

Draft

**Guidance for the Review of
Changes to Risk-Important Human Actions**

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ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) is addressing the human performance aspects of changes to operator actions that are credited for safety, especially those involving changes in the licensing basis of the plant; e.g., use of manual action in place of an automatic action for safety system operations. This report provides risk-informed guidance and acceptance criteria for the review of licensee proposals addressing such modifications. The review method uses a graded, risk-informed approach and provides guidance for reviewing the human performance aspects of changes to plant systems and operations. The evaluation method uses a two-step approach. The first step is a screening analysis of the plant modification and the affected human actions (HAs) to determine their risk importance. Three risk regions are defined: high, medium, and lower risk regions. In the second step, HAs are reviewed using human factors engineering criteria to ensure the proposed HA can be reliably performed when called upon in the plant. HAs in the high-risk region receive a detailed review and those in the medium-risk region receive a less detailed review that is commensurate with their risk. For HAs falling into the lower-risk region, no human factors review is performed.

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EXECUTIVE SUMMARY

The U. S. Nuclear Regulatory Commission (NRC) reviews changes in operator actions that are credited in plant safety analyses. Changes in credited action may result from a variety of plant activities such as: plant modifications, procedure changes, equipment failures, justifications for continued operations (JCOs), and identified discrepancies in equipment performance or safety analyses. Relevant review considerations are described in NRC information notices and generic issues. Information Notice (IN) 91-18 (NRC, 1991) discusses the conditions under which manual actions may be used in place of automatic actions for safety system operations. IN 97-78 (NRC, 1997) alerts licensees to the importance of considering the effects on human performance of such changes made to plant safety systems.

The document provides guidance to address the review of safety-related operator actions, including ECCS switchover, and other types of required operator actions. A graded, risk-informed approach is used in conformance with Regulatory Guide (RG) 1.174 (NRC, 1998) and guidance is provided for reviewing the human performance aspects of changes to plant systems and operations. Risk insights are used to determine the level of regulatory review the staff should perform. Human actions (HAs) that are considered more risk significant receive a detailed review, while those of less risk significance receive a less detailed, commensurate review. In keeping with RG 1.174, this guidance does not preclude other approaches for requesting changes to a plant's licensing basis or other approaches for requesting changes in HAs. Rather, this approach to the review of HAs is intended to improve consistency in regulatory decisions in areas where the results of risk analyses are used to help justify regulatory action.

A two-step evaluation method is used. The first step is a risk screening and analysis of the licensee's identification of affected HAs and a determination of their risk importance. The second is a human factors engineering (HFE) review of the affected HAs. Each is described below.

Risk Screening and Process

A screening analysis is used to locate the plant modification and its associated HAs in risk space using guidance similar to that of RG 1.174. Essentially, plant modifications and their associated HAs are categorized into high, medium, and lower risk based on the three regions discussed in the RG. This categorization is used to determine the level of graded human factors engineering (HFE) review needed. Important steps of this process are described below.

The licensee reviews the change to identify HAs involving new actions, modified actions, or modified task demands. A 10 CFR 50.59 evaluation is conducted by the licensee for any changes that affect the licensee's Final Safety Analysis Report (FSAR). This evaluation may result in the identification of an unreviewed safety question (USQ), which requires NRC review and approval.

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For the risk-informed review, the licensee would make an initial screening risk calculation and submit this to NRC with the request for approval/USQ submittal. If the action is verified to be in the lower risk region, then the licensee's change would be permitted with no further NRC human factors review. If the action is in the medium risk region then a moderate, top level human factors review is performed by NRC. If the action is in the high risk region, then a more detailed review is in order, which would include human factors, deterministic, and risk aspects.

These risk calculations for the high risk region would determine: (1) the change in risk, core damage frequency (CDF), due to the modification ($\Delta\text{CDF}_{\text{mod}}$) that includes the HA, and (2) the change in risk due to the failure of the new HA in question ($\Delta\text{CDF}_{\text{HA}}$). Similar calculations would be performed for large early release frequency (LERF). For these risk significant HAs, the intent of the detailed HFE review is to ensure that they can be successfully performed when required in order to limit the risk associated with the failure of the HAs.

Human Factors Engineering Review

In this step, the HAs are reviewed to ensure the proposed HA can be reliably performed when needed. Again, the details of the review are commensurate with the risk. Three levels of risk and NRC review are presented. The review criteria are based on an adaptation of existing NRC review guidance for human factors, as found in: NUREG-0800 (NRC, 1996a), NUREG-0711 (O'Hara, et al., 1994), NUREG-0700, Rev. 1, (NRC, 1996b), and IN 97-78 (NRC, 1998).

A Region I review is used for HAs in the high-risk category. Changes that belong to Region I require the most stringent review, including the following review elements:

- General Deterministic Review Criteria (e.g., current regulations and defense-in-depth considerations, as discussed in RG 1.17)
- HFE Program Management
- Operating Experience Review
- Functional Requirements Analysis and Functional Allocation
- Task Analysis
- Staffing
- Probabilistic Risk and Human Reliability Analysis
- Human-System Interface

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- Procedures
- Training
- Human Factors Verification and Validation
- Human Performance Monitoring Strategy (i.e., verifying that no adverse safety degradation results from the changes in operator actions and that the conclusions drawn from the evaluation remain valid over time).

HAs in the medium risk category receive a Region II review by the NRC. While the guidance addresses similar topical areas as the Region I review, the extent of the staff review is considerably less. The evaluation processes for this region are less prescriptive and provide greater latitude to the licensee for the collection and analysis of information than in Region I. The Region II evaluation process includes the following four elements:

- General Deterministic Review Criteria (same as the Region I element).
- Analysis - Reviews key considerations of the following elements of NUREG-0711: Operating Experience Review, Functional Requirements Analysis and Function Allocation, Task Analysis, and Staffing.
- Design of Human-System Interface (HSIs), Procedures, and Training - Reviews key considerations from the following elements of NUREG-0711: HSI Design, Procedure Development, and Training Program Development.
- Human Action Verification - Reviews the licensee's demonstration that the HAs can be successfully accomplished with the modified HSI, procedures, and training (e.g., a walk-through evaluation of the operator action under realistic conditions).

HAs in the *lower* risk category receive only a limited Region III review by the NRC. The staff review is limited to verification that the action is in fact in Region III. No human factors review is necessary. However, the licensee may use the Region II guidance themselves to address human factors considerations.

Final Decision on Acceptance of Human Actions

Once the NRC review of a proposed change in HAs is completed, a final decision is made based on the information that has been gathered, reviewed, and evaluated. The results of the different analyses are considered in an integrated manner (i.e., the decision is not driven solely by the numerical results of the risk assessment). This approach complements the NRC's deterministic

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approach, supports the NRC's traditional defense-in-depth philosophy, and takes into consideration both traditional engineering and risk information. Both qualitative and quantitative analyses and information are used. The main factors considered in the decision process include the following:

- Change in CDF - The increase in CDF due to: the modification ($\Delta\text{CDF}_{\text{mod}}$) and failure of the HA ($\Delta\text{CDF}_{\text{HA}}$).
- Change in LERF - The increase in LERF due to: the modification ($\Delta\text{LERF}_{\text{mod}}$) and failure of the HA ($\Delta\text{LERF}_{\text{HA}}$).
- HFE - The degree of confidence that operators can perform the actions required for the modification in question as determined by the HFE review criteria.
- Deterministic Criteria - Satisfaction of the deterministic review guidance provided in Section 3.1 of the Region I review guidance or Section 4.1 of the Region II review guidance.
- Time and Integrated Risk - Risks integrated over the length of time that a temporary change will be in place.

Additional factors that may also be used to determine the acceptability of a change include:

- The cumulative impact of previous changes and the trend in CDF and LERF (the licensee's risk management approach)
- The impact of the proposed change on operational complexity, burden on the operating staff, and overall safety practices
- Plant-specific performance and other factors (e.g., siting factors, inspection findings, performance indicators, and operational events).
- The benefit of the change in relation to its CDF/LERF increase
- The practicality of accomplishing the change with a smaller CDF/LERF impact, and
- The practicality of reducing CDF/LERF when there is reason to believe that the baseline CDF/LERF are above the guideline values (i.e., 10^{-4} and 10^{-5} per reactor year).

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PREFACE

This report was prepared by Brookhaven National Laboratory (BNL) for the Division of Systems Technology of the NRC's Office of Nuclear Regulatory Research as part of the project Credit for Operator Actions (JCN Y6022). The NRC Project Manager is Paul Lewis (301 415-6767); PML1@nrc.gov) and the BNL Principal Investigator is John O'Hara (631 344-3638; ohara@bnl.gov).

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ACRONYMS

ACRONYMS

AEOD	analysis and evaluation of operational data
ATWS	anticipated transient without scram
BNL	Brookhaven National Laboratory
BWR	boiling water reactor
CBP	computer-based procedures
CCDF	cumulative value of core damage frequency
CDF	core damage frequency
CR	control room
DBE	design basis event
DHR	decay heat removal
ECCS	emergency core cooling system
EOP	emergency operating procedures
FSAR	final safety analysis report
GDC	general design criteria
GI	generic issue
GTG	generic technical guidelines
HA	human actions
HFE	human factors engineering
HRA	human reliability analysis
HSI	human-system interfaces
I&C	instrumentation and control
IC	isolation condenser
IN	information notice
IPE	individual plant examination
JCO	justifications for continued operations
LERF	large early release frequency
LOCA	loss-of-coolant accident
NRC	Nuclear Regulatory Commission
OER	operating experience review
PRA	probabilistic risk assessment
PSF	performance shaping factors
PWR	pressurized water reactor
RAW	risk achievement worth
RCS	reactor coolant system
RG	regulatory guide
RIM	risk information matrices
RIS	regulatory issue summary
SAR	safety analysis report
SBO	station blackout

SLC	standby liquid control
SROA	safety-related operator action
SRV	safety relief valves
TMI	Three-Mile Island
USQ	unreviewed safety question
V&V	verification and validation

1 INTRODUCTION

In Information Notice (IN) 91-18 (NRC, 1991), the U.S. Nuclear Regulatory Commission (NRC) discussed the conditions under which manual actions may be used in place of automatic actions for safety system operations. In IN 97-78 (NRC, 1997), the NRC alerted licensees to the importance of considering the effects on human performance of such changes made to plant safety systems:

The original design of nuclear power plant safety systems and their ability to respond to design-basis accidents are described in licensees' FSARs and were reviewed and approved by the NRC. Most safety systems are designed to rely on automatic system actuation to ensure that the safety systems are capable of carrying out their intended functions. In a few cases, limited operator actions, when appropriately justified, were approved. Proposed changes that substitute manual action for automatic system actuation or that modify existing operator actions, including operator response times, that were not reviewed and approved during the original licensing review of the plant may raise the issue of an unreviewed safety question (USQ). Such changes must be evaluated under the criteria of 10 CFR 50.59 to determine whether a USQ is involved and whether NRC's review and approval are required before implementation... In the NRC staff's experience, many of the changes involving operator actions proposed by licensees do involve a USQ.

A definition of the term "safety-related operator action" (SROA) is provided in ANSI/ANS-58.8-1994:

A manual action required by plant emergency procedures that is necessary to cause a safety-related system to perform its safety-related function during the course of any DBE. The successful performance of a safety-related operator action might require that discrete manipulations be performed in a specific order. (p.4)

The guidance presented in this document can be used to address all SROAs, as well as other types of required operator actions.

The present document uses a graded, risk-informed approach in conformance with Regulatory Guide (RG) 1.174 (NRC, 1998) and provides guidance for reviewing the human performance aspects of changes to plant systems and operations. The guidance uses risk insights to determine the level of regulatory review the staff should perform. Human actions (HAs) that are considered more risk significant receive a detailed review, while those of less risk significance receive a less detailed review commensurate with their risk.

The evaluation method uses a two-step approach. The first step is a screening analysis of the licensee's identification of affected HAs and a determination of their risk importance. This information is used to locate the plant modification and its associated HAs in risk space using guidance similar to that of RG 1.174. Essentially, plant modifications and their associated HAs are categorized into high, medium, and lower risk based on the three regions discussed in the RG. This categorization is used to determine the level of graded human factors engineering

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(HFE) review needed.

In the second step, HAs are reviewed. The intent of this step is to ensure the proposed HA can be reliably performed when needed. Again, the details of the review are commensurate with the risk. Two levels of NRC review are presented. A Region I review is used for HAs falling into the high-risk category. It examines the licensee's planning, analysis, design activities, and verification and validation, as related to the change. The review criteria are based on an adaptation of existing NRC review guidance for HFE, as found in: NUREG-0800 (NRC, 1996a), NUREG-0711 (O'Hara, et al., 1994), NUREG-0700, Rev. 1, (NRC, 1996b), and IN 97-78 (NRC, 1998). The adaptation is based on a consideration of the types of cases for which this guidance will be used. This was accomplished by an analysis of past cases reviewed by NRC (Higgins, et al., 1999). While HAs in the high-risk area of Region I are generally not desired, there are certainly examples of such actions in plants today, such as, the PWR ECCS switchover, discussed above. Also, there may be extenuating circumstances in which the licensee can adequately justify a modification to add a Region I HA, e.g., if the change is temporary or if there are other changes that lower the core damage frequency (CDF). Another important consideration is whether and how well the licensee has addressed the HFE aspects of the modification.

HAs in the medium risk category would receive a Region II review by the NRC. While the guidance addresses the same topical areas as the Region I review, the extent of the staff review is considerably less.

Finally, the third region is called *lower* risk to indicate that the modification involves less risk than those in the high or medium regions. However, even at this lower level there is some residual risk that may be of continued concern, especially if many of these lower risk items accumulate. For HAs in the lower risk category (Region III), staff review would be limited to verification that the action is, in fact, in Region III. Such a verification can be accomplished by reviewing the licensee's risk results that show the placement of the action in that risk region. No human factors review is necessary. However, guidance, for human factors considerations, is provided for by the licensee use.

In keeping with RG 1.174, this guidance does not preclude other approaches for requesting changes to a plant's licensing basis or other approaches for requesting changes in HAs. Rather, this review approach is intended to improve consistency in regulatory decisions in areas where the results of risk analyses are used to help justify regulatory action. RG 1.174 notes that the principles, process, and approach discussed therein also provide useful guidance for the application of risk information to a broader set of activities than plant-specific changes to a plant's licensing basis (i.e., generic activities), and licensees are encouraged to use this guidance in that regard. Thus, it was adopted for this review process.

The RG notes that the use of probabilistic risk assessment (PRA) technology should be increased

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in all regulatory matters to the extent supported by the state of the art in PRA methods and data. Its application should complement the NRC's deterministic approach and support the NRC's traditional defense-in-depth philosophy. This approach to the NRC review of HAs also takes this concept into consideration.

RG 1.174 notes that decisions concerning proposed changes are expected to be reached in an integrated fashion, considering traditional engineering and risk information. They may be based on qualitative factors as well as quantitative analyses and information. Thus, the approach presented herein also considers such qualitative factors.

The Commission also noted on many occasions that the regulatory process should become "risk-informed" as opposed to "risk-based" (Thadani, 1998, p.1). Thus, the approaches described here retain some deterministic aspects, for example dealing with defense-in-depth, meeting existing regulatory requirements, and addressing the HFE aspects of the HAs.

This guidance is expected to contribute to satisfying the NRC's goals of (1) maintaining safety, (2) increasing public confidence, (3) increasing regulatory efficiency and effectiveness, and (4) reducing unnecessary regulatory burden. By implementing the guidance presented in this document, the NRC will improve the regulatory process in three areas: foremost, through safety decision-making enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees. The use of risk insights in licensee submittals requesting changes in HAs will assist the staff in the disposition of such licensee proposals.

