RAIO-0618-60581

June 21, 2018

Docket No. 52-048

U.S. Nuclear Regulatory Commission
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SUBJECT: NuScale Power, LLC Response to NRC Request for Additional Information No. 432 (eRAI No. 9415) on the NuScale Design Certification Application

REFERENCE: U.S. Nuclear Regulatory Commission, "Request for Additional Information No. 432 (eRAI No. 9415)," dated April 23, 2018

The purpose of this letter is to provide the NuScale Power, LLC (NuScale) response to the referenced NRC Request for Additional Information (RAI).

The Enclosure to this letter contains NuScale's response to the following RAI Question from NRC eRAI No. 9415:

- 18-46

This letter and the enclosed response make no new regulatory commitments and no revisions to any existing regulatory commitments.

If you have any questions on this response, please contact Steven Mirsky at 240-833-3001 or at smirsky@nuscalepower.com.

Sincerely,

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Enclosure 1: NuScale Response to NRC Request for Additional Information eRAI No. 9415

Enclosure 1:

NuScale Response to NRC Request for Additional Information eRAI No. 9415

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Response to Request for Additional Information
Docket No. 52-048

eRAI No.: 9415
Date of RAI Issue: 04/23/2018

NRC Question No.: 18-46

Regulatory Basis

10 CFR 52.47(b)(1) requires a design certification application to contain the proposed inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a plant that incorporates the design certification is built and should operate in accordance with the design certification, the provisions of the Atomic Energy Act, and the NRC's regulations.

The NRC uses 10 CFR 50.34(f)(2)(iii) as the basis to regulate the human factors aspects of a main control room design. This regulation indicates that designers of plants must apply state-of-the-art human factors principles when designing the main control room. Chapter 18 of the standard review plan (NUREG-0800) and NUREG-0711 direct NRC staff regarding the review of human factors considerations in the design of nuclear power plant control rooms. NUREG-0711 identifies design implementation as one of the twelve elements of an acceptable human factors program and provides acceptance criteria that staff use to review an applicant's design implementation (DI) implementation plan (IP).

Background Information

Design Implementation Objectives

The human factors design process described in NUREG-0711 considers design implementation to be one of the 12 elements necessary in a state-of-the-art human factors program. The design implementation element objectives found in Section 12.2 of NUREG-0711 are paraphrased below:

1. Verify that the as-built design conforms to the verified and validated design resulting from the human factors engineering (HFE) design process

2. Verify that the implementation of changes to the design consider the effects on human performance.

NuScale provided Revision 1 of "Human Factors Engineering Design Implementation Implementation Plan" for review with the design certification application.

Draft Standard ITAAC

A letter from NRC to NuScale dated April 8, 2016 (ML16096A121) contains a set of draft standard ITAAC that could be used in the design certification application. However, NRC staff note that the draft standard ITAAC specific to Human Factors (H01 and H02 in this document) may have been intended for a design certification application utilizing design acceptance criteria (DAC) for the human factors design. Revisions may be necessary to achieve ITAAC appropriate for the NuScale application. NuScale is not using DAC, and the design certification will include the NuScale standard plant MCR design, which is configured for the operation of 12 modules from one control room. NuScale committed to revising DCD Tier 1, Table 3.15-1, "Human Factors Engineering Inspections, Tests, Analyses, and Acceptance Criteria", in response to RAI No. 8781 (ML17172A712) resulting in one ITAAC for human factors engineering (HFE).

Description of the Issues

For the sake of clarity, staff will use the following terminology:

- **As-designed**: Refers to the HSI design described in the HSI RSR which will be the input to the HFE V&V process
- **As-designed, as modified by the V&V**: refers to the HSI design that includes all design changes necessary to resolve human engineering deficiencies (HEDs) that came out of the V&V process. The as-designed, as modified design is the output of the V&V, which includes the HED resolution processes. NuScale has committed to submitting the V&V results summary report prior to Phase 4 of the design certification review (ADAMS Accession No. ML16099A270).
- **As-designed, as modified by the DI**: refers to the design that incorporates the resolution of ultimately resolves any HEDs identified during the DI activities. This is the design that should match the "as-built" main control room design. The "as-designed, as modified by the V&V" design is the input to this process.

