Appendix A:
Guidance for the Formulation of Performance-Based Requirements

A. Guidance for the Formulation of Performance-Based Requirements

The following guidance provides a step-by-step approach to formulate a regulatory requirement that is focused on accomplishing a defined objective which corresponds to the result expected from performance-based regulation (see Chapter 3). An example of a typical performance objective is maintaining cladding integrity. In the conventional regulatory approach this objective is considered to be accomplished through a prescriptive approach of limiting cladding temperature and oxidation conditions to 2200 F and 17% respectively. In a performance-based approach, a different set of criteria, perhaps using a combination of qualitative and quantitative may be found to better fulfill the high-level guidelines.

Step 1 – Identifying the Performance Objective and its Context

Purpose – To define a performance objective for the SSC in such a way that one or more performance measures and criteria can be proposed for consideration.

Step 1a: What is the topic area with which the performance objective is associated?

This question is likely addressed during the review under Chapter 4, where the risk objectives are classified as falling under design, construction and operation. Additionally, from a regulatory standpoint, the objectives may fall under the categories public risk, worker risk and environmental risk. There could be significant differences in the information gathering and stakeholder identification depending on what is being addressed. A well defined performance objective is a pre-requisite for an effective performance measure. If a single performance objective will not be effective for establishing the requirements for the SSC, an Objectives Hierarchy (see NUREG/BR-0303) may need to be prepared.

Step 1b: Which of the NRC's performance goals does the performance objective address?

Clarifying the performance goal also improves the clarity with which NRC decision preferences may be incorporated in the consideration of performance measures or criteria. From the NRC's Strategic Plan (NUREG-1614, Vol. 3, August 2004) the two performance goals likely to be involved are "*Ensure protection of public health and safety and the environment*" and "*Ensure that NRC actions are effective, efficient, realistic, and timely*".

Step 1c: What are the expected outcomes and results from successful performance relative to the objective?

In general, the expected outcome is that the SSC performs its intended safety function adequately, and that the performance can be appropriately verified through regulatory oversight. In addition, this question addresses which part of the regulatory framework is appropriate for implementing the objective. In general, a regulation in the Code of Federal Regulations is likely to address higher level goals or objectives. Guidance documents are more likely to be directed at detailed or component level objectives.

Step 2 – Identifying the Safety Functions

Purpose – To identify the safety functions and systems that affect the performance objective (directly or indirectly).

Step 2a: What are the safety functions or concepts that can impact the performance objective?

The objective of this inquiry is to identify the most important functions. The PRA should be of help in this effort. However, some aspects of system performance may not be modeled in the PRA. Such aspects are generally those that cannot be easily quantified and must be considered qualitatively. It is key that the identification of important functions focus on successful outcomes rather than make assumptions because of inadequacies of the PRA model. In addition, consideration should be given to other aspects of the context which may include expected outcomes being fulfilled by other SSCs.

Step 2b: What equipment/systems/procedures are necessary to satisfy the safety function?

This addresses the technical evaluation that establishes the range of particular SSCs or support systems to be considered; for example, instrumentation, siting, safety conscious work environment, etc. Again, the evaluation can take advantage of the PRA where the modeling is adequate. Often, qualitative factors coupled with expert judgement can be as or more reliable than quantitative models that are not supported by sufficient data. This is especially the case when data from operating experience exists, even if the data is from a related but different industry.

Step 2c: What level of safety (based on appropriate metrics) is required to meet the performance objective?

This addresses the required level of safety that should have been addressed in the Chapter 4 evaluation. For example, the required level of safety for an accident within containment might be one that meets the objective of reducing, to an acceptable level, the risk of early containment failure. Hence, the metric in this case is the conditional containment failure probability. Another example might be that the required level of safety is to maintain at an acceptable level the core damage risk associated with certain configurations typical of specific modes of operations. Again, qualitative evaluations supported by expert judgement or operational data may be required.

Step 3 – Identifying Safety Margins

Purpose – To evaluate margins and identify performance measures (if any) that satisfy the performance objectives.

Step 3a: How much safety margin is available, and how robust is it, for performance monitoring to provide a basis for granting licensee flexibility?

The generic definition of a “margin” is that it is an expression of a difference between two system states. When the two states are associated with different levels of safety as reflected in the above evaluations related to outcomes, the “margin” becomes a safety margin. For regulatory purposes, the margin that is sought to be maintained is expressed by the first of these being the expected state and the other is one where a regulatory concern exists. The state of regulatory concern can be drawn from the frequency-consequence curve dealt with in Chapter 4.