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2.1 Affected Human Actions

Changes to HAs may result from a variety of plant activities such as: plant modifications, procedure changes, equipment failures, justifications for continued operations (JCOs), and identified discrepancies in equipment performance or safety analyses. The licensee should evaluate changes in these various activities to determine the affected HAs. Affected actions reflecting the following types of changes should be identified:

- New actions - an action that was not previously performed by personnel such as when an action formerly performed by automation is allocated to the operators.
- Modified actions - a change to the way actions were previously performed, such as through the introduction of new task steps (e.g., due to new system components, a modification to a component, or failed components), or the introduction of new control and display devices for performing the action.
- Modified task demands - rather than affecting the task steps themselves, a change in the plant may affect the task demands, or the amount of time available for its completion.

2.2 Risk Importance of the Affected Human Actions

Any of the above changes that affect the licensee's Final Safety Analysis Report (FSAR) will require a 50.59 evaluation to be performed. This evaluation may result in the identification of an USQ that requires NRC review and approval. The present document provides guidance for the NRC review of the submitted USQ describing the changes in HAs. This work also provides some less detailed guidance for instances in which the changed HAs do not rise to the level of a USQ.

The intent of the 10 CFR 50.59 process is to permit licensees to make changes to their facilities, provided the changes maintain the level of safety documented in the original licensing basis, such as the safety analysis report (SAR). Historically the process has been structured around the licensing approach to design-basis events. The staff has recognized that the 50.59 process needs improvement to become consistent with the Commission policy of risk-informed regulation (Thadani, 1998). Thus, the NRC has developed various proposals to formally modify the 50.59 process to incorporate risk insights. The methods provided in this document are consistent with the intent of the proposed modifications and combine risk-informed approaches with both qualitative and quantitative human factors review methods.

The three regions of RG 1.174 Acceptance Guidelines Figures are used for the first-cut, risk-informed insights, as discussed below. Figures 2.1 and 2.2 below (adapted from Figures 3 and 4

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of RG 1.174) contain the Acceptance Guidelines for Core Damage Frequency (CDF) and Large Early Release Frequency (LERF), respectively. These figures show a plant's baseline on the x-axis and Δ CDF and LERF due to a plant modification or change on the y-axis. The figures contain three regions on the x-y plane that determine whether a change is permissible or what other actions may be necessary if the change is to be implemented. In the high-risk area of Region I, the proposed changes would generally not be permitted. However, there may be extenuating circumstances in which the licensee can adequately justify the modification, e.g., if the change is temporary or if there are other changes that lower the CDF. Another important consideration is whether and how well the licensee has addressed the HFE aspects of the modification. In the medium-risk area of Region II, some changes are permitted. In the lower risk area of Region III, most changes would be permitted. In accordance with RG 1.174 methods (Section 3.3.2), the cumulative changes in risk from Regions I, II, and III should be tracked by the licensee.

Changes proposed by licensees may be permanent or temporary. Often temporary changes are proposed whereby licensees are substituting HAs for automatic equipment that is temporarily inoperable and cannot be restored within technical specification the time interval required by the plant technical specifications. For the permanent changes, NRC reviewers should use Figures 2.1 and 2.2 below for determining the risk importance and the appropriate level of review. For temporary changes an additional risk screening, that considers the time interval that the modification will be in place, should be performed. Such a screening is described in Section 2.4 below.

The risk associated with changes in the plant that affect HAs (including errors) must be determined to using Figures 2.1 and 2.2. There are two ways to determine the risk importance of HAs: through the use of the plant specific PRA and through the use of generic information. Trial applications of this method have shown that plant specific approaches are necessary to accurately place the affected HAs in the proper region. However, a method of using generic information is also discussed below.

Determining Risk Importance

The licensee should determine the risk importance of the proposed changes in order to place it on Figures 2.1 and 2.2 and to then determine the appropriate level of review. These may initially be simplified or scoping risk calculations. Any scoping type analyses should be appropriate to the modification or change in HA involved to ensure that actual changes in risk are reflected in the calculations. If the change is in Region II or Region III no further detailed risk calculations may be necessary. However, if the item is in Region I, then Section 3.7 of the Region I review calls for a requantified PRA and human reliability analysis (HRA) that addresses the change. This requantification should eventually account for all aspects of the change, including those that result from the Region I review. The details of the nature of the PRA/HRA modeling, that should be performed for a Region I action, are provided in Section 3.7.

2 RISK SCREENING PROCESS

In accordance with the principles of RG 1.174, licensee submittals are not necessarily required to include risk information. If a licensee is requesting approval of a modification involving changes in human actions and does not wish to have a risk-informed review, then NRC must still decide what level of human factors review to apply. The NRC may decide what level of review to apply on a wholly deterministic basis. Alternatively, the NRC may use generic information to make a conservative determination as to the appropriate level of review. This generic method is discussed below near the end of this section and summarized in Table 2.1. In the event that the licensee has not submitted risk information, but there appear to be unusual circumstances that could introduce significant and unanticipated risks, the NRC reviewer should consult the guidance in NRC Regulatory Issue Summary 2000-07, "Use of Risk-informed Decisionmaking in License Amendment Reviews" (NRC, 2000).

When using plant-specific PRAs to enter Figure 1, the licensees should calculate the change in risk in two ways: (1) the change in risk due to the modification ($\Delta\text{CDF}_{\text{mod}}$) that includes the new human action (HA), and (2) the change in risk due to the failure of the new HA in question ($\Delta\text{CDF}_{\text{HA}}$). These changes in risk are defined quantitatively as follows:

$$\Delta\text{CDF}_{\text{mod}} = [\text{new CDF (with modification in-place)} - \text{current baseline CDF}], \text{ and}$$

$$\Delta\text{CDF}_{\text{HA}} = \text{RAW (new HA)} = [\text{CDF with new HA failed} - \text{new CDF (with mod. in-place)}].$$

The Risk Achievement Worth (RAW) importance measure, is discussed in NUREG/CR-3385 (Vesely, et al., 1983). For this application the interval method of calculating the RAW was selected. The licensee/NRC should place both of the ΔCDF values on Figure 1 and then choose the most conservative result for use in the risk screening process.

A licensee may want to perform a one-time, plant-specific risk assessment to determine their risk significant HAs, and to place them in the regions of the figures. Many licensees have already done so in their IPEs. When a particular modification affecting HAs is proposed, the licensees can perform a plant-specific and human-action-specific risk evaluation for that modification to ensure proper placement on the Figures.

Calculations for LERF for use in Figure 2.2 would be done similarly to the above calculations for CDF and Figure 2.1. The calculation results and placement in Figures 2.1 and 2.2 should be submitted to the NRC.

An approximation to the risk importance of the HA can be determined generically using Tables A.1 and A.2 in Attachment A below, for boiling water reactors (BWRs) and PWRs respectively. These HAs were identified from the new risk-informed assessment process (Azarm, Higgins, and Chu, 1999) and from NUREG-1560. The HAs are organized into two groups. Group 1 contains the most risk-important HAs in the plant Risk Information Matrices (RIMs) used for the pilot risk-informed assessment process. Group 2 HAs are considered to be "potentially" risk-

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important. That is, they would appear in Region I for some, but not all, plants. Typically, they impact risk, but not as significantly as the Group 1 actions. However, at some plants they may be quite risk important. They are included in the second section of the plant RIMs as potentially important HAs.

These groups of generically important HAs can be used in a few ways. They can be used by the NRC and by licensees as a quality check on the results of the plant specific calculations. They can also be used to assist the NRC in determining an estimate of the risk importance of human actions associated with a modification, if the licensee has chosen not to make a risk-informed submittal. This will then assist the NRC in determining the appropriate level of human factors review for such situations.

Changes related to Group 1 actions typically fall into Region I. Thus, if a change to a Group 1 action is not in Region I, the technical basis for this result should be carefully understood and documented. If no risk submittal is made and the plant modification involves a Group 1 action, then the NRC should assume that it is a Region I change. Changes related to Group 2 actions typically fall into Regions I or II. Thus, if such a change is in Region III, the reasons should also be explained. If no risk submittal is made and the plant modification involves a Group 2 action, then the NRC should conservatively assume that it is a Region I change. It is important to note that, on a plant specific basis, actions not listed in Tables A.1 and A.2 may also be risk-significant, and can fall into either Region I or II. That is, one *cannot* conclude that if an action is not listed on either table, it is not important to risk. Thus, if no risk submittal is made and the plant modification involves an action that is not in Group 1 or 2, then the NRC should take the additional step of determining whether the action involves risk-important systems for the plant in question. The risk-important systems can be obtained from the plant IPE or from the Risk-Informed Inspection Notebooks that have been completed by the NRC for each plant. If the action involves a risk-important system, then treat the HA as in Region I. If it involves a system of moderate importance, treat the HA as in Region II. If the modification does not involve a system with any risk-importance, treat it as a Region III HA. This logic is summarized in Table 2.1.

HAs that have no impact on risk would be outside of the area depicted in the figures. This can be considered as below Region III. Changes in this area would be permitted with normal licensee modification controls.

**Table 2.1 Placement of HAs in Risk Regions
for Submittals without Risk Information**

Generic Groups that contain the HA	Systems involving the HA	Risk Region to place the HA
Group 1	NA	I
Group 2	NA	I
Neither Group	Risk important	I
Neither Group	Moderate risk importance	II
Neither Group	No risk importance	III

Comparison of PRA to Acceptance Guidelines

This section provides some guidance on comparing the results of the PRA with the risk guidelines that separate the Regions in Figures 2.1 and 2.2. Also, in the context of integrated decision-making, as discussed in Section 5, the guidelines should not be interpreted as being overly prescriptive. They are intended to provide an indication, in numerical terms, of what is considered acceptable. As such, the numerical values associated with defining the regions in the Figures are approximate values that provide an indication of the changes that are generally acceptable. An example application of the methodology is provided in Attachment B herein. Furthermore, the state of knowledge type (epistemic) of uncertainties associated with PRA calculations preclude a definitive decision with respect to which region the application belongs in based purely on the numerical results.

The intent of comparing the PRA results with the acceptance guidelines is to demonstrate (with reasonable assurance) that proposed increases in CDF or risk are generally small. This decision should be based on a full understanding of the contributors to the PRA results and the impacts of the uncertainties, both those that are explicitly accounted for in the results and those that are not. RG 1.174, Section 2.2.5 contains a discussion of the various types of uncertainty that may need to be addressed. This is a somewhat subjective process, and the reasoning behind the decisions should be well documented. Guidance on considerations is also contained in Section 2.2.5 of the RG.

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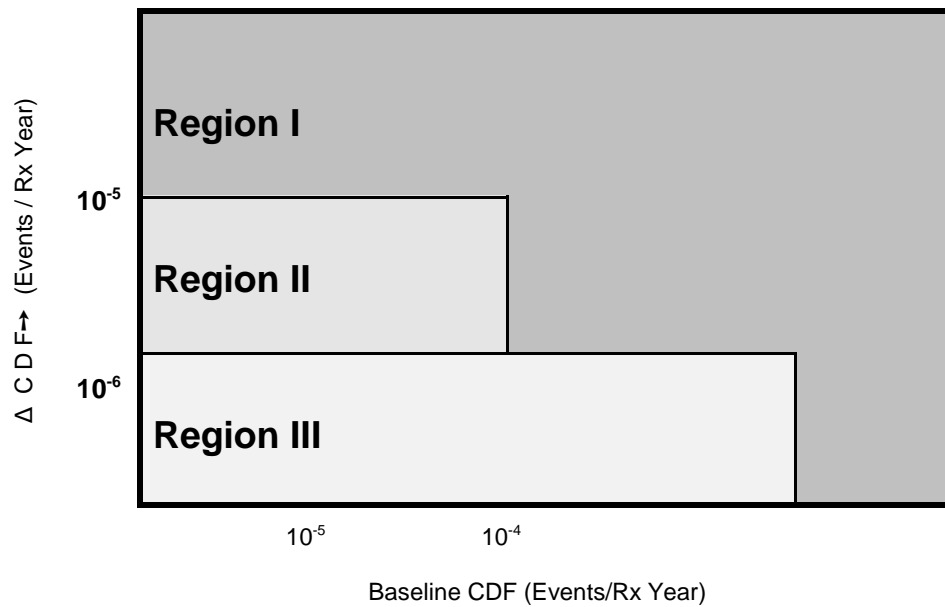


Figure 2.1 Acceptance Guidelines for Core Damage Frequency (CDF)
(Adapted from Figure 3 of RG 1.174)

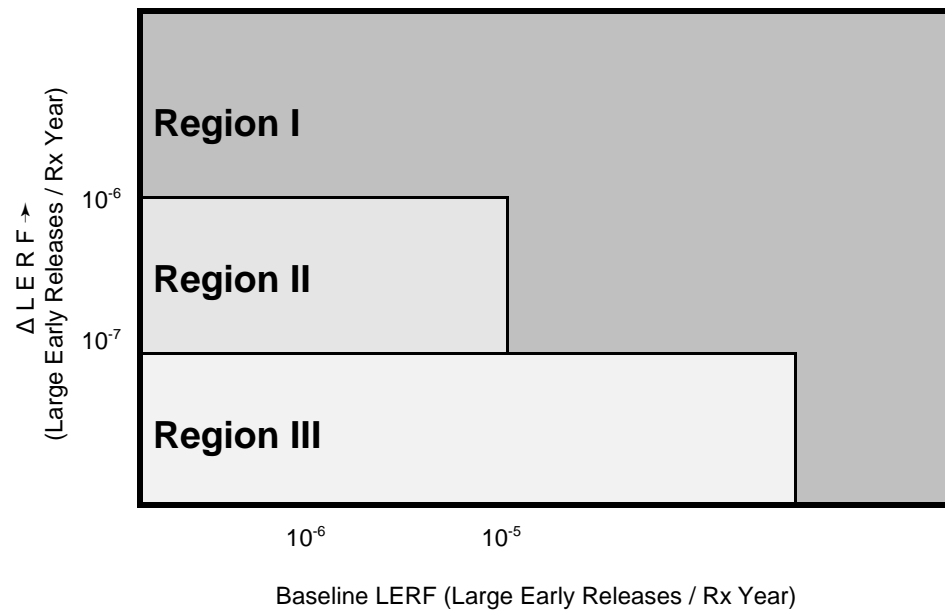


Figure 2.2 Acceptance Guidelines for Large Early Release Frequency (LERF)
(Adapted from Figure 4 of RG 1.174)

2.3 Level of HFE Review of the Affected Human Actions

Once the HAs in question are placed in the proper region of the risk figures, one can determine the level of review to be performed. The review guidance is arranged into two levels so that the more risk significant HAs (Region I) will receive a more thorough review and so that the less risk significant actions (Region II) can receive a more efficient review appropriate to their level of risk. HAs falling in Region III will only be reviewed to verify that they have been properly classified as Region III HAs and that they meet current regulations.

The discussion has two sections. The first section addresses cases in which the modification affecting the HA is a USQ. The second addresses cases in which the modification affecting the HA is not a USQ. Clearly the section of most interest to NRC reviewers is where there is a USQ involved, which results in a submittal to the NRC. For completeness we have included the case in which the modification does not constitute a USQ. Infrequently, this could be important, for example, if the modification was risk significant, but did not involve systems and accidents described in the FSAR. Thus, one would have a risk significant case that was not a USQ.

Modifications That are USQs

Based on the licensee's 50.59 analysis, if the modification affecting the HA is a USQ, then it is submitted to the NRC for review and approval. The reviewer should place the HA into the regions of Figures 2.1 and 2.2 to determine the level of required review (see Table 2.2).