1. The wording in the ITAAC currently requires verifying the as-built HSI design to the as-designed HSI, as modified by the integrated system validation (ISV) report, which means comparing the as-built design to the design specifications for the standard, generic, 12-unit control room design validated during ISV (one part of the V&V process). However, after V&V, and prior to construction of the control room, a COL holder may make changes to the HSI design, control room configuration, and plant system design. The evaluation of those changes is one of the DI activities discussed in NUREG-0711, Section 12.4.1. The as-built control room HSI and configuration should therefore be verified to be consistent with the design that was validated, as modified by the DI activities.

If the wording in the ITAAC is not clarified, there could be confusion while implementing important changes to the design that occur during DI activities, and there may also be delays in closing the ITAAC. This confusion may inhibit necessary changes to the design caused by updates to the PRA (which may cause changes to important human actions and may affect procedures and training), site specific design features, and any other changes to the design that occur after the V&V is complete but before plant startup.

2. Section 4, "Addressing Important Human actions," of the DI IP is written as though important human actions will be entirely addressed during V&V for the standard plant. However, it is possible that as the COL's PRA

evolves, additional risk-important human actions (RIHAs) may be identified that should be evaluated. Also, Section 2.0, "Design Implementation Assessments," says the as-built configuration is compared to the design documents used for ISV; however, as-built configuration should also be compared to the design documents modified during DI.

3. The DI IP describes a method for resolving and closing out HEDs. It appears that in some cases, unresolved design issues may no longer be tracked and the mechanism for communicating them with a COL holder is unclear.

An appropriate process is necessary to ensure that the COL holder will appropriately consider and implement the correct scope of activities during the design implementation process. Staff have reviewed the process described in the related documents and additional information is necessary to clarify and possibly modify the processes to ensure adequate outcomes. Please provide additional information responding to the questions below.

Question 1 – Revisions to the ITAAC: Clarification of Scope

Please explain how the acceptance criteria of the HFE ITAAC in DCD Tier 1, Table 3.15-1, Revision 1, is sufficient to address design changes that may result following V&V and prior to construction. If it is not sufficient, please revise the ITAAC in DCD Tier 1, Table 3.15-1 to ensure that the as-built HSIs are consistent with the as-designed configuration of the MCR HSI as modified by design implementation activities.

Question 2 – Clarification of COL Applicant Role with DI IP & ITAAC

NUREG-0711, section 12.3 "Applicant Products and Submittals" states:

NUREG-0711 indicates that an RSR should be provided when the activities described in an implementation plan are complete. Given the nature of DI activities, staff expects that it is the responsibility of the COL holder to provide the RSR or make it available for review. However, this is not made explicit in the application.

Please clarify the strategy used to ensure that the full scope of the design implementation activities will be properly conducted and documented by the COL, and that the final results will ultimately be documented in a manner consistent with NUREG-0711, Sections 12.3 and 12.4. Clarify how the role of the COL applicant will be communicated to them using just the ITAAC or revise the application to provide appropriate COL action item(s) or additional ITAAC.

Please revise the DI IP, Sections 2 and 4 to account for changes that may occur after V&V and before plant startup.

Question 3 – Closure of HEDs that are not resolved

NUREG-0711 Criterion 12.4.1(3) states "*The applicant should verify that all HFE-related issues in the issue-tracking system are adequately addressed."*

Section 3.0 of "Human Factors Engineering Design Implementation Implementation Plan," Rev. 1, addresses the use of the Human Factors Engineering Issues Tracking System (HFEITS) for documenting and tracking Human Engineering Discrepancies (HEDs) that were generated in the human factors process and will be resolved during DI. Section 3.0 indicates that some HEDs "may be on-going due to anticipated technology or other advancements; however, all HEDs are closed prior to DI completion."

It is clear from Section 3.0 that the intent is to close all HEDs by the time that the DI RSR is complete. However, it also indicates that in some cases, it may not be advantageous to resolve HEDs by the end of DI. It is unclear how any remaining issues will ultimately be tracked and resolved by an eventual COL applicant based on Section 3.0 because all HEDs will be closed, regardless whether the issue is "on-going" or not.

Please clarify how on-going issues (which may include validation of site specific differences, scalability of the design, unit differences, modifications to the design that occurred after the V&V, operating experience from other operating NuScale plants, etc.) will be corrected by COL applicants if they are no longer documented or tracked. Also describe how it is determined which on-going issues can be closed without resolution.

