "shall" requirements are not "performance-based" in the sense that there is lack of context for the prescription. Being "performance-based" requires assurance that the product accomplish outcome expectations. Moving from product to outcome, the application of the product may show that there are excessive failures of the outcome because the margin associated with the product resulting from use of the standard is just too large. Experts cannot be assumed to be infallible in the nuclear safety setting. Safety requires a monitoring system that documents the range of variability of the cutting and measurement processes. Such monitoring would show what margin is available for acceptable product. The margin associated with the outcome may be outside the scope of the particular standard, but there must be



awareness of the "bigger picture" for the standard to be useful in a "performance-based" manner. To be performance-based, the standard would have to consider the needs of the outcome and adjust the cutting and measurement accordingly.

And even if the text noted that the outcome would be a length accurate to within 1/16th of an inch all but one time in 10,000, that would be a very high "performance expectation" of the standard (which would make it highly useful for certain applications), but there would still be nothing necessarily in the "shall" requirements that could be characterized as "performance-based" because it is not clear how prescription of such extraordinary precision accomplishes success at the outcome level.

What would make this standard performance-based would be "shall" requirements that were not prescriptive in describing "how" to do each cutting step and each measurement step, but rather only set forth required "what to do" at a high level rather than "how to do it" at a prescriptive level. The how-to-do aspect would be left to the user to determine in context and document how the outcome expectation will be met by the user of the standard.

The point of the above is to explain that what makes the requirements in a standard "performance-based" are two attributes: first, the performance of the outcome is specified, and second, the steps needed to achieve that performance are not explicitly set down in prescriptive detail, but rather are at only a high level. It is this second attribute that is the determinant of whether a standard is "performance based" because it recognizes that prescribing details that do not contribute to the outcome increase costs unnecessarily.

The exact same logic, although with the wording changed from "performance-based" to "risk-informed," would apply to distinguish whether a standard's requirements are "risk-informed." However, in the case of a risk-informed outcome, the standard requirements would support ensuring the resulting risk was acceptable, including either the consequences were acceptable, the frequency was acceptable, or the combination of the frequency and consequence was acceptable.

It would be valuable for a "risk-informed and performance-based" standard to include information regarding how meeting the standard reduces the level of risk. The margins associated with the acceptable levels of frequency and consequence, given consideration to uncertainty, should also be identified. If there is no basis for expecting a reduction in risk, the requirement could be considered unnecessary.

APPENDIX D

Examples of Risk-Informed Performance-Based Attributes in ANS Standards

The following provides examples of RIPB <u>attributes</u> in ANS standards. The examples are organized to cross reference the attributes to those listed in Table 1 of the main body of this Guidance Document.

Different types of standards (i.e., standards that define a design basis event; standards that define a safety program, etc.) are used as examples because each of the types can been seen to be more (or less) easily amenable to make use of RIPB approaches. The examples offered are for illustration with reference to the version noted.

D.1 <u>Example 1:</u> ANSI/ANS-2.26-2004 (R2017), "Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design"

ANSI/ANS-2.26-2004 (R2017) is a "design basis event" type of standard.

D.1.1 Performance-Based (PB) Attributes

D.1.1.1 Attribute PB-1: Outcome

ANSI/ANS-2.26-2004 (R2017) states in the Scope section that:

This standard provides (a) criteria for selecting the seismic design category (SDC) for nuclear facility structures, systems, and components (SSCs) to achieve earthquake safety and (b) criteria and guidelines for selecting Limit States for these SSCs to govern their seismic design. The Limit States are selected to ensure the desired safety performance in an earthquake.²

In simple terms, the outcome could be stated to be:

"The outcome of the use of this standard is the identification of the Seismic Design Category (SDC) and Limit States for Structures, Systems, and Components (SSCs) to achieve earthquake safety." It is implied that Limit States provide the bases for acceptance criteria for ensuring desired safety performance.

D.1.1.2 Attribute PB-2: High-Level Criteria

Three examples of appropriate criteria that have this attribute are provided below:

One of the SDCs listed in Table 1 (page 3) shall be assigned to the SSCs based on the unmitigated consequences that may result from the failure of the SSC by itself or in combination with other SSCs.