“Robustness” of a safety margin means that the margin between two performance levels is significantly greater than uncertainty and normal variability in performance. If this condition is met, a very low probability exists of the performance parameter crossing a set limit, unless performance changes in a very significant way. In any case, wherever there is substantial uncertainty, achieving robustness requires that nominal performance levels be set more conservatively than when there is less uncertainty. Depending on the situation, uncertainty can be assessed using explicit models (e.g., PRAs), expert judgment, or actuarial methods based on operating experience.

The identification of performance measures (natural, constructed or combination) begins as a search process within the overall context of the performance objective. It is likely to involve iteration through the steps in this guidance as well as consideration of the factors that were involved in the application of the viability guidelines. The flexibility aspects should include operational flexibility as well as the means to fulfill regulatory responsibilities.

Step3b: What observable characteristics, quantitative and qualitative, exist within the safety functions identified in Step 2?

For example, observable characteristics may come from the results of periodic servicing, testing, and calibration of certain instruments. The operating margin would be based on a comparison between these results and the target values established under a maintenance program. Another example would be observations based on verification (through testing) of design margins of structures.

Step 3c: Can the contemplated constructed measures provide qualitative expressions capable of observation with reasonable objectivity?

As explained in NUREG/BR-0303, natural measures are preferred, but appropriate constructed measures may also prove adequate with proper consideration given to verification and validation. In some cases, a binary constructed measure might well suffice where the measure reflects a positive or negative response to a question such as , “Does a particular attribute exist?”

Step 4 – Selecting Performance Measures and Criteria

Purpose – To select a complement of performance measures and objective criteria (if possible) that both satisfy the viability guidelines and accomplish the performance objective.

Step 4a: Can the identified observable characteristics, together with objective criteria, provide measures of safety performance and the opportunity to take corrective action if performance is lacking?

This step is a part of the search process. Many technically significant performance objectives will require engineering judgement for exploring qualitative and/or quantitative measures while keeping in mind operational (or other) constraints. Measures of safety performance considered as candidates should be associated with the desired outcomes as directly as possible. Sometimes, it may prove quite effective to use proxy measures. For example, if the accomplishment of a performance objective calls for an analysis, the cost of the analysis may be one of the measures considered as a proxy for efficiency of obtaining the outcome.

Another of the highly desirable features of a good performance measure is that it should be identified at as high a level as practicable. If this feature is not sought, all systems and sub-systems involved in, say, risk-significant configurations might have been targeted for monitoring. The management of risk when various configurations are being considered may include monitoring strategies that target all systems and sub-systems, or a higher-level measure that may prove to be simpler, but as effective. The process of searching for parameters at a high level directs the analyst's attention to more cost-effective possibilities.

Step 4b: Can objective criteria be developed that are indicative of performance and that permit corrective action?

The search for threshold criteria that rely as little as possible on subjectivity is the next step in the search process. Parametric sensitivity analyses may help establish that the selected threshold is not in a region of highly unstable or non-linear behavior (so-called "cliff effects"). Some performance objectives are likely to be more difficult in the establishment of objective criteria that are indicative of performance than others. Also, selecting performance measures that permit sufficient time for corrective action may require probabilistic considerations (as considered in Chapter 4) and expert elicitation.

Step 4c: Is flexibility (for NRC and licensees) available consistent with level of margin?

The approach of setting criteria at as high a level as practicable can allow more flexibility. The benefits of flexibility must be balanced against assurance of opportunity to take appropriate corrective action and practicality of regulatory oversight. The basic principle involved is that more flexibility can be justified by higher levels and robustness of safety margin. Again, an iterative approach may be most suitable for optimum results. This is because questions of margin, corrective action, and flexibility strongly interact with one another. Strong linkages can exist between observable characteristics chosen as the performance measures to be used in a performance-based approach and the assessment of margin based on criteria applied to these parameters. For example, in the area of quality assurance, the quality of emergency backup power provided by a diesel generator would not necessarily be well-reflected just by the criteria that are applied to each component part of the diesel generator. Even if very strict quality criteria are applied to each of the component parts, the overall diesel generator performance may not meet regulatory standards. On the other hand, a diesel generator could adequately meet performance standards even if the component parts are only commercial grade.

Step 5 – Formulating a Performance-Based Requirement

Purpose – To determine the appropriate implementation of a performance-based approach within the regulatory framework.

Step 5a: Does the performance-based regulatory requirement provide necessary and sufficient coverage for the performance objective?

One of the important elements of coverage is consideration of defense-in-depth. As described in Chapters 3, 4, 5, and 6, NRC's defense-in-depth philosophy includes consideration of "prevention" and "mitigation" strategies which should operate in proper balance. Such considerations may require the use of more complex approaches based on decision theoretic concepts (also described in NUREG/BR-0303).