NuScale Response:

Response to Question 1:

The Human Factors Engineering Design Implementation Implementation Plan (HFE DI IP), RP-0914-8544, has been revised to state that the licensee will evaluate and resolve human engineering discrepancies (HEDs) identified after completion of the human factors verification and validation (V&V) element.

To close the current HFE ITAAC, the licensee is expected to compare the as-built control room configuration, which includes any post-V&V modifications, to the HFE design configuration validated by the integrated system validation (ISV). This comparison identifies post-V&V modifications as deviations. These deviations are reconciled by verifying the deviations were caused by approved modifications. This direction has been added to the DI IP and provides the capability of evaluating the deviations for their aggregate impact.

HFE inspections, tests, analysis, and acceptance criteria (ITAAC) in Tier 1, Table 3.15-1 is sufficient because it provides for a specific evaluation of post-V&V design changes.

Response to Question 2:

In 2015 and 2016, NuScale participated in a Nuclear Energy Institute (NEI) initiative with the NRC to standardize ITAAC which resulted in the development of NEI 15-02, "Industry Guideline for the Development of Tier 1 and ITAAC under 10 CFR Part 52". This initiative reached a conclusion on ITAAC applicable to the Office of New Reactors Human Factors Engineering branch. Two ITAAC, H01 and H02, were identified and are described in NEI 15-02 draft A of Revision 0 and restated in an attachment to an NRC letter to NuScale dated April 8, 2016, entitled "Transmittal of Draft Standard ITAAC". For NuScale, H01 is not applicable because the ISV Report referenced in ITAAC H01 will be submitted in the design certification application (DCA) as part of the HFE V&V Results Summary Report (RSR). The H02 ITAAC is quoted verbatim in the FSAR, Tier 1, Section 3.15.2, "Inspections, Tests, Analysis, and Acceptance Criteria."

The use of one ITAAC instead of a COL action item or a combination of a COL action item and ITAAC is based on the following:

- The DI IP is included by reference within the DCA which will be included by reference in the 10 CFR Part 52 appendix once DCA rulemaking is completed specific to the NuScale design. Licensees referencing the NuScale DCA will be required to properly conduct and document the actions specified in the DI IP.
- ITAAC receive full regulatory governance and are prescribed by regulation for actions needed to demonstrate that "a facility... will be constructed and operated in conformity with the design certification, the provisions of the Act, and the Commission's rules and regulations."

The DI review criteria are addressed as follows:

- The V&V RSR will list any aspects of the design that were not evaluated in the ISV and an HFE issue will be opened in the NuScale human factors engineering issue tracking system (HFEITS). If the evaluation cannot be completed until the as-built control room is available, the HFE issue will be rolled into the COL holder's programs and processes as outlined in the response to Question 1. Resolution of the HFE issue would be accomplished in accordance with 10 CFR Part 50, Appendix B related programs and processes. These programs and processes provide for sufficient regulatory oversight and make submittal of a DI RSR unnecessary. (NUREG-0711 Review Criterion 12.4.1(1))
- Evaluating aspects of the HFE design not addressed in the ISV is not completed until after the DCA is approved. This activity is part of verifying the as-built configuration properly reflects the design, which is within the scope of the existing ITAAC. This ITAAC result would be reported to the NRC. A COL action item, RSR, or additional ITAAC would be redundant to the ITAAC closure notification. Negative testing results are documented in the licensee's quality assuance (QA) policy related programs and processes and provide additional documentation available for audit. Review Criterion 12.4.1(2) is specifically addressed by the ITAAC. (NUREG-0711 Review Criterion 12.4.1(2))

- NuScale will resolve all priority 1 HEDs prior to DCA approval and priority 2 HEDs prior to turnover of HFE program responsibilities to the licensee. These HEDs address safety and plant operability issues. Issue resolution for the priority 1 HEDs will be described in the V&V RSR. Lower priority issues will be resolved by the NuScale or licensee's programs and processes. These remaining issues will be appropriately controlled by virtue of being included within 10 CFR Part 50 Appendix B programs and processes. (NUREG-0711 Review Criterion 12.4.1(3))
- The V&V phase of the HFE design process will be completed as part of the DCA. The V&V RSR will identify how each Important Human Action (IHA) is addressed and will also demonstrate that each action has been effectively addressed. Design changes that potentially impact IHA performance will be evaluated during the DI element and documented as part of the HFE ITAAC closure. (NUREG-0711 Review Criterion 12.4.1(4))

Based on this strategy and the DI IP changes outlined in the response to Question 1, the existing ITAAC is sufficient and appropriate to meet regulatory requirements.