Following determination of the regulatory requirements applicable to the project or to the facility, a safety analysis or integrated safety analysis shall be performed. The guidelines

² Indented text in italics recognizes a direct quote from another document.

provided in this standard and other applicable standards such as Refs. [4] and [5] should be used.

To achieve the objectives of this standard, the safety analyses shall evaluate the uncertainties with determining failure and the consequences of failure. The depth and documentation of the uncertainty analyses should be sufficient to support the judgment that categorization based on Table 1 (on page 3) and the design requirements in ASCE/SEI 43-05 produce a facility that is safe from earthquakes. [Note that this is also an example of a risk-informed approach.]

Note that although ANSI/ANS-2.26-2004 (R2017) includes many criteria that provide what needs to be done, it does include some prescriptive criteria and thus it invokes other consensus standards that provide very prescriptive criteria for the design of safety SSCs. For example:

SDC-1 and SDC-2 in conjunction with the International Building Code and SDC-3, SDC-4, and SDC-5 in conjunction with ANS-2.27, ANS-2.29, and ASCE/SEI 43-05 establish the design response spectra (DRS) and SSC design and analysis Requirements.

ANSI/ANS-2.26-2004 (R2017) also includes some guidance that supports use of a PB approach to achieving the standards outcome.

The scope and comprehensiveness of the safety analysis will vary with the complexity of the facility, its operations, and the contained hazard. The assignment of an SDC to an SSC determined to have a safety function is based on the objective of achieving acceptable risk to the public, the environment, and workers resulting from the consequences of failure of the SSC.

D.1.2 Risk-Informed Attributes

D.1.2.1 Attribute RI-1: Development of Risk Importance

An example of a criterion that has this risk-informed attribute is:

One of the SDCs listed in Table 1 (page 3) shall be assigned to the SSCs based on the unmitigated consequences that may result from the failure of the SSC by itself or in combination with other SSCs.

This criterion specifies that a higher SDC will be assigned to SSCs whose failure would have greater consequences. There is indirect reference to consideration of the single failure criterion through assessment of failure of an SSC by itself or in combination with other SSCs.

D.1.2.2 Attribute RI-2: Use of Risk Insights

An example of a criterion that has this attribute is:

The scope and comprehensiveness of the safety analysis will vary with the complexity of the facility, its operations, and the contained hazard. The assignment of an SDC to an SSC determined to have a safety function is based on the objective of achieving acceptable risk to the public, the environment, and workers resulting from the consequences of failure of the SSC.

D.2 <u>Example 2:</u> ANSI/ANS-2.3-2011 (R2021), "Estimating Tornado, Hurricane, and Extreme Straight Line Wind Characteristics at Nuclear Facility Sites"

ANSI/ANS-2.3-2011 (R2021) is also a "design basis event" related standard that could be applied for identifying a specific design basis extreme wind event.

D.2.1 Performance Based Attributes

D.2.1.1 Attribute PB-1: Outcome

ANSI/ANS-2.3-2011 (R2021) [C.8] states in the Scope section that:

This standard establishes criteria for acceptable guidelines to estimate the frequency of occurrence and the magnitude of parameters associated with rare meteorological events such as tornadoes, hurricanes, and extreme straight line winds at nuclear facility sites within the continental United States.

The outcome from the use of ANSI/ANS-2.3-2011 (R2021) [C.8] could be stated to be:

An estimate of "the frequency of occurrence and the magnitude of parameters associated with rare meteorological events ..."

This is a good, clear PB outcome statement related to expectations associated with inputs to safety analysis.

D.2.1.2 Attribute PB-2: High-Level Criteria

An example of a criterion that has this attribute is:

Tornado hazard probability models shall account for the following:

- (1) constant or gradations of velocity along and across the tornado path;
- (2) meteorological conditions affecting the site;
- (3) topographical features surrounding the site; and
- (4) biases in reporting occurrence and velocity of tornadoes on target structures.

This is performance-based because it provides broadly based statements on what needs to be considered but does not provide details on how to account for these items.

Another example of a criterion that has this attribute is:

Two basic approaches in the characterization of wind-generated missiles are recognized as acceptable in this standard:

- (1) a standard spectrum of missiles; and
- (2) a probabilistic assessment of the hazard.