Step 5b: Of the performance parameters selected in Step 4, which of them requires that a prescriptive approach be used to meet regulatory needs? Can a combination of performance-based and prescriptive measures be implemented such that the resolution of the regulatory issue is as performance-based as possible?

The search process for performance measures and criteria may reveal various permutations and combinations of prescriptive, less-prescriptive and performance-based strategies for individual components or sub-systems, . In some cases, specific prescriptive elements can be incorporated into a less prescriptive regulatory approach. The regulatory framework permits inclusion of prescriptive elements through Technical Specification or License Condition provisions.

Step 5c: Has the regulatory alternative been considered for implementation within each of the levels of the regulatory framework so that an optimum level is proposed?

For example, a prescribed parameter can be included in a Technical Specification or other license condition. It may be possible to provide flexibility in operation for parameters that do not have to be strictly controlled. Also, consideration should be given to incentives for licensees to increase the likelihood of improved safety outcomes.

Step 5d: Are licensees' incentives appropriately aligned, considering the overall complement of performance measures, criteria, the implementation, and the regulatory framework as a whole?

Licensees' flexibility can be coupled with positive and negative incentives. Examples of positive incentives occur when licensees may be able to reduce costs of operation if they meet specified levels of safety or trends in safety of operation. Examples of negative incentives occur when the enforcement policy may cause undesired consequences for the licensee when levels of safety or trends in safety are unfavorable.

Regulation that is based on sampling licensee performance needs to be designed with care, in order to avoid incentivizing performance in one important area at the expense of another, with a net adverse outcome. As a hypothetical example, regulation that sought only to minimize the unavailability of components might create an incentive to reduce maintenance to a level at which unreliability performance would be adversely affected. The regulatory framework itself should be subjected to critical scrutiny for inappropriate incentives.

Step 5e: Is it worth modifying the regulatory framework in the manner proposed, considering the particulars of the regulatory issue?

Among the high-level performance-based guidelines, the assessment guidelines are best suited to make this evaluation. A feedback process involving a wide range of stakeholders may be the most effective way to develop the required information. Such a process may explicitly consider the cost impacts of incorporating requirements in one or other part of the regulatory framework.

Appendix B:
Current Quantitative Guidelines for LWRs

B. Current Quantitative Guidelines for LWRs

B.1 Introduction

Two numerical objectives have currently been adopted as surrogates for the two QHOs:

- A core damage frequency (CDF) of $<10^{-4}$ per year as a surrogate for the latent cancer QHO

- A large early release frequency (LERF)of $<10^{-5}$ per year as a surrogate for the early fatality QHO.

The objective of this appendix is to demonstrate how the above two numerical objectives were derived from the QHOs.

B.2 Quantitative Health Objectives

The following are definitions of the QHOs taken directly from the Safety Goal Policy Statement:

- "The risk to an average individual[1] in the vicinity of a nuclear power plant of prompt fatalities[2] that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accident to which members of the U.S. population are generally exposed."

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[1]The Safety Goal Policy further states that the average individual in the vicinity of the plant is defined as the average individual biologically (in terms of age and other risk factors) and who resides within a mile from the plant site boundary. This means the dose conversion factors (DCFs) that translate exposure to dose (and hence risk) are for an average adult person (i.e., infant DCFs, etc. are not evaluated). In addition the average individual risk is found by accumulating the estimated individual risks and dividing by the number of individuals residing in the vicinity of the plant. (The statement also states that if there are no individuals residing within a mile of the plant boundary, an individual should, for evaluation purposes, be assumed to reside 1 mile from the site boundary).

[2]An accident that results in the release of a large quantity of radionuclides to the environment can result in acute doses to specific organs (e.g., red blood marrow, lungs, lower large intestine, etc.) in individuals in the vicinity of the plant. These acute doses can result in prompt (or early) health effects, fatalities and injuries. Doses that accumulate during the first week after the accidental release are usually considered when calculating these early health effects. The possible pathways for acute doses are: inhalation, cloudshine, groundshine, resuspension inhalation, and skin deposition. Cloudshine and inhalation are calculated for the time the individual is exposed to the cloud. Groundshine and resuspension inhalation doses for early exposure are usually limited to one week after the release. The doses accumulated during this early phase can be significantly influenced by by emergency countermeasures such as evacuation and sheltering of the affected population. Early fatality is generally calculated using a 2-parameter hazard function. A organ dose threshold is incorporated into the hazard function such that below the threshold the hazard is zero. (For example, the default value of the threshold for acute dose to red marrow is 150 rem in (Ref. B.1). An early fatality is defined as one that results in death within 1 year of exposure.