Response to Question 3:

NuScale uses the HFEITS database described in the DCA. Licensees, following the direction in the DI IP, use the programs and processes described in their QA program. The DI IP has been changed to address the documentation and tracking of issues that carry forward from or are identified after the ISV.

Priority 3 HEDs may not, in some cases, be completed prior to HFE program turnover to the licensee. Those priority 3 HEDs that are not completed will be tracked and resolved within the licensee's QA policy related programs and processes.

All HFE issues including those that might be closed without resolution are evaluated in accordance with RP-0914-8534, "Human Factors Engineering Program Management Plan," Section 5.4.7, "Human Engineering Discrepancy Resolution." The basis for issue closure without change is documented.

RP-0914-8544, Human Factors Engineering Design Implementation Implementation Plan, RP-0914-8534, Human Factors Engineering Program Management Plan, and FSAR, Section 18.11 have been revised to include specific milestones for when priority 1 and 2 HEDs are closed and to provide specific criteria for when HFE program control is turned over to the licensee. Specific direction has also been included to address how new HEDs that are identified after the V&V is complete are dispositioned.

Impact on DCA:

RP-0914-8544, Human Factors Engineering Design Implementation Implementation Plan, RP-0914-8534, Human Factors Engineering Program Management Plan, RP-0914-8543,

Human Factors Verification and Validation Implementation Plan, and Tier 2 Section 18.11 have been revised as described in the response above and as shown in the markup provided in this response.

Human Factors Engineering Design Implementation Implementation Plan

~~September 16, 2016~~
Draft Revision ~~1~~2
Docket: PROJ0769
NuScale Nonproprietary

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Department of Energy Acknowledgement and Disclaimer

This material is based upon work supported by the Department of Energy under Award Number DE-NE0000633.

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TABLES

Abstract

~~NUREG-0711 provides guidance for the development of methodologies to address the elements of the human factors engineering program. Design implementation is an element of the HFE program that verifies conformance of the as-built design to the planned design. The Design Implementation element is complete after the plant construction is complete.~~

~~This implementation plan describes the methodology for conducting the design implementation element. The methodology is consistent with the applicable provisions of Section 12 of NUREG-0711, Revision 3.~~This implementation plan describes the methodology for conducting the design implementation element of the human factors engineering (HFE) program. Design implementation is an element of the HFE program that verifies conformance of the as-built design to the planned design. The Design Implementation element is complete once the HFE inspections, tests, analyses, and acceptance criteria (ITAAC) item is closed.

The methodology described is consistent with the applicable provisions of Section 12 of U.S. Nuclear Regulatory Commission, "Human Factors Engineering Program Review Model," NUREG-0711, Rev. 3 (Reference 9.2.3).

Executive Summary

The methodology for design implementation ensures that the as-built HFE design of the NuScale Power plant accurately reflects the verified and validated design resulting from the human factors engineering design process. This implementation plan describes how ownership of the HFE program is transferred from NuScale to a licensee and the actions a licensee completes in order to close the HFE ITAAC. Design implementation activities include evaluation of those aspects of the design that were not addressed during human factors verification and validation. The methods used to verify that the final human-system interfaces, facility configuration, procedures, and training program conform to the planned design include~~ing configuration control,~~ ~~HFE~~subject matter expert reviews and~~,~~ plant walkdowns~~, and review of potential design changes~~. The HFE issues identified during these activities are documented, evaluated, and resolved in the licensee's quality assurance (QA) policy related programs and processes. Any changes to the human-system interfaces are addressed by the licensee.~~tracked as human engineering discrepancies within the HFE issues tracking system. Conformance of the as-built design to the planned design is assured by an inspections, tests, analysis, and acceptance criteria item that tracks the design implementation activities. Any changes to the human-system interfaces following fuel load are addressed by the holder of a combined license.~~

1.0 Introduction

1.1 Purpose

This document is designed to be implemented by a licensee and ensures actions needed to address the HFE ITAAC are completed. Because a transition in ownership of HFE design, configuration control, and corrective action resolution must occur, specific transition criteria are provided. Prior to meeting these criteria NuScale maintains responsibility for HFE program and process controls. When transition criteria are met, NuScale will provide a turnover package as described in Section 2.0 and the licensee assumes responsibility for the HFE program and process controls.