This is somewhat performance-based (i.e., high level) because it provides options for achieving acceptable outcomes.



D.2.2 Risk-Informed Attributes

None identified.

However, the following is an example of a **non**-RIPB feature:

The height of the radial inflow layer shall be at least 0.35 R. Above this height, the radial wind is assumed to be zero or to flow outward.

Note: This does not mean the standard or the criterion is not appropriate in that this provision may represent an optimization to obtain an outcome efficiently based on the science, industry history, and/or risk mitigations. There are times when it is very appropriate to be prescriptive using expert judgment and so, in this way, compliant with RIPB methods. It is recommended that the underlying assumptions inherent to such an approach be documented so that if the standard is applied when such assumptions have changed, this can be identified by the user and addressed in a way that conforms with intent.

D.3 <u>Example 3:</u> ANSI/ANS-2.21-2012 (R2016), "Criteria for Assessing Atmospheric Effects on the Ultimate Heat Sink"

<u>Note:</u> For the following example a draft was used to suggest how issues regarding application of this Guidance Document may arise while the draft is being worked on actively. This example only serves to illustrate specific points which may not apply as the draft is finalized.

ANSI/ANS-2.21-2012 (R2016) is a "design analysis" type standard. Its importance lies in the key role of establishing acceptable atmospheric conditions for the fundamental safety function of adequate heat removal. Restrictions on allowable atmospheric conditions could have economic impacts.

D.3.1 Performance Based Attributes

D.3.1.1 Attribute PB-1: Outcome

ANSI/ANS-2.21-2012 (R2016) [C.9] states in the Scope section that:

This standard establishes criteria for acceptable guidelines to estimate the frequency of occurrence and the magnitude of parameters associated with rare meteorological events such as tornadoes, hurricanes, and extreme straight line winds at nuclear facility sites within the continental United States.

Required analyses are provided for a meteorological assessment of the ultimate heat sink to ensure that design temperatures and cooling capacity requirements for the facility are met.

The outcome could be stated to be:

"A determination is made of whether design temperature and cooling capacity requirements for the ultimate heat sink of a facility are met."

The performance-based outcome accommodates uncertainty in the acceptability criteria. Risk-informed aspects of the approach are captured by the frequency evaluation.



Note that the introductory statement could be better written (to be consistent with other ANS introduction statements) as:

This standard establishes criteria for performing an analysis to determine whether design temperature and cooling capacity requirements for the ultimate heat sink for a facility are met.

Another example of a criterion that has this attribute is:

Ultimate heat sinks shall be designed to have the cooling capacity to provide sufficient cooling water at the maximum allowable inlet temperature under the most adverse meteorological conditions expected for the power plant climatic regime.

This is a good performance-based statement for the limiting challenge of a "design basis event."

Note that one element of performance-based approaches in industry is the verification that the outcome is met using measurements. The design goal under the most extreme conditions likely could not be verified by measurement, but measurement of parameters at actual conditions could be compared with calculational results to provide confidence that the goal is met. It would be good to consider whether adding this type of criterion would benefit standards.

D.3.2 Risk-Informed Attributes

D.3.2.1 Attribute RI-1: Development of Risk Importance

An example of a criterion that has this attribute is:

The results of the 10-year–or–longer simulation with several extreme events shall be used to perform extreme value statistical analyses that project the most extreme weather conditions for the expected license period of the power plant, which could be 60 years or more.

The U.S. Nuclear Regulatory Commission provides guidance in regard to the critical time period. In the case of a cooling lake, the lake temperature may reach a maximum in five days following a shutdown. Therefore, three critical time periods to be included in the assessment are five days, one day, and 30 days to ensure the availability of a 30-day cooling supply. The three periods need not occur contiguously but may be combined to produce a synthetic 36-day period that may be used as the design basis for the lake. In the case of a wet cooling tower, the meteorological conditions resulting in maximum evaporation and drift losses shall be the worst 30-day combination of the controlling parameters such as wet-bulb temperature and wind speed.

This does incorporate some risk-informed elements as it incorporates some factors that contribute to risk-informed decision making.