Region I - Using the risk-informed approach, the proposed change in this region would generally not be permitted. However, there may be extenuating circumstances in which the licensee justifies the modification, e.g., if the change is temporary or there are other corresponding changes that lower the CDF. If the NRC review in this Region is to proceed, it requires more substantial review by NRC than the other regions. Therefore, these reviews would use the more detailed Region I guidance, in Section 3, which includes a review of planning, analyses, design, and verification and validation activities (such as simulator trials), and a performance monitoring strategy.

Region II - Changes in this region are evaluated, but require a less detailed Region II review. The guidance is contained in Section 4.

Region III - The licensee should document and the NRC may verify that the HA is correctly located in Region III. The NRC may also verify that current regulations are still being met with the change in place (per Criterion 1 of Section 3.1, "General Deterministic Review Criteria "). Based on the location in Region III, the modification would be accepted based on the low risk, without NRC review of its HFE aspects. Licensees should be encouraged to utilize the Region II guidance contained in Section 4 to ensure that the HAs can be accomplished as assumed. If the change resulted in certain of the

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current regulations not being met, then the NRC may decide to "bump up" the NRC review of the item to a Region II review. Note that even though these HAs constitute a USQ, verification of their low risk by the NRC permits acceptance without a detailed NRC HFE review. Possible future changes to 10 CFR 50.59 could consider not requiring any submittal to the NRC for these types of activities.

Modifications That are Not USQs

If the licensee's 50.59 safety evaluation determines that no USQ is involved with the change in question, but the HA is still risk important (as defined above), then the licensee should evaluate the change themselves as shown in Table 2.3. It may seem that there could be no such items as a Region I change that is not a USQ. However, there may be items that involve notable risk that were not originally addressed in the licensee's Final Safety Analysis Report (FSAR), such as severe accident mitigation items, that are impacted by changes. These items may not pass the USQ test.

Table 2.2 Levels of Review for Human Actions Involving USQs

Risk Significance of HA	NRC Review Actions
Region I	<ul style="list-style-type: none">– Change generally not permitted.– Licensee may want to make case due to extenuating circumstances, such as a temporary modification.– Then will require the full Region I HFE review.
Region II	<ul style="list-style-type: none">– Region II HFE review
Region III	<ul style="list-style-type: none">– Change permitted by NRC without detailed review.– Verify change is in Region III and meets current regulations.– Region II HFE review guidance is provided for licensee use.

Table 2.3 Levels of Review for Human Actions Not Involving USQs

Risk Significance of HA	NRC Review Actions
Region I	<ul style="list-style-type: none">– Licensee should re-check 50.59 safety evaluation, since such a HA probably should be classified as a USQ. (note 1)– If still not a USQ, then licensee should address the Region II HFE review guidance and inform NRC of planned actions.
Region II	<ul style="list-style-type: none">– Licensee should address the Region II HFE review guidance.
Region III	<ul style="list-style-type: none">– Licensee change acceptable with normal onsite change control procedures.

Note: The NRC observed (Thadani, 1998, p. 5) that once a proposed change is identified as falling within the scope of 50.59, the chances that it will not be classified as a USQ is, by design of the rule, very small.

2.4 Integrated Risk Increase

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Changes associated with operator actions are often temporary changes, implemented to address equipment or analysis problems until other, more permanent corrective actions can be planned and completed. In making the final decision on acceptability of a change in operator actions, several items should be considered: the amount of time that a modification is in place, the details of the change, the results of the appropriate Region I or II review, and the risk associated with the modification. Such an integrated evaluation is discussed in the final section of this report. This section gives a method to quantitatively evaluate, in an integrated fashion, both the increase in risk and the length of time that the risk increase will be in place. This would be used for the final decision, not for screening evaluation that determines the appropriate level/Region of review.

The risk calculated by a PRA can be expressed in a variety of ways: as an instantaneous value (often calculated for configuration risk management purposes), an average value of CDF over a reactor year (the most common value that is cited), or a cumulative value of core damage frequency (CCDF) computed over a defined time interval. The CCDF can be calculated accurately using statistical techniques. A simplified method of viewing the cumulative or integrated risk is to multiply the CDF times the time in question. This gives reasonable results for our purposes here. Thus equations for integrated risk can be written as follows:

$$\text{Integrated CDF Risk (mod)} = \Delta\text{CDF}_{\text{mod}} \times \text{time (mod), or}$$

$$\text{Integrated LERF Risk (mod)} = \Delta\text{LERF}_{\text{mod}} \times \text{time (mod),}$$

where:

Integrated Risk (mod) is the integrated risk due to the modification over the time that the change or modification is to be in place, expressed as CDF or LERF;

$\Delta\text{CDF}_{\text{mod}}$ is the change in Core Damage Frequency due to the modification;

$\Delta\text{LERF}_{\text{mod}}$ is the change in Large Early Release Frequency due to the modification; and

time (mod) is the length of time that the change or modification is to be in place.

The value of Integrated CDF Risk (mod) can be roughly interpreted as the change in the expected number of core damage events in the plant in question over the time period due to the modification.

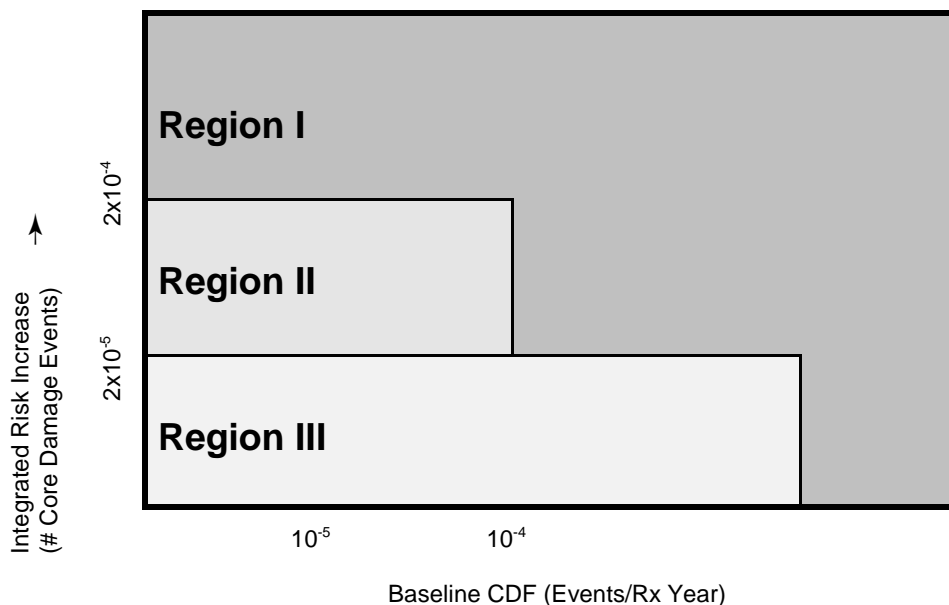
RG 1.174 is designed to address changes to the licensing basis of a plant and primarily addresses permanent changes. As such, Figures 3 and 4 of the RG, that contain the acceptance guidelines for CDF and LERF, do not explicitly address time. However, based on the assumption of a permanent change and a typical remaining plant lifetime of 20 years, one can calculate the implicit integrated risk that is being allowed. This is done by multiplying the ΔCDF and ΔLERF

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on the y-axes of the Figures by 20 years. The resulting new figures are shown below as Figures 2.3 and 2.4. The Regions in the Figures can be interpreted similarly to the three Regions of the Figures of RG 1.174, namely: Region I - changes normally not permitted without extenuating circumstances; and Region II and III - changes permitted, track cumulative impacts of multiple changes.

We have now developed an expression for the integrated risk due to the modification over the time and Figures that contain acceptance guidelines for the integrated risk. The licensee should plot the integrated risk due to the ΔCDF_{mod} and the $\Delta LERF_{\text{mod}}$ on Figures 2.3 and 2.4. The example application provided in Attachment B herein also gives results for the integrated risk associated with the example.

The integrated risk information will be useful in making the final decision on the implementation of the modification, as discussed in Section 5 herein. For example, one may allow a larger value of risk increase, if the time that the modification will be in place is relatively short. Conversely, longer periods of time for changes entail greater integrated risk.



**Figure 2.3 Guidelines for Integrated Risk Increase - Core Damage Events
(Product of Δ CDF and Time)**

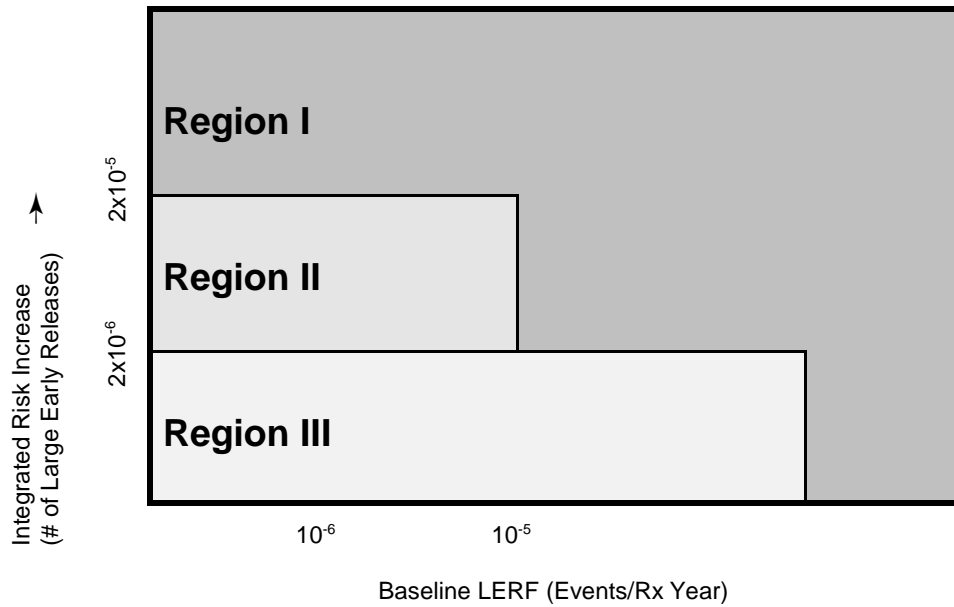


Figure 2.4 Guidelines for Integrated Risk Increase - Number of Large Early Release Events (Product of Δ LERF and Time)

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The guidance presented in this section was derived mainly from RG 1.174, NUREG-0711, and NUREG-0700, Rev 1. These documents can be consulted for additional information.

The review guidance is specified in a broad and generic form to accommodate the broad diversity of plant and HA modifications that the guidance must address. Thus, the guidance must be tailored to the requirements of each specific review. For any specific review, one or more of the review elements presented below may not be applicable.

3.1 General Deterministic Review Criteria

Objective

The objective of this section is to provide adequate assurance that deterministic aspects of design, as discussed in RG 1.174, have been appropriately considered by the licensee. Deterministic aspects include: ensuring the change meets current regulations, and does not compromise defense-in-depth.

Scope

The deterministic review criteria apply to all modifications associated with Region I HAs.

Criteria

- (1) The licensee should provide adequate assurance that the change meets current regulations, except where specific exemptions are requested under 10 CFR 50.12 or 10 CFR 2.802. For example, a change might be identified as risk significance when using a standard PRA to screen for risk. However, an exemption might be granted under one or more of the following regulations: 10 CFR 20, 10 CFR 50 Appendix A, Criterion 19, and 10 CFR 50 Appendices C through R.
- (2) The licensee should provide adequate assurance that the change does not compromise defense-in-depth. Defense-in-depth is one of the fundamental principles upon which the plant was designed and built. Defense-in-depth uses multiple means to accomplish safety functions and to prevent the release of radioactive materials. Defense-in-depth is important in accounting for uncertainties in equipment and human performance, and for ensuring some protection remains even in the face of significant breakdowns in particular areas. Defense-in-depth may be changed but should overall be maintained. Important aspects of defense-in-depth include:

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- A reasonable balance is preserved among prevention of core damage, prevention of containment failure, and consequence mitigation.
- There is no over-reliance on programmatic activities to compensate for weaknesses in plant design. This may be pertinent to changes in credited operator actions.
- System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers).
- Defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed. Caution should be exercised in crediting new operator actions to provide adequate assurance that the possibility of significant common cause operator errors are not created.
- Independence of barriers is not degraded.
- Defenses against human errors are preserved. One way to help ensure this for risk important HAs is to establish procedures for a second check or independent verification that such important actions have been properly executed.
- The intent of the General Design Criteria (GDC) in Appendix A to 10 CFR Part 50 is maintained. GDCs that may be relevant are 3 - Fire Protection, 13 - Instrumentation and Control, 17 - Electric Power Systems, 19 - Control Room, 34 - Residual Heat Removal, 35 - ECCS, 38 - Containment Heat Removal, and 44 - Cooling Water.
- Safety margin are often used in deterministic analyses to account for uncertainty and provide an added margin to provide adequate assurance that the various limits or criteria important to safety are not violated. Such safety margins are typically not related to HAs, but the reviewer should take note to see if there are any that may apply to the particular case under review. It is also possible to add a safety margin (if desired) to the HA by requiring a demonstration that the action can be performed within some time interval (or margin) that is less than the time required by the analysis.

3.2 Licensee's General Approach to HFE

Objective

The objective of this review is to provide adequate assurance that the licensee has made a commitment to address the human performance aspects of the HA to ensure that the action can be reliably accomplished.

Scope

This review addresses the licensee's approach to addressing HFE considerations in the development and implementation of the proposed changes in the HAs.

Criteria

The criteria for this review are identified below.

- (1) Licensee personnel involved in designing and implementing the changes in HAs should include the expertise, such as operations, human factors, training, and system design, necessary to fully analyze HAs and to design the human-system interfaces (HSIs), procedures, and training necessary to provide adequate assurance that the actions can be reliably performed.
- (2) The licensee should commit to the proper development, execution, oversight, and documentation of the modifications to the HSI, procedures, and training to provide adequate assurance that the actions can be reliably performed.
- (3) The licensee should commit to a structured, top-down systems approach to analyzing human performance considerations associated with the change and developing and implementing necessary modifications to the HSI, procedures, and training. The approach should include the following:
 - Operating experience review
 - Functional requirements analysis and allocation
 - Task analysis
 - Staffing analysis
 - Probabilistic risk assessment and human reliability analysis

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- HSI design
 - Procedure design
 - Training design
 - Human factors verification and validation
- (4) Plant personnel who are affected by the HA should be identified, including licensed control room operators as defined in 10 CFR Part 55 and the following categories of personnel defined by 10 CFR 50.120: nonlicensed operators, shift supervisor, shift technical advisor, instrument and control technician, electrical maintenance personnel, mechanical maintenance personnel, radiological protection technician, chemistry technician, and engineering support personnel.
- (5) The applicable components of the HSI, procedures, and training programs for accomplishing the HA should be identified.

3.3 Operating Experience Review

Objective

The objective of this review is to provide adequate assurance that the licensee has identified and analyzed HFE-related problems and issues encountered previously in designs and human tasks that are similar to the planned modification so that issues that could potentially hinder human performance can be addressed.

Scope

The operating experience review (OER) encompasses all proposed changes to HAs and addresses the operating histories of plant systems, HAs, procedures, and HSI technologies. The scope of the HSI technology review can be graded as follows:

- (1) If existing HSI components are to be used without modification and if they are currently used for safety-related functions within the plant, then a review of the operating experience with those HSI components is not necessary.
- (2) If existing HSI components are to be used without modification but they are not currently used for safety-related functions then the operating experience with those HSI components should be reviewed.

- (3) If new HSI components are to be installed or the existing HSI is to be modified using HSI technologies that have not been previously used in the plant for safety-related functions then the operating experience with those HSI components should be reviewed.