This document provides the implementation plan (IP) for design implementation (DI) within the NuScale ~~plant human factors engineering (~~HFE~~)~~ program. DI demonstrates that the HFE program "as-built" design of the human-system interface (HSI), facility configuration, procedures, and training program accurately reflects the verified and validated design resulting from the HFE design process. DI activities also include an evaluation of those aspects of the design that were not addressed during the human factors verification and validation (V&V) including new human error deficiencies (HEDs) identified after completion of the V&V.

Features evaluated during DI generally include those that cannot be accurately simulated:

- ergonomic considerations such as lighting and background noise
- HSIs outside of the main control room (MCR) but within the NuScale plant HFE program scope

Priority 3 ~~Human engineering discrepancies (~~HEDs identified~~) generated~~ during V&V and HEDs identified after completion of the V&V are tracked and resolved in accordance with Section 3.0 of this document. ~~that do not have any impact on plant safety or plant performance and operability, but are determined to require resolution, are resolved during DI. The HEDs that are generated after completion of V&V that are determined to require resolution are also resolved during DI. Resolution of the HEDs is in accordance with the process described in the HFE Program Management Plan (Reference 8.2.1).~~

~~Any reevaluation or HFE program activity iterations that are needed after V&V are conducted and documented during DI. The DI element of the HFE program is complete after the plant construction is complete. Any changes to the HSI following fuel load are addressed by the combined license holder.~~

Completion of DI activities ~~is tracked and confirmed by an inspections, tests, analysis, and acceptance criteria (ITAAC) item. This~~ ensures that the as-built HFE design conforms to the verified and validated design resulting from the HFE design process hereafter called the post V&V HFE design. The HFE ITAAC tracks completion of DI activities and therefore~~. Therefore~~, a results summary report (RSR) is not prepared for the DI element of the HFE program. ~~as part of design certification.~~

1.2 Scope

For the MCR and each local control station (LCS), the DI element confirms that:

- ~~the facility configuration of~~ the as-built design matches the post V&V HFE design ~~aspects of the facility that were simulated during the integrated system validation (ISV).~~
- other aspects of the facility that were not simulated but are relevant to the overall HFE program are evaluated using an appropriate V&V method.
- HFE design changes made subsequent to completion of the V&V have been properly integrated into the post V&V HFE design.

The HSIs, procedures, and training program evaluated for conformance apply to the MCR and certain LCSs during normal, abnormal, and emergency operating conditions. This IP does not apply to maintenance or refueling activities, activities completed by craft/technical personnel (i.e., mechanical, electrical, or instrumentation and control (I&C), health physics, chemistry, engineering, or information technology), or activities associated with ~~the remote shutdown station (RSS),~~ the technical support center ~~(TSC)~~, emergency operations facility ~~(EOF)~~, operations support center ~~(OSC)~~, or any other emergency response facilities ~~unless they are determined to impact licensed operator responsibilities~~ (see Reference 9.2.1).

1.3 Abbreviations and Definitions

Table 1-1. Abbreviations

Term	Definition
DC	design certification
DI	design implementation
HED	human engineering discrepancy
HFE	human factors engineering
~~HFEITS~~	~~human factors engineering issue tracking system~~
HPM	human performance monitoring
HSI	human-system interface
IHA	important human action
IP	implementation plan
ISV	integrated system validation
ITAAC	Inspections, tests, analyse~~i~~s, and acceptance criteria
LCS	local control station
MCR	main control room
NRC	Nuclear Regulatory Commission
QA	quality assurance
RSR	results summary report
~~RSS~~	~~remote shutdown station~~
SME	subject matter expert
~~TSC~~	~~technical support center~~

Term	Definition
V&V	verification and validation

2.0 Configuration Control of HSIs

Changes to the post V&V HSI design will be controlled under the NuScale Appendix B programs and processes and the applicable 10 CFR 52 Appendix, Section VIII.B.5 (50.59-like process). NuScale is responsible for maintaining HFE design configuration control until the turnover requirements are met.

NuScale design activities supporting Chapter 18 of the Design Certification (DC) are complete when the DC is approved by the NRC. Chapter 18 is supported by completion of the following:

- all priority 1 HEDs are closed
- retesting required for priority 1 HED closure is completed satisfactorily
- the V&V results summary report is submitted
- all NRC Requests for Additional Information are satisfactorily addressed

NuScale will be prepared to turnover responsibility for HFE program implementation to the licensee when:

- 10 CFR 52 Appendix specific to the NuScale DC is issued.
- the licensee's QA policy is approved by the NRC.