- “The risk to the population in the area of nuclear power plant of cancer fatalities[3] that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks resulting from all other causes.”

These QHOs have been translated into two numerical objectives, as follows:

Early Fatality —

The individual risk of a prompt fatality from all “other accidents to which members of the U.S. population are generally exposed,” such as fatal automobile accident, etc., is about $5x10^{-4}$ per year. One-tenth of one percent of this figure implies that the individual risk of prompt fatality from a reactor accident should be less than $5x10^{-7}$ per reactor year (ry). The “vicinity” of a nuclear power plant is understood to be a distance extending to 1 mile from the plant site boundary. The individual risk (IER) is determined by dividing the number of prompt or early fatalities (societal risk) to 1 mile due to all accidents, weighted by the frequency of each accident, by the total population to 1 mile and summing over all accidents. For example:

The conditional probability of an individual becoming a prompt (or early) fatality (CPEF) for an accident sequence “n” can be expressed by the following:

$$CPEFn = \frac{EFn}{TP(1)}$$ Equation 1

Where: EF_n = number of early fatalities within 1 mile conditional on the occurrence of accident sequence “n”

TP(1) = total population to 1 mile

It follows that the individual early risk (IER) is the sum of the CPEF (weighted by the frequency/ry) for all accidents (N) that result in a large early release of sufficient magnitude to cause early fatalities:

$$IER = \sum_{1}^{N}(CPEFn * LERFn)$$ Equation 2

Where: $LERF_n$ = frequency/ry of a large early release capable of causing early fatalities for accident sequence “n”

[3]Lifetime 50-year committed doses can result in latent cancer fatalities. These doses occur during the early exposure phase (within one week of the release) from the early pathways, i.e. cloudshine, groundshine, inhalation, and resuspension inhalation, and the long-term phase from the long-term pathways that include groundshine, resuspension inhalation, and ingestion (from contaminated food and water). Just as early exposure can be limited by protective actions such as evacuation during the early phase, chronic exposure during the long-term phase can also be limited by actions such as population relocation, interdiction of contaminated land for habitation if it cannot be decontaminated in a cost-effective manner (within a 30-year period), food and crop disposal, and interdiction of farmland. A piecewise linear dose-response model is generally used to estimate cancer fatalities. A dose and dose rate reduction factor is used at low dose rates (<0.1 Gy per hour) and for low doses (< 0.2 Gy) to estimate cancer fatalities based on the recommendations of the International Commission on Radiation Protection in their ICRP 60 report. Up to 20 organs are included for estimation of latent cancers (e.g., lungs, red bone marrow, small intestine, lower large intestine, stomach, bladder wall, thyroid, bone surface, breast, gonads, etc.)

Latent Fatality —

"The sum of cancer fatality risks resulting from all other causes" is taken to be the cancer fatality rate in the U.S. which is about 1 in 500 or $2x10^{-3}$ per year. One-tenth of one percent of this implies that the risk of cancer to the population in the area near a nuclear power plant due to its operation should be limited to $2x10^{-6}$/ry. The "area" is understood to be an annulus of 10-mile radius from the plant site boundary. The cancer risk is also determined on the basis of an individual, i.e., by evaluating the number of latent cancers (societal risk) due to all accidents to a distance of 10 miles from the plant site boundary, weighted by the frequency of the accident, dividing the total population to 10 miles, and summing over all accidents. For example:

The conditional probability of an individual becoming a latent, cancer, fatality (CPLF) for an accident sequence "m" can be expressed in a similar manner to that shown above:

$$CPLF_m = \frac{LF_m}{TP(10)} \qquad \text{Equation 3}$$

Where: LF_m = number of latent, cancer, fatalities within 10 miles conditional on the occurrence of accident sequence "m"
TP(10) = total population to 10 miles

It follows that the individual latent risk (ILR) is the sum of the CPLF (weighted by the frequency/ry) for all accidents (M) that result in a release of sufficient magnitude to cause latent cancer fatalities:

$$ILR = \Sigma_1^M (CPLFm * LRFm) \qquad \text{Equation 4}$$

Where: LRF_m = frequency/ry of a large release capable of causing latent cancer fatalities for accident sequence "m"

B.3 Surrogate for Latent Fatality QHO

Even at a densely populated U.S. site, if a plant's core damage frequency is 10^{-4} per year or less, the latent cancer fatality QHO is generally met with no credit taken for containment. This can be demonstrated numerically by assuming that one accident sequence "x" dominates the latent cancer fatality risk and the LRF, which is defined as:

$$LRFx = CDFx * CLLRPx \qquad \text{Equation 5}$$

Where: CDF_x = core damage frequency for accident sequence "x"
$CLLRP_X$ = conditional large late release probability for accident sequence "x"

Assuming a worst case scenario:

- an open containment
- an unscrubbed release, and
- a large opening in containment.