Criteria

The criteria for reviewing the licensee's OER are identified below.

- (1) *Plant Systems* - The licensee's review should include information pertaining to (1) the operation and maintenance of the plant system prior to the change in the HAs, and (2) the operation and maintenance of similar systems within the same plant or at other plants. The operating experience should include the performance of the plant systems during surveillance and maintenance tests, especially for plant systems that are not used during normal plant operations.
- (2) *Human Actions* - The licensee's review should identify performance issues associated with procedural guidance, training, and HAs for the system prior to the proposed change to the actions, including the types of actions performed, the procedures available for those actions, and the adequacy of those procedures. In addition, the OER should examine the types of HAs, procedural guidance, and training provided for similar implementations within the same plant or at other plants.
- (3) *HSI Technologies* - The licensee's review should identify human performance issues associated with HSI technologies for the proposed changes in the HAs.
- (4) *Recognized Industry HFE Issues* - The basis for the OER should include:
 - Unresolved safety issues/generic safety issues
 - Three-Mile Island (TMI) issues
 - NRC generic letters and information notices
 - Office for Analysis and Evaluation of Operational Data (AEOD) Issues
 - Low power and shutdown operations
 - Operating plant event reports

NUREG-6400 (Higgins and Nasta, 1996) reviews these operating experience topics and may provide issues relevant to the proposed changes in the HAs.

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- (5) *Issues Identified by Plant Personnel* -Interviews and surveys with personnel should be conducted to determine operating experience related to the plant system before the change in the HAs. Discussions of plant operations and HFE/HSI design should be limited to topics relevant to the change in the HA.
- (6) *Development of Design Input* - Issues identified by the operating experience review should be documented as input to the design of modifications to the HSI, procedures, and training, and tracked to provide assurance that they are addressed.

3.4 Functional Requirements Analysis And Functional Allocation

Objective

The objective of this review is to provide adequate assurance that the licensee has:

- (1) Defined any changes in the plant's safety functions (functional requirements analysis), and
- (2) Provided evidence that the allocation of functions between humans and automatic systems provides an acceptable role for plant personnel; i.e., the allocations take advantage of human strengths and avoid functions that would be negatively affected by human limitations (functional allocation).

Scope

This review addresses all plant functions affected by the change in operator actions including changes to the functions and to their allocation between personnel and automatic systems. The level of detail in the functional requirements and allocation analyses may be graded based on: (1) the degree of difference between the HAs before and after the change; (2) the extent to which difficulties occurred in prior operations, as identified through the OER; and (3) the risk level associated with the change. The following additional considerations apply:

- (1) If new safety functions are introduced or existing ones changed, then reviews of both the functional requirements analysis and function allocation analysis should be conducted. (This situation is not likely to occur since it would involve a significant deviation from the design basis that was originally approved by the NRC.)
- (2) If the function allocation is changed, or if the risk level is well into Region I (as determined by the PRA/HRA review criteria) then a review of the function allocation should be conducted. (Many cases will have changed function allocations. An example may be the reallocation of responsibility from an automatic system to personnel for the initiation, on-going control, or termination of a function.)

- (3) If the function allocation is not changed then no function allocation analysis is needed and the licensee should proceed with task analysis. (An example may be a manual action performed for a safety-related function that is now required under a new scenario. That is, the function is the same but the initiating circumstances are different.)

Review Criteria

The criteria for reviewing the licensee's functional requirements analysis and functional allocation are identified below.

- (1) New or changed safety functions should be described, including comparisons before and after the proposed change. The set of plant system configurations or success paths that are responsible for or capable of carrying out the safety function should be clearly defined and the ones affected by the proposed changes in the HAs should be identified. This functional decomposition should address:
- High-level functions [e.g., maintain reactor coolant system (RCS) integrity] and critical safety functions (e.g., maintain RCS pressure control)
 - Specific plant systems and components
- (2) For the functional allocation analysis, a description should be provided for each of the high-level functions allocated to the human as a result of the proposed change. The description should include the following:
- Purpose of the high-level function
 - Conditions under which the high-level function is required
 - Parameters that indicate that the high-level function is available
 - Parameters that indicate the high-level function is operating (e.g., flow indication)
 - Parameters that indicate the high-level function is achieving its purpose (e.g., reactor vessel level returning to normal)
 - Parameters that indicate that operation of the high-level function can or should be terminated

Note that parameters may be described qualitatively (e.g., high or low), rather than as specific numerical values or setpoints.

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- (3) The technical basis for the proposed modifications to the functions (e.g., new functions and changes in what a function does), compared to the situation before the change in the HAs, should be documented.
- (4) The technical basis for all relevant functional allocations should be documented. The basis for function allocations can be successful operating experience. This analysis should reflect (a) sensitivity, precision, time, and safety-related requirements; (b) required reliability; and (c) the number and level of skills of personnel required to operate and maintain the system.
- (5) The allocation analysis should consider not only the personnel role of initiating manual actions but also responsibilities concerning automatic functions, including monitoring the status of automatic functions to detect system failures.
- (6) The demands associated with the proposed allocation of functions should be considered in terms of all other human functions that may impose concurrent demands upon the personnel. The overall level of workload should be considered when allocating functions to the personnel. The assessment of workload may change as the design matures. Early in the process, workload may be assessed based on information obtained from a review of operating experience. Once task analysis information is available, workload can be examined on the basis of the task characteristics, such as how many tasks have to be performed and their characteristics, such as how quickly they need to be performed and how precise the actions have to be. Once more detailed design information becomes available, workload can be assessed based on the subjective evaluation of subject matter experts, such as operations personnel. When a design is completed and a mockup, simulator, or actual equipment is available, data on workload can be collected through trials where the HAs are actually performed (see O'Hara, et al., 1997 for a discussion of workload measurement).

3.5 Task Analysis

Objective

The objective of this review is to provide adequate assurance that the licensee's task analysis identifies the behavioral requirements of the tasks personnel are required to perform. The task analysis should form the basis for specifying the requirements for the HSI, procedures, and training based on the tasks personnel will perform. The results are also used as basic information for developing staffing and communication requirements of the plant

Scope

The task analysis addresses HAs in their entirety, including all pertinent plant conditions,

situational factors, and performance shaping factors. While the primary focus is operator tasks, tasks performed by other personnel (e.g., maintenance, test, inspection, and surveillance) that occur at the same time as the HAs and directly influence the actions are included in the task analysis.

Criteria

The criteria for reviewing the licensee's task analysis are identified below.

- (1) The licensee should identify the information that is required to inform personnel that the HA is necessary, that the HA has been correctly performed, and that the HA can be terminated.
- (2) Task analyses should provide detailed descriptions of what the personnel must do. The licensee should identify how human tasks or performance requirements are being changed. All types of information from Table 3.1 that are relevant to the HA should be addressed.
- (3) The task analysis should consider all human tasks including monitoring of automated system(s) and performing backup actions if the system fails.
- (4) The task analysis should address the full range of plant conditions and situational factors, and performance shaping factors anticipated to influence human performance. The range of plant operating modes relevant to the HAs (e.g., abnormal and emergency operations, transient conditions, and low-power and shutdown conditions) should be included in the task analysis.
- (5) The human task requirements that result from the changes in the actions should be assessed to determine whether they are compatible with each individual's responsibilities (i.e., will not interfere with or be disrupted by the cognitive and physical demands of other tasks and responsibilities).

Table 3.1 Types of Task Analysis Output

Type of Information	Example
Information Requirements	identify proper component identify proper control identify relevant task parameters (units, precision, and accuracy) identify results of control actions identify when actions are completed
Decision-making Requirements	decisions type (relative, absolute, probabilistic) evaluations to be performed
Response/Performance Requirements	type of action to be taken task frequency, tolerance and accuracy task completion time and temporal constraints (task ordering) physical position (stand, sit, squat, etc.) biomechanics <ul style="list-style-type: none"> - movements (lift, push, turn, pull, crank, etc.) - forces required
Communication Requirements	personnel communication
Workload	cognitive physical overlap of task requirements (serial vs. parallel task elements)
Task Support Requirements	special and protective clothing job aids or reference materials required tools and equipment required
Workplace Factors	ingress and egress paths to the worksite workspace envelope required by action taken typical and extreme environmental conditions, such as lighting, temp, noise
Situational and Performance Shaping Factors	stress reduced manning
Hazard Identification	identification of hazards involved, e.g., potential personal injury

- (6) Certain human tasks will need qualified instrumentation in accordance with RG 1.97 (NRC, 1983). The task analysis should identify the necessary safety grade of the control and display equipment used for human tasks. The RG defines Type A variables as "those variables to be monitored that provide the primary information required to permit the control room operators to take the specified manually controlled actions for which no automatic control is provided and that are required for safety systems to accomplish their safety function for design basis accident events" (NRC, 1983, p. 1.87-4). Primary information is further defined in the RG as information that is essential for the direct accomplishment of the specified safety functions, but does not include those variables that are associated with contingency actions that may also be identified in written procedures. Table 1 of RG 1.97 provides detailed Category 1 criteria that Type A variables should meet. In general, these Category 1 criteria provide for environmental and seismic qualification, redundancy, quality assurance, continuous display, good human factors design, and an emergency power supply. Therefore, HAs, which are required for safety systems to accomplish their safety function for design basis accident events and for which no automatic control is provided, will need control and display instrumentation in accordance with RG 1.97. (This RG allows for consideration of alternative approaches that are adequately justified and include consideration of the risk significance of the actions involved.) Thus, credit should only be given for these types of HAs if they can be completed using control and display instrumentation that is consistent with RG 1.97.
- (7) The task analysis should identify reasonable or credible, potential errors, including the following types:
- Errors of omission (i.e., failure to perform actions)
 - Foreseeable errors of commission (i.e., performing actions that are not required, as when personnel incorrectly assess conditions; performing the correct action on the wrong control, including controls not related to the action; performing the wrong action or actions on the right control; performing actions in the wrong sequence).
- Errors of omission and commission should be determined for credible scenarios in which the HAs might be performed. The scenarios should include multiple-failure events.
- (8) The potential consequences of errors should be identified. The licensee should address how errors can be prevented, detected, and recovered from. The ability of personnel to recover from errors in the performance of manual actions and the expected time required to make such a recovery should be evaluated.
- (9) The required time for task completion should be determined from analyses such as task

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and time line analyses of event scenarios, safety analyses, risk analysis, and thermal-hydraulic analysis, as appropriate. These analyses should include time for recovering from credible human errors, as described in NRC Information Notice 97-78 (NRC, 1997). (The required time for task completion should be compared to estimates of the time actually needed by personnel to complete the tasks. This is addressed in Section 3.11, Human Factors Verification and Validation).

3.6 Staffing

Objective

The objective of this review is to provide adequate assurance that the licensee has analyzed the proposed change in HAs to determine the number and qualifications of personnel based on task requirements and applicable regulatory requirements. Adding additional manual actions or shifting tasks to periods of high workload may increase staffing requirements.

Scope

The staffing analysis addresses personnel requirements for all conditions in which the HA may be performed.

Criteria

The criteria for reviewing the licensee's staffing analysis are identified below.

- (1) Staffing levels should be evaluated to determine their adequacy with respect to any additional burden that may be imposed by the plant or HA modifications. The staffing levels should be adjusted if necessary. The evaluation should be based on an analysis of
 - Current nominal (typical shift complement of personnel) and minimal staffing levels (as identified administrative procedures)
 - Required actions determined from the task analysis
 - The physical configuration of the work environment (e.g., control room and control consoles configurations that may affect the ability of personnel to work together)
 - The availability of plant information from individual workstations from individual and group view components of the HSI
 - Required interaction between personnel for situation assessment, planning, and

control activities

- Availability of personnel considering other activities that may be ongoing and for other possible responsibilities outside the control room (e.g., fire brigade)
- Required interaction between personnel for administrative, communications, and reporting activities
- Relevant actions described by 10 CFR 50.47 and NUREG-0654 (NRC, 1980) (to provide an acceptable, initial response to key functional areas required by the emergency plan).

3.7 Probabilistic Risk and Human Reliability Analysis

Objective

The objectives of this review are to provide adequate assurance that the licensee has (1) updated the PRA model to reflect system, component, and HA changes that may be necessary based on the proposed modification or HAs; (2) performed an analysis of the potential effects of the proposed changes upon plant safety and reliability, in a manner consistent with current, accepted PRA/HRA principles and practices, and (3) the risk insights derived from the results are addressed in the selection of HAs; development of procedures, HSI components, and training in order to limit risk and the likelihood of personnel error and to provide for error detection and recovery capability.

Scope

This review addresses PRAs and HRAs conducted by the licensee to evaluate changes in systems, components, and human tasks that result from the proposed changes in HAs.

Criteria

The criteria for reviewing the licensee's PRA and HRA activities are identified below.

- (1) The PRA and HRA should be modified to reflect the changes in systems, components, and human tasks. Human interactions with plant systems and components should be analyzed at least at the level modeled in the plant's current PRA.
- (2) The HRA should follow a structured, systematic, and auditable process to provide adequate assurance that the reliability of the HA is accurately estimated so that its effect on plant safety using the PRA can be assessed.

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- (3) The PRA/HRA should address any human interactions that may be involved with the modified plant systems and components at the level currently modeled in the plant PRA, for example,
 - Errors of omission and commission
 - Miscalibration and component restoration errors
 - Recovery actions
- (4) The analysis of HAs should include the identification of performance shaping factors (PSFs), that is, factors that influence human reliability through their effects on performance. PSFs include factors such as environmental conditions, HSI design, procedures, training, and supervision.
- (5) Human-system analyses and evaluations should be used to provide an understanding of task requirements including (a) demands placed on plant personnel, (b) interfaces with plant equipment, and (c) time constraints within which critical tasks must be accomplished. The analysis of human tasks should at a minimum include (a) descriptions and analyses of human tasks developed during the task analysis, (b) modified plant procedures, and (c) modified HSI design characteristics.
- (6) Human error quantification methods (such as the technique for human error rate prediction, THERP, Swain and Guttman, 1983), performance models (such as action dependency), human error data sources (such as the "Nuclear Computerized Library for Assessing Reactor Reliability" (NUCLARR), Gertman et al., 1990), and PSFs should be specifically identified and selected on the basis of their appropriateness to the types of actions being analyzed. When data from PRAs, performed for other plants, are to be used in the HRA, a rationale should be provided to justify its use including any modifications of these data.
- (7) Because of the inherent uncertainty of numerical estimation, sensitivity and/or uncertainty analyses should be performed.
- (8) Risk-important HAs associated with the modification should be identified from the PRA/HRA and used as input to the design of procedures, HSI components, and training. These actions should be developed from the Level 1 (core damage) PRA and Level 2 (release from containment) PRA including both internal and external events. They should be developed using selected (more than one) importance measures and HRA sensitivity analyses to provide adequate assurance that an important action is not overlooked because of the selection of the measure or the use of a particular assumption in the analysis.

- (9) Risk-important HAs that are identified by means of PRA/HRA as posing definite challenges to plant safety and reliability (e.g., those in Region I) should be analyzed by function allocation analysis, task analysis, HSI design, procedure design, and training to minimize the likelihood of human error and provide for error detection and recovery capability. Some actions (e.g., those resulting in risk well into Region I) should cause the planned design change or modification to be reconsidered. Other alternatives considered should include automation.
- (10) The licensee should use the information from the modified PRA/HRA to calculate changes in CDF, LERF, and integrated risk (if a temporary change is involved). These values should be plotted on the screening Figures of Section 2 to indicate the relative risk significance of the modification in question.

3.8 Human-System Interface Design

Objective

The objective of this review is to evaluate the HSI design, for those changes in HAs that require changes to the HSI, to provide adequate assurance that the licensee has appropriately translated function and task requirements into the detailed design of the HSI through the systematic application of HFE principles and criteria.