Approval of the QA policy establishes programs and processes comparable to those used in the NuScale HFE program. Turnover of the HFE program implementation responsibilities to the licensee is supported by the following:

- all priority 2 HEDs are closed
- retesting required for priority 2 HED closure is completed satisfactorily

Turnover of HFE responsibilities to the licensee marks the end of NuScale engineering activities associated with the DC Chapter 18 implementation.

When turnover requirements are met NuScale will provide the following material:

1. The HFE design configuration validated by the ISV.
2. The procedures and training documentation used to support the ISV.
3. NuScale Generic Technical Guidelines (GTGs) for emergency procedures.
4. HFE design changes and testing results demonstrating design change acceptability for all priority 1 HEDs identified after submittal of the V&V RSR.

5. HFE design changes and testing results demonstrating design change acceptability for all priority 2 HEDs that were not addressed in the V&V RSR.

6. HFE design changes made as a result of addressing priority 3 HEDs.

When the licensee assumes responsibility for the HFE program, they will track and resolve HEDs under their QA policy related programs and processes.

~~2.0~~3.0 Design Implementation Assessments

Design implementation uses the following methods to verify that the final HSIs, facility configuration, procedures, and training program conform to the post V&V HFE design: ~~planned design that resulted from the HFE design process and V&V activities:~~

- ~~configuration control~~
- ~~HFE~~subject matter expert (SME) review
- plant walkdowns
- ~~review of design changes~~

The licensee is responsible for completing assessments of the following elements:

- conditions that could not be accurately simulated in the ISV
- negative findings in the comparison of the as-built configuration to the post V&V HFE design
- open priority 3 HEDs
- new HEDs identified as the design matures

Each of these elements could potentially identify the need for an HFE design change. The licensee's programs and processes determine when such changes are implemented. It is expected that some HFE design changes will not have sufficient priority to be implemented prior to the ITAAC closure. For those that do, the design change amends the post V&V HFE design. The amended design is used as the standard for verifying that the as-built configuration is consistent with the design. ITAAC closure is designed to verify the amended HFE design is properly integrated with the post V&V HFE design.

To accomplish this integration the licensee performs the following actions:

- the as-built design is compared to the post V&V design. Deviations are documented.
- each deviation is justified. If the deviation is caused by implementing an approved modification then the deviation is considered justified.
- deviations that cannot be justified are resolved in accordance with Section 4.0
- when all deviations are justified, the deviations as a group are evaluated to determine if there is any collective significance that would invalidate the ISV conclusions

3.1 Human System Interface Assessment

The DI assessments for software and~~,~~ hardware~~, and facility~~ configurations confirm clear configuration-controlled design traceability for HSI components (alarms, controls, and indications~~, and procedures~~) and peripheral equipment. ~~The as-built configuration is compared to the drawings, specifications, and other final design documents used for ISV to determine conformance. If the as-built configuration is not confirmed to be in~~

~~conformance with these design documents, further HFE review is conducted to determine if the as-built HSI is equivalent to the HSI of the ISV.~~

The DI assessment for HSI configuration is conducted by plant walkdown and SME reviews and includes:

- Conformance with HFE design documents such as the HFE style guide, display schematics, drawings and specifications
- Screen navigation
- Control functionality
- Automation functionality
- Alarm and notification functionality
- Procedure interface functionality

3.2 Facility Configuration Assessment

The DI assessment for facility configuration is conducted by performing plant walkdowns ~~and includes~~that include the:

- physical configuration of workstations, panels, and displays
- visibility and sight lines
- accommodations for communication
- inclusion of emergency plan and personal protection equipment
- lighting
- background noise
- environmental controls/conditions (e.g., temperature and humidity)

The evaluation of aspects of the facility not simulated (e.g., LCSs) but relevant to the overall HFE program include:

- a walkdown to confirm conformance to the latest approved HFE design documentation including the HFE style guide.~~approved by the HFE team and that these components do not challenge conclusions of the V&V.~~
- a ~~subject matter expert (~~SME~~)~~ review of:
  - the suitability of the LCS for executing the operating procedures where operating procedures direct use of that LCS (i.e., typically not computer-based procedures).
  - the suitability of those procedures.