Given an open containment and all of the conditions necessary for a large release, $CLLRP_X = 1.0$. Therefore $LRF_X = CDF_X$ and equation 4 becomes:

$$ILRx = CPLFx * CDFx \qquad \text{Equation 6}$$

CPLF values were reported for a range of NPPs in the supporting documentation for NUREG-1150 (Ref. B.2). For the purposes of this example the Surry (Ref. B.3) results will be utilized. The largest CPLF (within 10 miles) for internal initiators is reported in Table 4.3-1 of reference Z to be $4*10^{-3}$. This CPLF value corresponds to a large opening in containment and a very large release. It is therefore consistent with the worst case assumptions for accident scenario “x”. Using this value of CPLF and assuming a CDF goal of 10^{-4} per year an estimate of the individual latent risk can be made using Equation 6:

$$ILR_X = (4*10^{-3}) * (10^{-4}) = 4*10^{-7}/\text{year}$$

The ILR corresponding to a CDF = 10^{-4} per year is less than the latent cancer QHO of $2*10^{-6}$ per year by a factor of five. Therefore using a CDF goal of 10^{-4} per year will ensure that the latent cancer QHO is generally met with reasonable margin.

B.4 Surrogate for Early Fatality QHO

The early fatality QHO is more restrictive than the latent cancer QHO. If a plant’s large early release frequency (LERF) is 10^{-5} per year or less, the early fatality QHO is generally met. This can again be demonstrate numerically by assuming that one accident sequence “y” dominates the early fatality risk and the LERF, which is defined as:

$$LERFy = CDFy * CLERPy \qquad \text{Equation 7}$$

Where: CDF_y = core damage frequency for accident sequence “y”
$CLERP_y$ = conditional large early release probability for accident sequence “y

Again assuming a worst case scenario:

- an open containment which occurs early in the accident sequence
- an unscrubbed release that also occurs early before effective evacuation of the surrounding population, and
- a large opening in containment.

Given an open containment and all of the conditions necessary for a large early release, $CLERP_y$ = 1.0. Therefore $LERF_y = CDF_y$ and equation 2 becomes:

$$IERy = CPEFy * CDFy \quad \text{Equation 8}$$

CPEF values were again taken from the Surry (Ref. Z) results. The largest CPEF (within 1 mile) for internal initiators is reported in Table 4.3-1 of reference Z to be $3*10^{-2}$. This conditional risk value corresponds to a large opening in containment and a very large release that is assumed to occur early before effective evacuation of the surrounding population. It is therefore consistent with the worst case assumptions for accident scenario “y”. Using this value of CPEF and assuming a LERF goal of 10^{-5} per year an estimate of the individual early risk can be made using Equation 8:

$$IER_y = (3*10^{-2}) * (10^{-5}) = 3*10^{-7}/\text{year}$$

The IER corresponding to a LERF = 10^{-5} per year is less than the early fatality QHO of $5*10^{-7}$ per year by a factor of about two. Using a LERF goal of 10^{-5} per year will generally ensure that the early fatality QHO is met.

Therefore a LERF of 10^{-5}/year is an acceptable surrogate for the QHOs.

B.5 References

B.1 A discussion of the dose conversion factor databases embedded in MACCS and their use for various types and purposes of calculations performed in the code is contained in the MACCS2 code manual [Chanin and Young, “Code Manual for MACCS2: User’s Guide, NUREG/CR-6613, Vol. 1: SAND97-0594, Sandia National Laboratories, May 1998.]

B.2 USNRC, “Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants,” NUREG-1150, December 1990.

B.3 USNRC, “Evaluation of Severe Accident Risks: Surry, Unit 1,” NUREG/CR-4551, Vol. 3, October 1990.

Appendix C:
Safety Characteristics of the Generation IV Future Reactors

C. Safety Characteristics of the Generation IV New Reactors

UNDER DEVELOPMENT

Appendix D: Probabilistic Risk Assessment Quality Needs for New Reactors

D. PRA Quality Needs for New Reactors

UNDER DEVELOPMENT

Appendix E:
Assessment of Part 50 for New Reactors

E. Assessment of Part 50 for New Reactors

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Appendix F:
Completeness Check

F. Completeness Check

UNDER DEVELOPMENT

GLOSSARY

TO BE WRITTEN