Scope

This review addresses the design of temporary and permanent modifications to the HSI, including new HSI components and the modification of existing ones, for the proposed changes in the HAs. The intended focus of this review is the *designs* that result from the HSI design process. Where changes in HAs result in modifications to large portions of the HSI or in the use of HSI technologies that do not have proven operating histories, the review may also examine the HSI design *process* using the review criteria of Sections 8.4.2 and 8.4.3 of NUREG-0711, Rev. 1. The review addresses aspects of the HSI and the work environment that affect the ability of the personnel to perform the HAs. Depending upon the scope of the HAs and the HSI components used to perform those actions, the review may include the following:

- (1) Control and display device design
- (2) Information and control interface design details, such as graphic display formats, symbols, dialog design and input methods.
- (3) Workspace layout (e.g., main control room and remote shutdown facility layouts)
- (4) Control panel, console, and workstation layouts

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- (5) Overall work environment (e.g., temperature, humidity, ventilation, illumination, and noise)

Criteria

The criteria for reviewing the licensee's HSI design are identified below.

- (1) The following sources of information should provide input to the HSI design process, as applicable:
- Regulatory requirements - Applicable regulatory requirements should be identified as inputs to the HSI design process.
 - Analysis of personnel task requirements - The analyses performed in earlier stages of the design process should be used to identify requirements for the HSI. These analyses include:
 - Functional requirement analysis and allocation
 - Task analysis
 - Staffing analyses
 - System requirements - Constraints imposed by the overall instrumentation and control (I&C) system should be considered throughout the HSI design process, including functional requirement specification, concept design, detailed design, and design integration.
 - Predecessor designs - Lessons learned from the OER regarding other complex human-machine systems that have similar human tasks or similar HSI technologies should be used as an input to the HSI design.
 - HFE guidelines - HFE guidelines should be used to provide information regarding characteristics that the HSI design should possess.
- (2) Functional requirements for modifications to the HSI should be developed to address:
- Personnel functions and tasks that support their role in the plant as derived from function, task, and staffing analyses
 - Personnel requirements for a safe, comfortable working environment.

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- (3) The design should seek to minimize the probability that errors will occur and maximize the probability that errors will be detected and personnel will be able to recover from them.
- (4) When developing HSI components for actions performed either in the control room or locally in the plant, the following factors should be considered:
 - Communication, coordination, and workload
 - Feedback
 - Local environment
 - Inspection, test, and maintenance.
- (5) The layout of HSI components within consoles, panels, and workstations should be based upon (1) analyses of human roles (job analysis) and (2) systematic strategies for organization such as arrangement by importance, frequency of use, and sequence of use.
- (6) Personnel and task performance should be supported during minimal, nominal, and high-level staffing.
- (7) HSI characteristics should support human performance under the full range of environmental conditions, e.g., normal as well as credible extreme conditions. For the main control room requirements should address conditions such as loss of lighting, loss of ventilation, and main control room evacuation. For the remote shutdown facility and local control stations, requirements should address constraints imposed by the ambient environment (e.g., noise, temperature, contamination) and by protective clothing (if necessary).
- (8) The HSI should be designed to support inspection, maintenance, test, and repair of both plant equipment and the HSI. The HSI should be designed so that inspection, maintenance, test, and repair of the HSI does not interfere with other plant control activities (e.g., maintenance tags should not block the view of plant indications).
- (9) Changes to the HSI design should be documented to include:
 - The detailed HSI description including its form, function and performance characteristics
 - The basis for the HSI design characteristics with respect to operating experience

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and literature analyses, tradeoff studies, engineering evaluations and experiments, and benchmark evaluations

- Records of the basis of the design changes.

3.9 Procedure Design

Objective

The objective of this review is to provide adequate assurance that applicable plant procedures have been appropriately modified, where needed, to provide adequate guidance for the successful completion of the HAs, and that the procedures adequately reflect changes in plant equipment and HAs. In the procedure development process, HFE principles and criteria should be applied along with all other design requirements to develop procedure modifications that are technically accurate, comprehensive, explicit, easy to use, and validated.

Scope

This review addresses all plant procedures that provide guidance to personnel for the affected actions, including the following types

- Emergency operating procedures (EOPs)
- Plant and system operations (including startup, power, and shutdown operations)
- Abnormal and emergency operations
- Alarm response

The scope includes both temporary and permanent modifications to these procedures.

Criteria

The criteria for reviewing the licensee's procedure modifications are identified below.

- (1) Plant procedures should be modified to provide new guidance for the proposed changes in the HAs. Exceptions may be made where the adequacy of the existing procedures can be justified. Such a justification should indicate how the existing procedures provide necessary and sufficient guidance for the changed HAs and do not contain information that is inaccurate or no longer relevant.
- (2) The basis for procedure development should include

- Plant design bases
 - System-based technical requirements and specifications
 - Task analyses results for revised HAs
 - Risk-important HAs identified in the HRA/PRA
 - Initiating events to be considered in the EOPs, including those events in the design bases
 - EOPs and generic technical guidelines (GTGs).
- (3) Procedures should identify how the operating crew should independently verify that the HAs have been successfully performed.
 - (4) All procedures should be verified and validated to provide adequate assurance that they are correct and can be carried out. Their final validation should be performed as part of the validation activities described in Section 3.11.
 - (5) If the change in the HAs also involves the introduction of a computer-based procedure system, then a review should be conducted to determine the impact of providing computer-based procedures (CBPs) and to specify where such an approach would improve procedure utilization and reduce operating crew errors related to procedure use. The justifiable use of CBPs over paper procedures should be documented. An analysis of alternatives in the event of loss of CBPs should be performed and documented.
 - (6) Any changes in the HSI should be reflected in the modifications of the procedures.
 - (7) Procedural modifications should be integrated across the full set of procedures; alterations in particular parts of the procedures should not conflict nor be inconsistent with other parts. For example, an HSI component that is modified for a HA may also affect other actions that have not been modified. Therefore, procedure changes should not be limited to only the changed HAs.

3.10 Training Program Design

Objective

The objective of this review is to provide adequate assurance that the licensee's training program results in adequate training for the HAs. The review should provide adequate assurance that

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appropriate training has been developed and conducted for the HAs, including any changes in qualifications, as described in NRC Information Notice 97-78 (NRC, 1997).

Scope

This review addresses the licensee's training programs for all licensed and non-licensed personnel who perform the changed HAs. The scope includes both temporary and permanent modifications to training programs.

Criteria

The criteria for reviewing the licensee's training program are identified below.

- (1) The licensee's training program should be modified to address the knowledge and skill requirements for all changes in HAs for the licensed and non-licensed personnel. The scope of the training should include:
 - Pertinent plant functions and systems
 - The full range of relevant HSI components
 - The full range of relevant procedures
 - The range of plant conditions in which in the HAs might be performed
- (2) Learning objectives should be derived from an analysis that describes desired performance for the HAs after training has been completed. This analysis should include but not be limited to training issues identified in the following HFE activities:
 - Operating Experience Review - previous training deficiencies and operational problems that may be corrected through additional and enhanced training, and positive characteristics of previous training programs
 - Function Analysis and Allocation - functions identified as new or modified, if applicable
 - Task Analysis - tasks identified during task analysis as posing unusual demands, new or different tasks, and tasks requiring high coordination, high workload, or special skills

- Human Reliability Assessment - requirements for coordinating individual roles to reduce the likelihood and/or consequences of human error associated with HAs
- HSI Design - design features whose purpose or operation may be different from the past experience or expectations of personnel or otherwise difficult to use
- Plant Procedures - tasks that have been identified during procedure development as being problematic (e.g., procedure steps that have undergone extensive revision as a result of plant safety concerns).

3.11 Human Factors Verification and Validation

Objective

Verification and validation (V&V) consists of five activities with the following objectives:

- (1) HSI task support verification - Provide adequate assurance that the HFE/HSI design provides all necessary alarms, displays, and controls to support plant personnel tasks.
- (2) HFE design verification - Provide adequate assurance that the HFE/HSI design conforms to HFE principles, guidelines, and standards.
- (3) Integrated system validation - Provide adequate assurance that the HFE/HSI design can be effectively operated by personnel within all performance requirements applicable to the HA, including the following
 - All pertinent staffing considerations are acceptable for nominal and minimal shift levels, such as shift staffing, assignment of tasks to crew members, and crew coordination within the control room and between the control room and local control stations and support centers.
 - The HAs can be accomplished within time and performance criteria
 - The integrated system performance is consistent with all functional requirements, including tolerance of failures of individual HSI features
- (4) Final plant HFE/HSI design verification - Provide adequate assurance that the final product as built conforms to the verified and validated design that resulted from the HFE design process.

Scope

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- (1) The general scope of V&V includes the following factors as applicable to the proposed changes to the HAs:
 - HSI hardware and software
 - Procedures
 - Workstation and console configurations
 - Design of the overall work environment
 - Trained personnel
- (2) The typical order of V&V activities is:
 - HSI task support verification
 - HFE design verification
 - Integrated system validation
 - Human factors issue resolution verification
 - Final plant HFE/HSI design verification
- (3) All V&V activities are applicable regardless of whether the change in the HA involves changes in the HSI.

Criteria

HSI Task Support Verification

- (1) All aspects of the HSI (e.g., controls, displays, procedures, and data processing) that are required to accomplish the HAs should be verified as available through the HSI. For HAs that require qualified instrumentation in accordance with RG 1.97, it should be verified that the HSI provides such qualified instrumentation.

HFE Design Verification

- (1) All aspects of the HSI (e.g., controls, displays, procedures, and data processing) used for the HAs should be verified as consistent with accepted HFE guidelines, standards, and principles.

- (2) Deviations from accepted HFE guidelines, standards, and principles should be acceptably justified on the basis of a documented rationale such as trade study results, literature-based evaluations, demonstrated operational experience, or tests and experiments.

Integrated System Validation

Validation Testbeds

- (1) For HAs performed in the main control room, the plant training simulator should be used as the testbed when conducting the validation tests.
- (2) For HAs performed at locations outside of the main control room, the use of a simulation or mockup should be considered to verify that human performance requirements can be achieved. If a simulation or mockup is not available, then considerations should be given to conducting drills in the plant. The conduct of these drills should not interfere with plant operations (e.g., drills may be conducted when the plant is shutdown or the affected systems are removed from service).
- (3) When simulations or mockups are used to evaluate HAs performed outside of the main control room, the important characteristics of the task-related HSI components and task environment (e.g., lighting, noise, heating and ventilation, and protective clothing and equipment) should be included in the testbed.

Plant Personnel

- (1) Participants in the validation tests should be the plant personnel who will perform the changed actions. Actions that will be performed by licensed personnel should be validated using licensed personnel rather than training or engineering personnel. Similarly, actions allocated to non-licensed personnel should be validated using non-licensed personnel.
- (2) To properly account for human variability, each of the normal crews should participate in the validation tests. This will help provide adequate assurance that variation along most of the significant dimensions that influence human performance are included in the validation tests. Participation is not necessary for personnel who do not normally operate or maintain the plant (e.g., administrative personnel who hold operating licenses). If all crews are not included in the validation tests then a justification should be provided, indicating how the sample of personnel includes all of the relevant capabilities and characteristics to the overall population and is not biased by specific characteristics (e.g., the sample included the best operators).
- (3) In selection of personnel, consideration should be given to the assembly of nominal and

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minimum crew configurations, including shift supervisors, reactor operators, shift technical advisors, etc., that will participate in the validation tests. The composition of operations personnel need only include categories of personnel that are relevant to the HAs.

Operational Conditions

- (1) Integrated system validation should include dynamic evaluations for a range of operational conditions for which the HA is required. Conditions that are expected to contribute to system performance variation should be specifically identified.
- (2) The scenarios should reflect a range of situational factors that are known to challenge human performance, such as:
 - Failure events, such as I&C instrumentation and HSI failures
 - Adverse or inhospitable environmental conditions such as poor lighting, extreme temperatures, high noise, and simulated radiological contamination.
- (3) The operational conditions should be developed into detailed scenarios. The following information should be defined to provide adequate assurance that important performance dimensions are addressed and to allow scenarios to be accurately presented for repeated trials:
 - Description of the scenario mission and any pertinent "prior history" necessary for personnel to understand the state of the plant upon scenario start-up
 - Specific initial conditions (precise definition provided for plant functions, processes, systems, component conditions and performance parameters)
 - Events (e.g., failures) to occur and their initiating conditions, e.g., time, parameter values, or events
 - Precise definition of workplace factors, such as environmental conditions
 - Data to be collected and the precise specification of what, when and how data are to be obtained and stored (including videotaping requirements, questionnaire and rating scale administrations)
 - Specific criteria for terminating the scenario.
- (4) Scenarios should have appropriate task fidelity so that realistic task performance will be

observed in the validation tests and so that results can be generalized to actual operation in the real plant.

- (5) When evaluating performance associated with the use of HSI components located remote from the main control room, the effects on crew performance due to potentially harsh environments (i.e., high radiation) should be realistically simulated (i.e., additional time to don protective clothing and access radiologically controlled areas).

Plant Performance Measurement

- (1) The variables used in the performance measures should include performance of the plant and personnel, as described below.
- (2) Measures that assess personnel task performance should be used, including the following:
 - For each specific scenario, the tasks that personnel *are required to* perform should be identified and assessed. Such tasks can include necessary primary (e.g., start a pump) as well as secondary (e.g., access the pump status display) tasks. This analysis should be used for the identification of errors of omission by identifying tasks which should be performed. The proper completion of required tasks should be verified.
 - The tasks that are *actually* performed by personnel during simulated scenarios should be identified and quantified.
 - The variable(s) used to quantify tasks should be chosen to reflect the important aspects of the task with respect to system performance, such as:
 - Task success or failure
 - Task completion time
 - Errors (omission and commission)
 - Subjective reports of participants
- (3) Performance criteria for the measures used in the evaluations should be established. The approach used for establishing the criteria should be based upon the type of comparisons made between the measures and criteria, e.g., requirement-referenced, benchmark referenced, normative referenced, and expert-judgement referenced. (See "performance criteria" in the glossary for a definition of these terms and O'Hara, et al., 1997, for a more in-depth discussion).

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- (4) Anthropometric and physiological factors include such concerns as visibility of indications, accessibility of control devices, and ease of control device manipulation. These factors should be assessed where appropriate so they can be addressed should difficulties arise.

Validation Test Design

- (1) Scenario Sequencing - When crews perform more than one scenario, the order in which scenarios are presented to crews should be balanced to provide adequate assurance that the same types of scenarios are not always being presented in the same position, e.g., the easy scenarios are not always presented first.
- (2) Validation Test Procedures - Detailed, clear, and objective validation test procedures should be available to govern the conduct of the validation tests. They should be developed with the goal of minimizing opportunities for tester expectancy bias and participant response bias. These procedures should include:
- Information pertaining to the experimental design, i.e., an identification of which crews receive which scenarios and the order that the scenarios should be presented.
 - Detailed and standardized instructions for briefing the participants to minimize this source of bias.
 - Specific criteria for the conduct of specific scenarios, such as when to start and stop scenarios, when events such as faults are introduced, and other information discussed in Operational Conditions, Criterion 3 above.
 - Scripted responses for test personnel who will be acting as plant personnel during validation test scenarios.
 - Guidance on when and how to interact with participants when simulator or testing difficulties occur.
 - Instructions regarding when and how to collect and store data via the various collection techniques (simulation computers, special purpose data collection devices, video recorders, observation checklists, and subjective rating scales and questionnaires).
 - Procedures for documenting validation data, i.e., identifying and maintaining validation test record files.