3.3 Procedures and Training Material Assessment

The DI assessment of procedures and training material compares the final HSIs, procedures, and training material with the post V&V HFE design and the procedures and training material supporting the development of that design. Any identified discrepancies should be corrected, or justified.

Emergency operating procedures should be evaluated against the GTGs. The GTGs provide the design basis for these procedures and are a more authoritative source than the emergency procedures used for the ISV.

- ~~an SME evaluation of training material used for the MCR and LCS HSIs to ensure it comprehensively includes the material provided to operators who participated in the ISV.~~

~~Where configuration-controlled design traceability, HFE review for HSI equivalency to the HSI of the ISV, and/or plant walkdown do not confirm that the as-built HSIs, procedures, and training program design is the planned design, an HED is generated. If an HED evaluation determines that a design change would potentially resolve the HED, a design change review is conducted to determine the significance of the differences between planned and as-built. If the design change review concludes that the design change has no impact on the completed ISV, then a specific validation method (e.g., tabletop walkthrough, mockup, part-task simulator, or plant walkdown) is determined. If the ISV results are impacted by the design changes, the applicable portion(s) of ISV are repeated.~~

~~The design change review also determines the need to reiterate or repeat other elements or activities of the HFE program and the extent of this rework.~~

~~3.0~~4.0 Human Factors Engineering Issue~~s Tracking System~~ Resolution

The following milestones are associated with HED resolution:

- all priority 1 HEDs will be resolved prior to issuing the V&V RSR.
- all priority 2 HEDs generated during V&V activities and those identified after completion of the V&V are resolved by NuScale prior to turning over configuration HFE program control to the licensee.
- all priority 3 HEDs generated during V&V and those identified after completion of the V&V are either resolved by NuScale prior to turning over HFE program responsibilities to the licensee or transferred to the licensee.

The transferred HEDs and HEDs identified during the DI activities described in Section 3.0 are tracked and resolved in the licensee's QA policy programs and processes. Some HEDs may be on-going due to anticipated technology or other advancements.

For each HED, an evaluation is conducted to determine:

- if the configuration, procedure, or training design is equivalent to the V&V HFE design. If equivalent, the basis for the equivalency shall be documented and design, procedure and training documentation revised as necessary.
- if a design change is needed to correct the as-built configuration so it conforms to the post V&V HFE design.
- If the current design is different from the post V&V design but potentially acceptable. If potentially acceptable, a design change review is conducted to determine the significance of the differences between planned and as-built. If the design change review concludes that the design change is acceptable and has no impact on the completed ISV results, then a specific validation method (e.g., tabletop walkthrough, mockup, part-task simulator, or plant walkdown) is determined. If the ISV results are impacted by the design changes, the applicable portion(s) of ISV are repeated.
- if procedure changes are necessary, procedural changes are validated in accordance with the licensee's procedure change process.
- if training changes are necessary. Training changes are validated in accordance with the licensee's program for Systematic Approach to Training.

~~HFE issues found during the DI activities described in Section 2.0 are documented, evaluated, and tracked as HEDs within the HFE issues tracking system (HFEITS) (see Reference 8.2.1). As described in the human factors V&V IP (Reference 8.2.2), HEDs from earlier HFE program elements and those generated during V&V activities are closed prior to ISV.~~

~~HEDs generated during V&V that do not affect plant safety or plant performance and operability, but determined to require resolution, and HEDs generated after completion of V&V that are determined to require resolution are *resolved* during DI. Some HEDs may not be resolved during HFE program activities and may be on-going due to anticipated technology or other advancements; however, all HEDs are *closed* prior to DI completion.~~

~~4.0~~5.0 Addressing Important Human Actions

Important human actions (IHA) are determined, addressed, and tracked by the Treatment of Important Human Actions element of the HFE program. Features that provide for reliable implementation of the~~The~~ IHAs are incorporated into the HSI ~~(alarms, controls, indications, and procedures)~~ design (e.g., alarms, controls, indications, and procedures).

As described in the human factors V&V IP (Reference 9.2.2~~8.2.2~~), IHAs are considered among the significant conditions, personnel tasks, and situational factors sampled during V&V activities as the ISV scenarios are developed. The ISV assesses the successful performance of the integrated crew and the HSI for IHAs. During V&V, HEDs are processed when discrepancies are found for any IHA. HEDs found during V&V are resolved ~~during DI~~ as described in Section 4.0~~3.0~~. A description of how the HFE program addressed each IHA is submitted as part of the V&V RSR.