APPENDIX E

Frequently Asked Questions Regarding Risk-Informed, Performance-Based, and this Guidance Document

1. How is the Guidance Document to be used by standards writers and reviewers with no familiarity about risk-informed, performance-based (RIPB) concepts?

The Guidance Document provides information that will help standards writers and reviewers understand RIPB concepts and provides references that can be used to get additional information. Most importantly the Guidance Document identifies ANS resources (e.g., Risk-Informed, Performance-Based Principles and Policy Committee, and the Joint Committee on Nuclear Risk Management) that can help them get support to overcome difficulties. Additionally, training is available to standards writers and reviewers to better understand RIPB principles and how to apply them.

2. Is the Guidance Document relevant to a specific technology or design being developed by a potential vendor?

The Guidance Document is relevant to every design and the standards that support the development of nuclear facility technologies including nonreactor and decommissioning facilities. However, as discussed in this Guidance Document, some standards will use RIPB to different degrees and in different manners or maybe not at all depending on the identified outcomes desired for the documents being produced.

3. How does the Guidance Document apply to ANS standards currently in use for operating light water reactors?

The committees and WGs responsible on a continuing basis for maintenance of these standards can use the Guidance Document to evaluate how a current standard might be revised to become more effective if RIPB approaches are adopted.

4. How to make use of the Guidance Document to decide on "level of detail" (LoD) issues?

The LoD in a standard can be important for standards providing "what" is needed to meet the outcome of the standard rather than "how" to meet the outcome. References provided in the Guidance Document address defining performance objectives in a structured approach through which a user of the standard can see how much detail is really needed to ensure clarity. More detail than is needed can lead to confusion and unintended consequences. This also relates to the level of prescription that is considered necessary to have confidence in achieving the outcome and the degree of flexibility which is considered appropriate. The Guidance Document discusses this and also includes examples where the LoD is discussed for specific standards.

5. How is the Guidance Document to be used to incorporate RIPB concepts and methods in standards developed by other Standards Developing Organizations (SDOs) or by standards developed by the International Organization of Standardization (ISO)?

The Guidance Document is available as a reference for other SDOs or ISO committees. The concepts in the Guidance Document are also applicable to how standards from these organizations can be made more RIPB.

6. I'm having some trouble understanding the difference between "risk-informed," "risk-based," and "risk-insights." Can you explain the differences?

Try it like this: "risk-informed" process involves the use of risk assessments, such as PRA results, in conjunction with current traditional engineering requirements such that current outcome objectives are met and changes to the outcomes result in an acceptable risk condition. An example would be modification to a test frequency, while maintaining the requirement to perform the test. "Risk-based" is not generally used in application space but would only involve using the quantitative risk results in support of a change, including removal of a requirement all together. A qualitative risk insight would involve relative risk contributions, such as the relative risk contribution between operator actions and component failures.

7. What is the difference between "outcomes" and "outputs"?

The difference between "outcomes" and "outputs" is fundamental and profound.

- Outputs are what is produced, be it physical or virtual, for a specific type of customer or end user.
- Outcomes are the difference the product makes.
- Outcomes are the benefits to the customers (internal to processes or external to projects).
- Outputs are important products, services, profits, and revenues.
- Outcomes create meanings, relationships, and differences.

8. Can you provide some examples of what you call "outcomes"?

Outcome – Calculation of reactor decay heat over time is the result of using an ANS Standard. Heat removal capability that reliably maintains acceptable temperature profiles in the reactor and associated systems is the outcome that would be achieved.

In calculating reactor decay heat, it is necessary to use scientific first principles, representative data, and applicable equations; therefore, defining the exact steps to perform should be the best means for achieving this outcome.

9. What do you mean by RIPB "attributes"?

Webster's Dictionary definition: a quality or feature regarded as a characteristic or inherent part of someone or something. As applied to the results of applying the RIPB approach, "attributes" offer specific criteria by which characteristics of outcomes can be critically examined.

As applied to the Guidance Document: flexibility, observations indicative of margins, and required actions to achieve outcomes compliant with identified risks. Additionally, the "attributes" can help identify and implement monitoring of the right parameters. For example, cost and operational complexity can become obscured unless outcomes are examined critically to identify and correct requirements.