- (3) Validation Test Personnel Qualifications - Validation test administration personnel should be knowledgeable of the use and importance of validation test procedures, the types of errors that may be introduced into validation test data through the failure to follow validation test procedures or interact properly with participants, and the importance of accurately documenting the validation tests.
- (4) Participant Training - Participants should be trained in the HA, including the use of any new or revised operating procedures and HSI, and interactions with other personnel. Participants should be trained to near asymptotic performance (i.e., stable, not significantly changing from trial to trial) and tested prior to conducting actual validation test trials.
- (5) Pilot Testing - A pilot study should be conducted prior to conducting the integrated validation tests to provide an opportunity to assess the adequacy of the validation test design, performance measures, and data collection methods.

Data Analysis and Interpretation

- (1) Validation test data, time and errors, should be analyzed through a combination of quantitative and qualitative methods.
- (2) The relationship between observed performance data and the established performance criteria should be clearly established and justified based upon the analyses performed. Time data should be analyzed by the licensee to determine the confidence level that the HA can be performed within the time criterion. Attachment C provides an approach that may be used for making this analysis.
- (3) The statistical and logical basis for the determination that performance of the integrated system is and will be acceptable should be clearly documented.

Final Design Verification

- (1) Following design process V&V activities, a design description should be developed that describes the detailed design and its performance criteria.
- (2) Aspects of the design that were not addressed in design process V&V should be evaluated using an appropriate V&V method. Aspects of the design addressed by this criteria may include features that cannot be evaluated in a simulator, such as CR lighting and noise.
- (3) The in-plant HFE (e.g., the HSI, procedures, and training implemented in the plant) should conform to the design description that resulted from the HFE design process and V&V activities.

3.12 Human Performance Monitoring Strategy

Objective

The objective of this review is to provide adequate assurance that the licensee has prepared a human performance monitoring strategy for ensuring that no adverse safety degradation occurs because of the changes that are made and to provide adequate assurance that the conclusions that have been drawn from the evaluation remain valid over time. A human performance monitoring strategy will help to ensure that the confidence developed by the completion of the integrated system validation is maintained over time. There is no intent to periodically repeat the full integrated system validation, however, there should be sufficient evidence to provide reasonable confidence that operators have maintained the skills necessary to accomplish the assumed actions.

The results of the monitoring need not be reported to the NRC, but should be retained onsite for inspection.

Scope

The scope of the performance monitoring strategy should provide adequate assurance that the:

- (1) HFE/HSI design can be effectively operated by personnel, including within the control room and between the control room and local control stations and support centers.
- (2) HAs can be accomplished within time and performance criteria.
- (3) Integrated system performance is maintained within the performance established by the integrated system validation.

Criteria

- (1) A human performance monitoring strategy should be developed and documented by the licensee. The strategy should be capable of trending human performance after the changes have been implemented to demonstrate that performance is consistent with that assumed in the various analyses that were conducted to justify the change. Licensees may integrate, or coordinate, their performance monitoring for risk-informed changes with existing programs for monitoring operator performance, such as the licensed operator training program. If a plant change requires monitoring of actions that are not included in existing training programs, it may be advantageous for a licensee to adjust the existing training program rather than to develop additional monitoring programs for risk-informed purposes.

- (2) The program should be structured such that (1) HAs are monitored commensurate with their safety importance, (2) feedback of information and corrective actions are accomplished in a timely manner, and (3) degradation in performance can be detected and corrected before plant safety is compromised.
- (3) Plant or operator performance under actual design conditions may not be readily measurable. When actual conditions cannot be simulated, monitored, or measured, whatever information most closely approximates performance data in actual conditions should be used.
- (4) As part of the monitoring program, it is important that provisions for specific cause determination, trending of performance degradation and failures, and corrective actions be included. The cause determination should identify the cause of the failure or degraded performance to the extent that corrective action can be identified that would preclude the problem or provide adequate assurance that it is anticipated prior to becoming a safety concern. The program should address failure significance, the circumstances surrounding the failure or degraded performance, the characteristics of the failure, and whether the failure is isolated or has generic or common cause implications. The monitoring program should identify and establish any corrective actions necessary to preclude the recurrence of unacceptable failures or degraded performance.

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The guidance presented in this section was derived mainly from RG 1.174, NUREG-0711, and NUREG-0700, Rev 1. These documents can be consulted for additional information.

4.1 General Deterministic Review Criteria

Objective

The objective of this section is to provide adequate assurance that deterministic aspects of design, as discussed in RG 1.174, have been appropriately considered by the licensee. Deterministic aspects include: ensuring the change meets current regulations; and does not compromise defense-in-depth.

Scope

The deterministic review criteria are applicable to all modifications associated with Region II HAs.

Criteria

- (1) The licensee should provide adequate assurance that the change meets current regulations, except where specific exemptions are requested under 10 CFR 50.12 or 10 CFR 2.802. Examples of regulations that may be affected by a change, but that may be identified as risk significant when using a standard PRA to screen for risk include the following: 10 CFR 20, 10 CFR 50 Appendix A, Criterion 19, and 10 CFR 50 Appendices C through R.
- (2) The licensee should provide adequate assurance that the change does not compromise defense-in-depth. Defense-in-depth is one of the fundamental principles upon which the plant was designed and built. Defense-in-depth uses multiple means to accomplish safety functions and to prevent the release of radioactive materials. It is important in accounting for uncertainties in equipment and human performance, and for ensuring some protection remains even in the face of significant breakdowns in particular areas. Defense-in-depth may be changed but should overall be maintained. Important aspects of defense-in-depth include:
 - A reasonable balance is preserved among prevention of core damage, prevention of containment failure, and consequence mitigation.
 - There is no over-reliance on programmatic activities to compensate for weaknesses in plant design.

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- System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers).
- Defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed.
- Independence of barriers is not degraded.
- Defenses against human errors are preserved.
- The intent of the General Design Criteria in Appendix A to 10 CFR Part 50 is maintained.

4.2 Analysis

Objective

The objective of the review is to provide adequate assurance that the licensee has analyzed the changes to HA and identified HFE inputs for any modifications to the HSI, procedures, and training that may be necessary.

Scope

The review criteria are applicable to all modifications associated with Region II HAs.

Criteria

- (1) *Operating Experience Review* - Operating experience should be identified that is related to the plant system(s) and HAs that need to be addressed by the plant modifications. Appropriate input to the design should be made based on the results of the operating experience review.
- (2) *Functional and Task Analysis*
 - The licensee should identify how the personnel will know when the HA is necessary, that is performed correctly, and when it can be terminated.
 - Task analyses should provide detailed descriptions of what the personnel must do. The licensee should identify how human tasks or performance requirements are being changed. All types of information from Table 3.1 that are relevant to the HA should be addressed.

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- The task analysis should identify reasonable or credible, potential errors and their consequences, including the following types: Errors of omission (i.e., failure to perform actions within the required time), and foreseeable errors of commission (i.e., performing actions that are not required, as when personnel incorrectly assess conditions; performing the correct action on the wrong control, including controls not related to the action; performing the wrong action or actions on the right control; performing actions in the wrong sequence). The licensee should address how errors can be prevented, detected, and recovered from.
- (3) *Staffing* - The effects of the changes in HAs upon the number and qualifications of current staffing levels of operations personnel for normal and minimal staffing conditions.

4.3 Design of HSIs, Procedures, and Training

Objective

The objective of the review is to provide adequate assurance that the licensee has supported the HA by appropriate modifications to the HSI, procedures, and training.

Scope

The review criteria are applicable to all modifications associated with Region II HAs.

Criteria

- (1) *HSIs* - Temporary and permanent modifications to the HSI should be identified and described. The modifications should be based on task requirements, HFE guidelines, and resolution of operating experience issues.
- (2) *Procedures* - Temporary and permanent modifications to plant procedures should be identified and described. The modifications should be based on task requirements and resolution of operating experience issues. Justification should be provided when the plant procedures are not modified for changes in operator tasks.
- (3) *Training* - Temporary and permanent modifications to the operator training program should be identified and described. The modifications should be based on task requirements and resolution of operating experience issues. Justification should be provided when the training program is not modified for changes in operator tasks.

4.4 Human Action Verification

Objective

The objective of this review is to provide adequate assurance that the licensee has demonstrated that the HA can be successfully accomplished with the modified HSI, procedures, and training.

Scope

The review criteria are applicable to all modifications associated with Region II HAs.

Criteria

- (1) An evaluation should be conducted at the actual HSI to determine that all required HSI components, as identified by the task analysis, are available and accessible.
- (2) A walk-through of the HA under realistic conditions should be performed to determine that:
 - The procedures are complete, technically accurate, and usable
 - The training program appropriately addressed the changes in plant systems and HAs
 - The HAs can be completed within the time criterion for each scenario that is applicable to the HAs.

The scenario used should include any complicating factors that are expected to impact the crew's ability to perform the HA.

- (3) The walk-throughs should include at least one crew of actual operators.

5 FINAL DECISION ON ACCEPTANCE OF HUMAN ACTIONS

Once the various portions of the NRC review of a proposed change in HAs are completed, a final decision must be made. At this point a significant amount of information has been gathered, reviewed, and evaluated that can be used to assist in the final decision. This information includes:

- the various risk values related to the change or modification, including their location on the acceptance guideline figures,
- the time associated with the change,
- the results of the Region I or Region II review, which includes both human factors information relating to the ability of operators to reliably perform the actions in question, as well as deterministic review aspects of the proposed change,
- answers to RAIs that NRC has developed providing additional information or commitments,
- other factors related to the plant in question that may bear on the decision.

These various factors need to be considered in an integrated risk-informed fashion, that considers risk, but does not wholly base the final decision on risk. RG 1.174 notes that the use of PRA technology should be increased in all regulatory matters, but it should be done in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy. RG 1.174 also notes that decisions concerning proposed changes are expected to be reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information. The review guidance in this document takes these concepts into consideration.

It is noted that HAs in the high-risk area of Region I are generally not desired, but there are certainly examples of such actions in plants today, e.g., the PWR ECCS switchover situation described in Generic Issue B-17. Also, there may be extenuating circumstances in which the licensee can adequately justify a modification to add a Region I HA, e.g., if the change is temporary or if there are other changes that lower the CDF. Another important consideration is whether and how well the licensee has addressed the HFE aspects of the modification.

The results of the different elements of the various analyses discussed in Sections 2, 3, and 4 must be considered in an integrated manner. None of the individual analyses is sufficient in and of itself. Thus, the decision will not be driven solely by the numerical results of the PRA. Each type of information helps in building an overall picture of the implications of the proposed change on risk. The PRA has an important role in putting the change into its proper context as it impacts the plant as a whole. As the discussion in the previous section indicates, both

5 FINAL DECISION ON ACCEPTANCE OF HUMAN ACTIONS

quantitative and qualitative arguments may be brought to bear. Even though the different pieces of evidence used to argue that the principle is satisfied may not be combined in a formal way, they need to be clearly documented. The proposed change should be given increased NRC management attention when the calculated values of the changes in the risk metrics approach the criterion levels of the guidelines.

The main factors in the decision process are discussed here first and then supplementary decision factors are listed that may assist when the decision is difficult to make.

Main Decision Factors

- (1) *Change in CDF* - One consideration is the value of ΔCDF_{mod} or the increase in Core Damage Frequency due to the modification, as well as the ΔCDF_{HA} or the increase in CDF due to failing the HA in question. The placement of these values into the regions of Figure 2.1 can also be considered. In many cases the ΔCDF_{HA} will be notably larger than the ΔCDF_{mod} . The confidence one has that the change in CDF is at the value shown by ΔCDF_{mod} is partially determined by the results of the human factors review noted in #3 below.
- (2) *Change in LERF* - Another consideration is ΔLERF , similar to CDF in #1 above.
- (3) *Human Factors* - Another consideration is the degree of confidence that operators can perform the actions required for the modification in question. This is determined by the aggregate evaluation in Sections 3.2 through 3.12 of the Region I review guidance and Sections 4.2 through 4.4 of the Region II review guidance.
- (4) *Deterministic Criteria* - Another consideration is the more traditional deterministic review guidance provided in Section 3.1 of the Region I review guidance and Section 4.1 of the Region II review guidance.
- (5) *Time and Integrated Risk* - Another consideration is the length of time that the change will be in place, if only a temporary modification. The integrated risk over time can be considered, per Section 2.4 above.

Supplemental Decision Factors

Additional factors may also be used, as appropriate, to determine the acceptability of a change. These include:

- The cumulative impact of previous changes and the trend in CDF (the licensee's risk management approach)

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- The cumulative impact of previous changes and the trend in LERF (the licensee's risk management approach)
- The impact of the proposed change on operational complexity, burden on the operating staff, and overall safety practices
- Plant-specific performance and other factors (for example, siting factors, inspection findings, performance indicators, and operational events), and Level 3 PRA information, if available
- The benefit of the change in relation to its CDF/LERF increase
- The practicality of accomplishing the change with a smaller CDF/LERF impact
- The practicality of reducing CDF/LERF when there is reason to believe that the baseline CDF/LERF are above the guideline values (i.e., 10^{-4} and 10^{-5} per reactor year).

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GLOSSARY

Component - An individual piece of equipment such as a pump, valve, or vessel; usually part of a plant system.

Function - An action that is required to achieve a desired goal. Safety functions are those functions that serve to ensure higher-level objectives and are often defined in terms of a boundary or entity that is important to plant integrity and the prevention of the release of radioactive materials. A typical safety function is "reactivity control." A high-level objective, such as preventing the release of radioactive material to the environment, is one that designers strive to achieve through the design of the plant and that plant operators strive to achieve through proper operation of the plant. The function is often described without reference to specific plant systems and components or the level of human and machine intervention that is required to carry out this action. Functions are often accomplished through some combination of lower-level functions, such as "reactor trip." The process of manipulating lower-level functions to satisfy a higher-level function is defined here as a control function. During function allocation the control function is assigned to human and machine elements.

Human-system interface (HSI) - The means through which personnel interact with the plant, including the alarms, displays, controls, and job performance aids. Generically this includes maintenance, test, and inspection interfaces as well.

Human factors - A body of scientific facts about human characteristics. The term covers all biomedical, psychological, and psychosocial considerations; it includes, but is not limited to, principles and applications in the areas of human factors engineering, personnel selection, training, job performance aids, and human performance evaluation (see "Human factors engineering").

Human factors engineering (HFE) - The application of knowledge about human capabilities and limitations to plant, system, and equipment design. HFE ensures that the plant, system, or equipment design, human tasks, and work environment are compatible with the sensory, perceptual, cognitive, and physical attributes of the personnel who operate, maintain, and support it (see "Human factors").

Mockup - A static representation of an HSI (see "Simulator").

Performance criteria - The criteria against which measured performance is compared in order to judge its acceptability. Approaches to the establishment of performance criteria include:

Requirement Referenced - This is a comparison of the performance of the integrated system with respect to an accepted, quantified, performance requirement. For many variables a requirement-referenced approach can be used; i.e., requirements for plant, system, and operator performance can be defined through engineering analysis as part of

the design process. Plant parameters governed by technical specifications and time requirements for critical operator actions are examples of performance measures for which a requirement-referenced criteria can be determined. For performance measures where such specific requirement referenced criteria cannot be used alternative criteria development methods must be used.

Benchmark Referenced - This is a comparison of the performance of the integrated system with that of a benchmark system which is predefined as acceptable under the same conditions or equivalent conditions. Such an approach is typically employed when no accepted independent performance requirements can be established. Performance is evaluated through comparisons to an accepted benchmark rather than through an absolute measurement. For example, the evaluation may test whether the plant under review can be operated to stay within a level of operator workload not exceeding that associated with Plant X. Plant X is identified as acceptable for reasons such as its acceptable operating history and operators report their workload levels to be acceptable. In this case the performance measure must be obtained for Plant X and the new system, under similar operational conditions, and then compared. In the establishment of benchmark-referenced criteria, similar test conditions should be established for the benchmark system and system under evaluation.

Normative Referenced - Normative-referenced comparison is similar to a benchmark reference comparison, however, the performance criterion is not based upon a single comparison system, it is based upon norms established for the performance measure through its use in many system evaluations. The new system performs as compared to the norms established under the same conditions or equivalent conditions. This approach can be used when no accepted independent performance requirements can be established, but repeated use of the same performance measure enables the development of performance norms for acceptable and unacceptable systems.

Expert-Judgement Referenced - This is a comparison of the performance of the integrated system with criteria established through the judgement of SMEs.

Performance shaping factors (PSFs) - Factors that influence human reliability through their effects on performance. PSFs include factors such as environmental conditions, HSI design, procedures, training, and supervision.

Primary tasks - Those tasks performed by the operator to supervise the plant; i.e., monitoring, detection, situation assessment, response planning, and response implementation.

Safety-related operator action - A manual action required by plant emergency procedures that is necessary to cause a safety-related system to perform its safety-related function during the course of any Design Basis Event. The successful performance of a safety-related operator

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action might require that discrete manipulations be performed in a specific order.

Secondary tasks - Those tasks that the operator must perform when interfacing with the plant, but are not directed to the primary task. Secondary tasks may include: navigating through and paging displays, searching for data, choosing between multiple ways of accomplishing the same task, and making decisions regarding how to configure the interface.

Simulator - A facility that physically represents the HSI configuration and that dynamically represents the operating characteristics and responses of the plant in real time (see "Mockup").

Subject Actions - the operator actions that are being modified or that will accomplish an actions previously accomplished by automatic systems

System - An integrated collection of plant components and control elements that operate alone or with other plant systems to perform a function.

Task - A group of activities that have a common purpose, often occurring in temporal proximity, and that utilize the same displays and controls

Testbed - The representation of the human-system interface and the process model used in testing.

Validation - The process by which the integrated system (consisting of hardware, software, and personnel elements) is evaluated to determine whether it acceptably supports safe operation of the plant.

Validity - The characteristics of the methods and tools used in the validation process. See the specific uses of the term: construct validity, convergent validity, performance representation validity, statistical conclusion validity, system representation validity, and test design validity.

Verification - The process by which the human-system interface design is evaluated to determine whether it acceptably reflects personnel task requirements and HFE design guidance.

Vigilance - The degree to which an operator is alert.

Workload - The physical and cognitive demands placed on plant personnel.

ATTACHMENT A

Generic Risk-Important Human Actions

This attachment contains two tables of generic risk-important HAs for BWRs and PWRs, respectively. Each table is further divided into "Group 1" risk-important HAs and "Group 2" potentially risk-important HAs. To facilitate readability of the tables, the names of common events and plant systems are given in acronyms. These acronyms are defined in the acronym list on page xv of this report.

Table A.1 Generic BWR Risk-Important Human Actions

Group 1: BWR Risk-Important Human Actions	
Human Actions	Description and Reasons for Risk-Importance
Perform Manual Depressurization	On selected sequences, such as SBO, manual depressurization is required after failure of high pressure injection systems to allow for injection with low pressure systems. A complicating factor is that some procedures initially direct the operator to inhibit ADS. In some PRAs this appears in cutsets up to 45 % of CDF. Operators typically depressurize by manually operating the SRV.
Vent Containment	On a transient or LOCA sequence, with failure of the PCS, containment temperature and pressure increase and must be controlled. This can be done by containment heat removal, suppression pool cooling, or containment venting. Actions are required to remove DH before adverse conditions are reached (e.g., high Suppression Pool temperature leading to loss of ECCS pumps).
Align Containment or Suppression Pool Cooling	
Initiate SLC	Manual initiation of SLC is needed for ATWS sequences.
Actions During Shutdown	Almost all actions, including actuation of various equipment, are done manually during shutdown. The operator's understanding of the plant configuration is necessary for the successful manual actions.

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Group 2: BWR Potentially Risk-Important Human Actions	
Human Actions	Description and Reasons for Risk-Importance
Level Control in ATWS	Effective Rx Vessel level manual control at lower than normal levels (e.g., near the top of the active fuel) is needed during an ATWS in order to reduce core power.
Align/Initiate Alternative Injection	During loss of injection and loss of DHR events, alternate sources of injection must be manually aligned and initiated. Sources may include: SW, firewater, CRD, FW booster pumps, SP cleanup, and a few plant unique systems.
Recover Ultimate Heat Sink	The importance of recovery of SW or the ultimate heat sink depends on the cooling requirements of mitigating systems and the time available before they fail after loss of cooling. Recovery is also needed to allow adequate removal of DH from the core and containment. Some of these are possible from the main CR, while others require local operator actions.
Inhibit ADS	Some IPEs conclude that core damage will occur if ADS is not manually inhibited in an ATWS event due to instabilities created at low pressures.
Mis-calibrate Pressure Switches	Various pressure switches are important for initiating ECCS and operating ECCS permissives. Common cause mis-calibration of these switches can affect multiple trains of safety systems.
Initiate IC	For the early design BWR plants, this action is important during accidents to ensure the continued viability of the cooling from the IC.
Control FW Events	The actions of operators to properly control the FW system as an injection source after loss-of-instrument air can be important in transient and small LOCA sequences.
Manually Initiate Core Spray or Other Low Pressure System	Where low pressure injection systems fail to automatically actuate, operator action to manually initiate them becomes necessary.
Mis-calibrate Low Pressure Core Spray Permissives	Personnel calibrate the permissive needed to open the low pressure core spray and LPCI injection valves, which are needed in several sequences. Miscalibrate can lead to failure of these systems also included in this action is the failure to restore these permissive after testing.
Provide Alternate Room Cooling	On transient sequences, loss of HVAC (due to various reasons) can jeopardize ECCS equipment operation causing its failure and loss of all core cooling. The operators may be able to take actions to provide alternate room cooling, such as opening doors and providing blowers. Particular important rooms are plant specific. An example of such a room is the HPCI room.
Recover Injection Systems	This action relates to operator recovery of failed or unavailable injection systems and can be important in sequences where such failures are dominant.
Shedding of DC Load After SBO	While often not well modeled, operator action to shed DC loads is needed to extend the battery charge in order to operate the AC independent HPCI and RCIC systems and to keep the SRVs open (to allow low pressure vessel injection from a diesel-driven fire pump). This extends the time to core damage and the time that operators have for recovery of AC power.
Similar actions to those in Group I	Actions that are substantially similar (but not identical) to those contained in Group 1 of this Table should be considered as potentially risk important, if they involve the same systems, components, or actions.
Actions involving the most risk-important systems	Each plant has one or two systems that are clearly the most risk significant in the plant. Human actions associated with these systems should be considered as potentially risk important. When modifications associated with these risk important systems are being considered, new human actions may be created that were not in the original PRA, but that will be risk important.

Table A.2 Generic PWR Risk-Important Human Actions

Group 1: PWR Risk-Important Human Actions	
Human Actions	Description and Reasons for Risk-Importance
Restore Room Cooling	In scenarios involving loss of the HVAC system, the room cooling can be re-established either by recovery of HVAC or opening doors and utilizing portable fans. Particular important rooms are plant specific. An example is the ECCS rooms.
Establish Recirculation	In LOCA scenarios, the switching of ECCS lines from the injection to the recirculation mode is done manually. Failure to do so or human error involving the valve alignment is important.
Feed and Bleed	Failure of the operator to initiate and perform the feed and bleed operation of the reactor coolant system as a last resort of heat removal is important.
Provide Water Supply for AFW	Use of water pumps to transfer water, from other sources of make up to the CST for use by AFW, is considered important in scenarios when long term cooling through SG is needed.
Extend Battery Duration	In SBO scenarios, the operator can extend the duration of the availability of DC by load management and load shedding to assure the availability of turbine driven AFW pump and the necessary instrumentation and control. This human action is considered important in most PRAs.
Recover Emergency AC or Offsite Power	Some losses of AC power can be recovered by either manual transfer of the source of power, or recovery of onsite normal/emergency AC power. This recovery action is considered risk significant in many PRAs.
Action During Shutdown	Almost all actions, including actuation of various equipment, are done manually during shutdown. The operator's understanding of the plant configuration is necessary for the successful manual actions.

Group 2: PWR Potentially Risk-Important Human Actions	
Human Actions	Description and Reasons for Risk-Importance
Make up to RWST	In some Westinghouse 3-loop plants, credit is given for operator action to provide make up to the RWST.
Recover of RCP Seal Cooling	In some plants there are means of alternate cooling for RCP seals that could be relied on in scenarios involving loss of CCW. However, the alignment of the system is manual and requires operator action.
Actions in Response to ATWS	Upon failure of RPS, the operator should perform several actions, starting with manual scram, ensuring turbine trip, and most importantly initiating boron injection.
Isolate ISLOCA	In some plants there is a capability to isolate an interfacing systems LOCA through manual actions. Operator failure to isolate an interfacing LOCA in the LPI system is considered risk significant in these plants.
Initiate AFWS	This human action involves failure to manually start the motor driven AFW pump, given auto start failure, and failure to manually start the locked-out turbine driven AFW pump.
Similar Actions to Those in Group I	Actions that are substantially similar to those contained in Group 1 of this Table should be considered as potentially risk important, if they involve the same systems, components, or actions.
Actions Involving the Most Risk Important Systems	Each plant has one or two systems that are clearly the most risk significant in the plant. Human actions associated with these systems should be considered as potentially risk important. When modifications associated with these risk important systems, are being considered new human actions may be created that were not in the original PRA, but that will be risk important.

ATTACHMENT B

Example Application of Screening Process

Application to the NUREG-1150 Model

This example uses one of the NUREG-1150 plant PRA models, a BWR, to present two test cases that simulate actual plant changes, where credited operator actions would replace automatic equipment actuations. The PRA was reviewed to determine a suitable risk-important automatic component. The Emergency Service Water (ESW) valve on the outlet of the Emergency Diesel Generator (EDG) heat exchanger was selected. Each of the four EDGs has an ESW valve that opens automatically on EDG start in order to provide cooling water to the diesel (valves A, B, C, and D). This is one of the most risk-important individual components modeled in the PRA.

The first example case assumes that there is a mechanical problem with this valve on one EDG that cannot quickly be repaired. Therefore, the licensee has requested that they be allowed to credit an operator with opening the valve manually when required. The second example case assumes that there is some design problem common to all four valves that requires operator action to open them.

Case 1 - Valve for One EDG

This example case assumes that an operator action will replace the automatic opening of valve B. The failure rate of the valve to operate automatically is 1×10^{-3} failures /demand. This will be replaced in the PRA model with an operator action that has an appropriate human error probability (HEP). The NUREG-1150 PRA for the plant was examined for similar operator actions to determine an appropriate HEP to use. Similar actions were identified with HEPs that varied from 0.06 to 0.1. Screening HEP values of 0.5 were also used in the PRA for operator actions, where detailed HEP calculations were not developed. Thus, this example was run twice, with HEPs of both 0.06 and 0.1 to bracket the reasonable values and also to obtain sensitivity results that would illustrate how the results may be affected by uncertainty in the HEP values.

Risk screening calculations were carried out and the results plotted in Figure B.1 to see which risk regions they fall into. The following screening parameters were computed:

$\Delta CDF_{\text{mod}} = [\text{new CDF (with modifications in-place)} - \text{current baseline CDF}]$, and

$\Delta CDF_{\text{HA}} = \text{RAW (new HA)} = [\text{CDF with new HA failed} - \text{new CDF (with modifications in-place)}]$.

These values were computed for the two HEP cases.

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The ΔCDF_{mod} values for both HEP cases fall into Region II. The ΔCDF_{mod} is not strongly affected by changing the assumed HEP from 0.06 to 0.1. The core damage frequency will increase by a bit less than $5\text{E-}6/\text{Rx-year}$, due to this change in the plant. If one assumes that the needed operator action fails, then the figure shows that the ΔCDF_{HA} is in Region I. The increase in CDF is about $4\text{E-}5/\text{Rx-year}$. Again there is little sensitivity in the CDF increase value to the assumption of whether the HEP is 0.06 or 0.1. Based on our risk screening criteria, the most conservative result (of ΔCDF_{mod} or ΔCDF_{HA}) should be chosen for use in the risk screening process. Therefore, this modification falls in Region I and would receive the Region I review. The Region I review is detailed and should ensure that the operator action to open the valve would be successfully performed when needed. This should in turn provide confidence that the increase in CDF would be at the lower ΔCDF_{mod} value rather than at the higher ΔCDF_{HA} value.

One can also evaluate the integrated risk due to the change to one ESW valve per Section 2.4 of the risk screening process. For this evaluation the time that the change will be in place (in years) is multiplied by the ΔCDF_{mod} . This illustration used times of 1, 6, and 12 months that the change would be in place. Figure B.2 below shows the results for HEP values of 0.06 and 0.1. As time increases, the integrated risk increases. Nonetheless, for all of the three periods and both HEPs postulated, the integrated risk related to the change remains in Region III. This would tend to indicate that the integrated risk is reasonable. Note that this does assume that appropriate steps are in place in the plant to ensure the human error probabilities (HEPs) stay at the assumed values. The Region I HFE review should support this assumption.