10. PRAs frequently suggest <u>risk end points</u>. How are they to be treated?

The following addresses this issue as gaps in the guidance as offered by JCNRM (in italics) and responses that illustrate material offered in the RP3C RIPB Guidance Document.

The author of the standard needs to identify the <u>risk end point</u> at issue. Perhaps the "risk end point" is a reactor core damage accident, or perhaps it is that an equipment item will be unavailable when needed, or that a calibration procedure will be done incorrectly.

An ANS standard that typically addresses scenarios such as reactor core damage accident, equipment unavailability, or improper calibration would have statements within its "Purpose" and "Scope" sections addressing what the user of the standard would be required to do so as to <u>avoid</u> such scenarios. In other words, ANS standards are typically written in success space. The RP3C RIPB Guidance Document (GD) would direct the WG working on such a standard toward achieving success relative to performance objectives such as "assurance of adequate core cooling," "assurance of availability of safety critical equipment," or "assurance of proper calibration of safety-related I&C." Hence, what has been called the "risk end point" represents failure of achieving a performance objective. References in the GD such as NUREG/BR-0303 would direct the standards writer to contextualizing each performance objective within an objectives' hierarchy that defines an overall outcome. Within an objectives' hierarchy, failure of any single performance objective does not necessarily imply failure of achieving the overall outcome. The standards writer would be enabled by the GD to prioritize performance objectives in making integrated safety decisions.

Then, the author of the standard needs to identify the metric used for measuring that risk end point. It could be core damage frequency, or it could be the number of hours per year that an equipment item is unavailable, or it could be the probability that a calibration procedure is performed incorrectly.

The metric used in an ANS standard relative to a risk end point can be quite varied depending on the particular context within the standard. The metric need not necessarily be probabilistic. If the risk end point is expressed as a performance objective, the guidance within the GD would direct the standard writer to identify observable parameters that can be monitored for the purposes of validation and verification of conformance with the standard.

Then, the author of the standard needs to determine a <u>threshold</u> or criterion separating an "acceptable" from an "unacceptable" outcome. An example of a threshold might be when the calibration is done incorrectly only one time in 300. Below that threshold, things are acceptable, and above it, things are unacceptable.

The guidance provided in the GD treats the threshold in a manner different from that suggested in the input from JCNRM. The guidance is consistent with NRC's RIPB White Paper definition of a performance-based approach as described in Appendix B of the GD. The threshold is set in such a way that violating it would not create a safety concern. This provision leads to the evaluation of margins as described in NUREG/BR-0303.

Using the example in the JCNRM input, the ANS standard may call for implementing a calibration procedure in a way that the user of the standard may find confusing. The GD would direct the WG to look for outcomes of success and failure regarding intermediate steps such as calibration of instruments so that the context of each "shall" statement in the standard is clearly understood as part of validating the outcome. However, if the GD is applied properly, the WG would go further



and do a functional analysis to understand why the calibration is important and what margins are available so as to establish more clearly the demarcation between success and failure. All of this is captured in Table 1 of the GD when it calls for clearly defining the outcome.

Finally, the author of the standard needs to identify <u>how to measure</u> (or analyze) the performance or risk to determine if it is above or below the threshold.

The author of an ANS standard using the GD would focus more attention on the margins available to avoid safety concerns than on the risk associated with crossing a threshold. Other guidance referenced in the GD addresses scenarios where the margins may not have been correctly estimated.

11. Where do I find out what the responsibilities of a member of a standards' WG are?

Please begin by reviewing the "ANS Standards Committee Procedures Manual for Consensus Committees," Sections 6 and 7.

An ANS WG is the writing committee for ANS consensus standards. These groups of about a dozen people each are responsible for creating the text of ANS standards that have been approved by the ANS SB through the Project Initiation Notification System and assigned to them. They make decisions about existing standards' maintenance and respond to requests for clarification or interpretation of existing standards.

WGs routinely use an online platform to communicate and conduct routine business and standards development. This platform provides a place to share current drafts with committee members and to collaborate. WGs meet as often as needed, with some choosing to meet at bi-annual ANS meetings held in June and November of each year. Further information may be obtained on the ANS website www.ans.org under the heading "Standards."