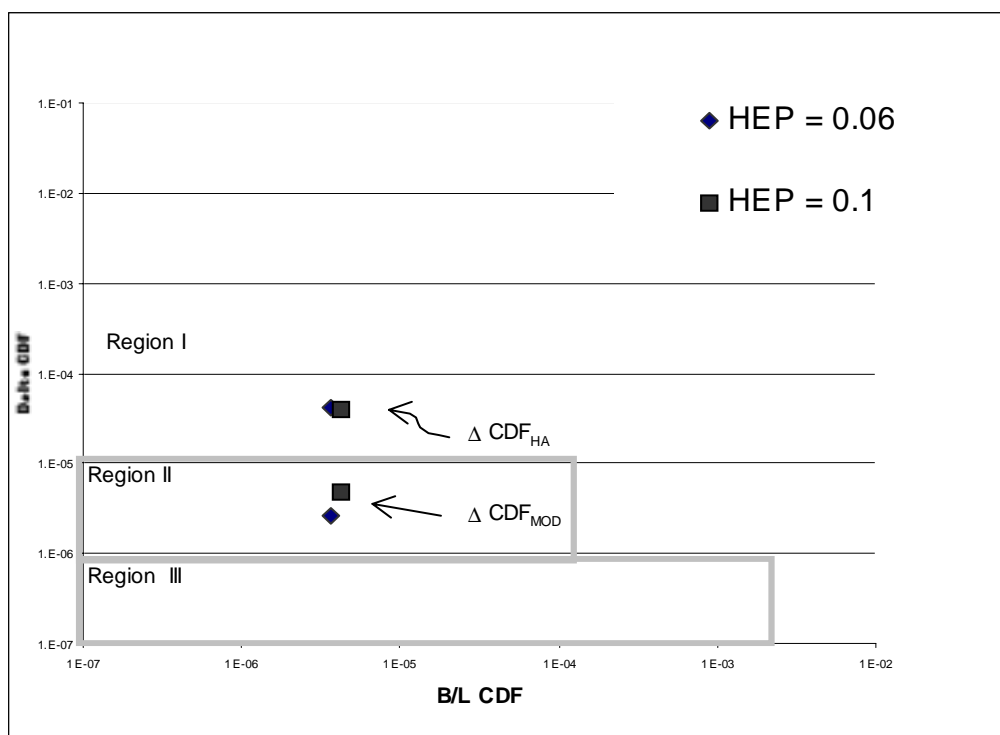


Figure B.1 Modifications to One Valve

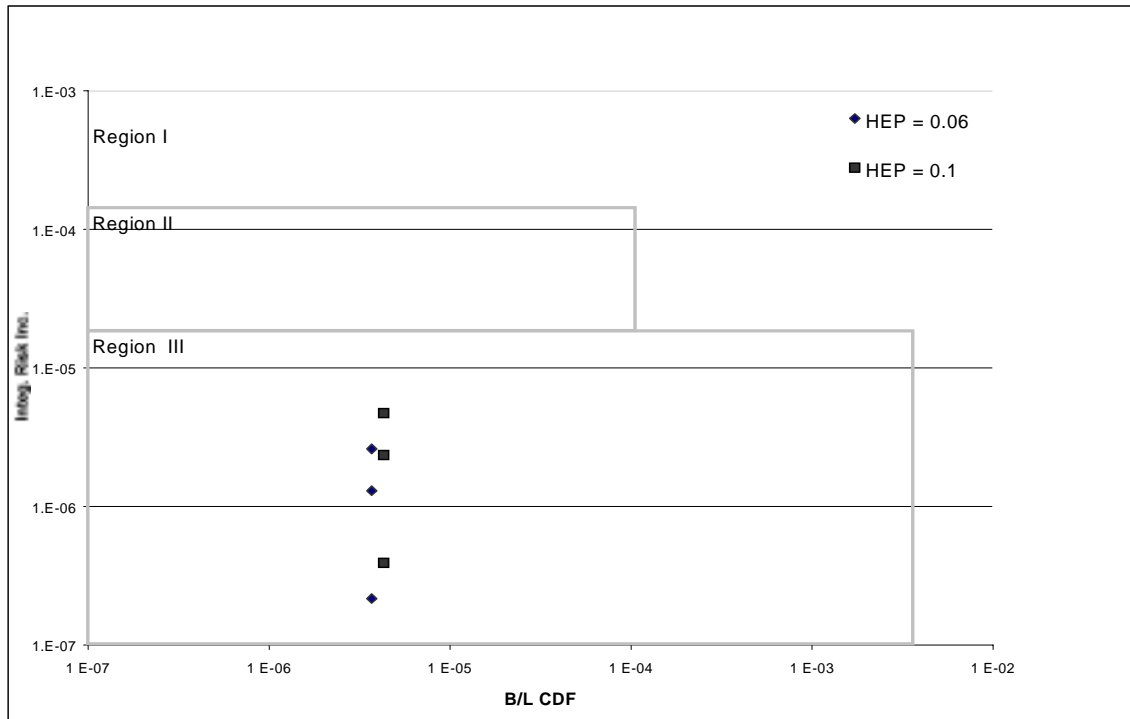


Figure B.2 Integrated Risk, Modifications to One Valve

Case 2 - Valves for All Four EDGs

In this example, operator actions are needed to replace the automatic opening of all four ESW valves from the EDGs. The failure rate of the valves to operate in automatic is 1xE-3 failures/-demand. This was replaced in the PRA model with an operator action with HEPs of 0.06 and 0.1 as above.

Risk screening calculations for ΔCDF_{mod} and ΔCDF_{HA} were conducted and the results plotted in Figure B.3.

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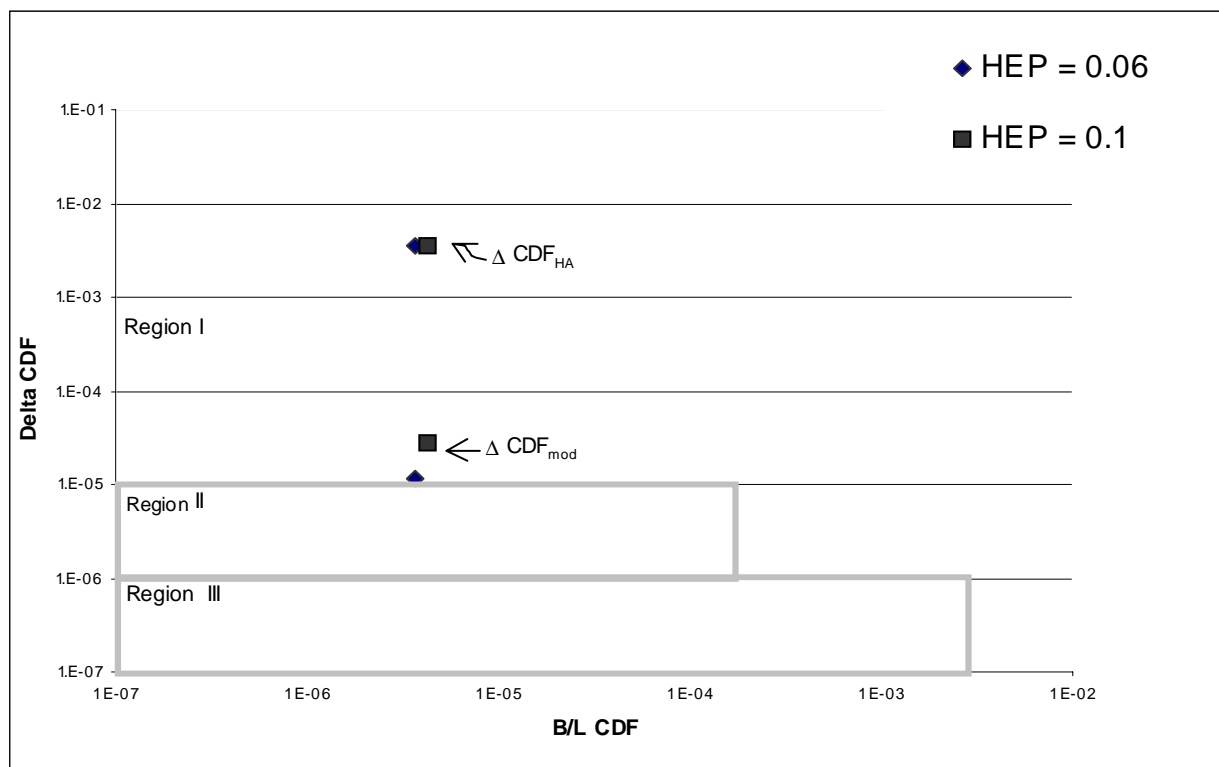


Figure B.3 Modification to All 4 Valves

The ΔCDF_{mod} for both HEP values falls inside the Region I area of the Figure. The value is not strongly dependent on the HEP selected. The two values of ΔCDF_{HA} are above 1E-03 and are significantly into Region I. Due to the high risk if the operator actions fail, as indicated by the ΔCDF_{HA} values, NRC may consider disapproving this proposed change without performing the detailed Region I review. However, such a decision should not be based strictly on risk considerations. Other factors, as noted in Section 5, should be considered. If the NRC decides to perform the detailed Region I review, it is important to ensure that the actions can be successfully and reliably performed.

Again, one can evaluate the integrated risk due to the change to all four ESW valves per Section 2.4 of the risk screening process. The time that the change will be in place is multiplied by the ΔCDF_{mod} . This example also used times of 1, 6, and 12 months. Figure B.4 below shows that for five of the six cases, the change remained in Region III. For the case of 12 months and an HEP of 0.1, the change entered Region II. This would tend to indicate that the integrated risk is reasonable. Again, note that this does assume that appropriate steps are in place in the plant to ensure the HEP stays at the assumed values. The Region I HFE review should support this assumption.

The integrated risk evaluation gives additional information to consider in the decision process.

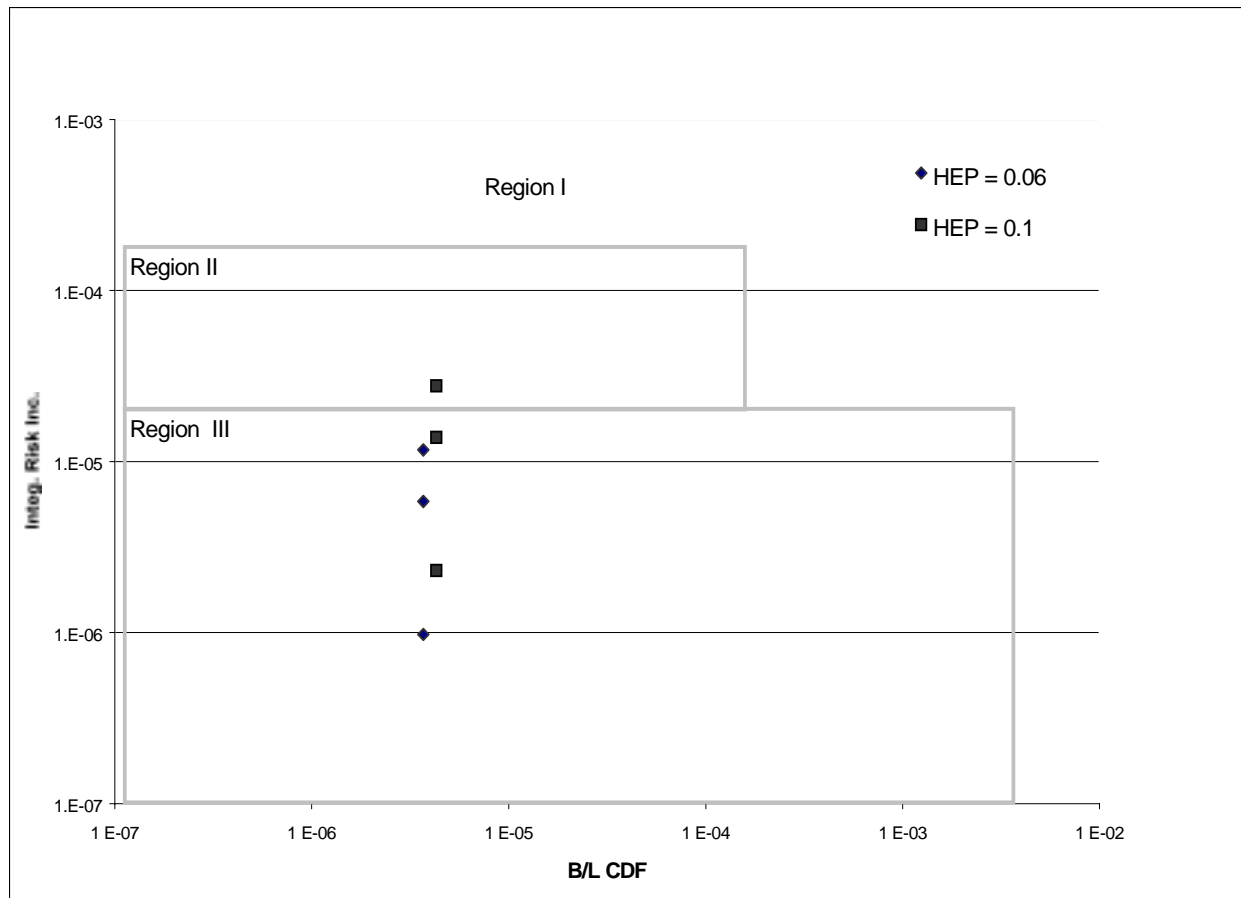


Figure B.4 Integrated Risk for Four Valve Case

ATTACHMENT C

An Approach to the Statistical Analysis of Time Data

The Region 1 Review validation methodology yields a sample of time data that can be compared with the time criterion (the time available to perform the action). This attachment describes a simple method for making this comparison. While the analysis is quite simple, an example is provided for readers unfamiliar with basic statistics.

The approach uses the variability of the completion times observed in a limited number of test trials to estimate proportion of crews that would be expected to complete an action within the time criterion (or, equivalently, the time within which an acceptable proportion of crews would be expected to complete the scenario). It is assumed that if a large number of crews completed a given scenario the times taken to complete the scenario would be distributed normally, and that the times actually collected in test trials are sampled randomly from such a distribution.

Due to the variability of task performance, only probabilistic statements can be made about the adequacy of performance relative to a time criterion, e.g., that there is a high probability that a task will be completed within the available time.

Relating time data to probabilities involves two steps. First the mean and standard deviation of the sample values are calculated; then tabled values of probabilities associated with standard normal scores are used to estimate quantities of interest. The process is described in detail, with examples, below.

Step 1. Calculate the mean and standard deviation of the observed values

First, calculate the average time taken to perform the task, i.e., the arithmetic mean of the observed completion times:

$$T_{\text{avg}} = (T_1 + T_2 + \dots T_N)/N$$

Example: Suppose the following times were observed:

Crew ₁	=	2 minutes
Crew ₂	=	4 minutes
Crew ₃	=	6 minutes
Crew ₄	=	6 minutes
Crew ₅	=	7 minutes

$$\begin{aligned} T_{\text{avg}} &= (2 + 4 + 6 + 6 + 7)/5 \\ &= 25/5 \\ &= 5 \end{aligned}$$

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Then calculate the standard deviation (SD) of observed values from the average using the following formula:

$$SD = \sqrt{\frac{\sum (T_n - T_{avg})^2}{N - 1}}$$

Example:

$$SD = \sqrt{\frac{9+1+1+1+4}{5-1}} = 2$$

With this information, and tabled normal probability values (see Table C.1), either one of two logically equivalent estimates can be made. One can estimate the proportion of crews expected to complete an action within a specified time criterion (2A), or one can estimate the time within which a specified proportion of crews would be expected to complete an action (2B).

Step 2A. The proportion of crews expected to complete an action within the available time

To estimate the proportion of crews expected to complete an action within a specified time, first express the criterion time in terms of standard deviation units from the sample mean. For example, assume for example that 10 minutes are available to complete the action. The number of standard deviations between the mean and the criterion value (the z score) is given by the following formula:

$$z = (T_c - T_{avg}) / SD$$

Example:

$$\begin{aligned} z &= (T_c - T_{avg}) / SD \\ &= (10 - 5) / 2 \\ &= 2.5 \end{aligned}$$

Next, determine the probability associated with the criterion time. This value may be determined by using a table of probability values for portions of a standard normal distribution. Such tables are provided in most introductory-level textbooks on probability and statistics. Selected values from such a table are given in Table C.1.

Based on the table, if the criterion time is 2.5 standard deviation units above the sample mean, it is expected (based on the sample data and the assumptions described above) that roughly 99.5%

of crews would complete the action within 10 minutes.

Step 2B. The time within which a given proportion of crews would be expected to complete an action

One can estimate the time within which a specified proportion of crews will complete an action by multiplying the tabled z value for the chosen probability by the standard deviation based on the sample and adding the result to the average value for the sample. For example, to estimate the time within which 98% of crews would be expected complete an action, first determine from the table the z -score associated with the probability value; a proportion of .98 corresponds to a z -score of about 2. Then multiply this value by the standard deviation and add the result to the sample average:

$$\begin{aligned} T_{.98} &= T_{\text{avg}} + (z_{.98} \cdot SD) \\ &= 5 + (2 \cdot 2) \\ &= 9 \text{ minutes} \end{aligned}$$

Thus, based on the sample data and the assumptions described above, 98% of crews would be expected to complete the action in 9 minutes or less.

Table C.1 Selected z -Scores and Normal Probabilities

z	Proportion
0.00	0.5
0.25	0.6
0.52	0.7
0.84	0.8
1.28	0.9
1.64	0.95
2.06	0.98
2.33	0.99
2.57	0.995

NOTE: Since the mean and standard deviation are estimated from very few cases, and because proportions less than .90 are not of practical interest, the values shown in this table should provide sufficient resolution for the purposes of this analysis. If needed,

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intermediate values can be obtained from tables of the area under the normal probability curve, which can be found in any text on statistics, probability, or quality control.

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