~~5.0~~6.0 Additional Considerations for Human Factors Engineering Aspects of Control Room Modifications

The licensee's responsibilities for HFE program implementation begin when the 10 CFR 52 Appendix specific to the NuScale DC is issued and the licensee's QA policy is approved. Approval of the QA policy establishes programs and processes comparable to those used in the NuScale HFE program. After assuming HFE program responsibility,~~completion of start-up testing and provisional turn over,~~ a licensee institutes a human performance monitoring (HPM) program to evaluate impacts on human performance going forward. The HPM program evaluates design change proposals for HSI design, procedures, or training against the design bases established for the as-built design. ~~The design change proposal evaluation considers HEDs in HFEITS regardless of which stage of the design in which they were initiated.~~

The licensee's HFE program ~~activity~~should implement the guidance of NUREG-0711, Human Factors Engineering Program Review Model, Revision 3.~~results that are invalidated by design changes are reconducted to support plant modification without reducing human performance (see Section 2.0).~~

~~A licensee's design change process is governed by regulatory requirements such as 10 CFR 50.59, Changes, tests, and experiments (Reference 8.2.3).~~

~~6.0~~7.0 Results Summary Report

Completion of DI activities is tracked and confirmed by an ITAAC item. This ensures that the as-built design conforms to the verified and validated design resulting from the HFE design process. Therefore, an RSR is not prepared for the DI element of the HFE program as part of design certification.

~~7.0~~8.0 NUREG-0711 Conformance Evaluation

Table 8-1~~7 1~~ indicates where each NUREG-0711, Rev. 3 (Reference 0~~8.2.4~~) criterion is met in this IP.

Table 8-1~~7 1~~. Conformance with NUREG-0711

Review Criteria Stated in NUREG-0711, Rev. 3	DI IP Section No. and paragraph
12.4 Review Criteria 12.4.1 Final HFE Design Verification for New Plants and Control Room Modifications 1. The applicant should evaluate aspects of the design that were not addressed in V&V by an appropriate V&V method. *Additional Information: Aspects of the design addressed by this criterion may include design characteristics, such as new or modified displays for plant-specific design features.*	Section 1.2, all paragraphs Section 3.0~~2.0, all paragraphs~~
2. The applicant should compare the final HSIs, procedures, and training with the detailed description of the design to verify that they conform to the planned design resulting from the HFE design process and V&V activities. This verification should compare the actual HSI, procedures, and training materials to design descriptions and documents. Any identified discrepancies should be corrected, or justified. *Additional Information: Final design means the design existing in the actual plant.*	~~Section 2.0, all paragraphs~~ Section 4.0~~3.0~~, all paragraphs
3. The applicant should verify that all HFE-related issues in the issue-tracking system (Section 2.4.4) are adequately addressed.	Section 2.0~~3.0~~, all paragraphs Section 4.0, all paragraphs
4. The applicant should provide a description of how the HFE program addressed each important HA.	Section 6.0~~4.0~~, all paragraphs
12.4.2 Additional Considerations for Reviewing the HFE Aspects of Control Room Modifications In addition to any of the criteria above that are relevant to the modification being reviewed, the following should be addressed. 12.4.2.1 General Criteria for Plant Modifications 1. The applicant should provide reasonable assurance that the reactor fuel is safely monitored during the shutdown period while physical modifications to the control room are being made.	The remaining criteria are not applicable to the NuScale HFE program. They are to be addressed as part of the licensee HFE program in Section 6.0.~~N/A, Section 5.0~~
2. The applicant should verify that modifications in the plant's procedures and training reflect changes in plant systems, personnel roles and responsibilities, and in HSIs resulting from the new systems.	~~N/A,~~ Section 6.0~~5.0~~
3. Installation should be planned to minimize disruptions to work of plant personnel.	~~N/A,~~ Section 6.0~~5.0~~
4. The applicant should verify that operations and maintenance personnel are fully trained and qualified to operate and maintain all modifications made to the plant before starting up with the new systems and HSIs in place.	~~N/A,~~ Section 6.0~~5.0~~

Review Criteria Stated in NUREG-0711, Rev. 3	DI IP Section No. and paragraph
5. The applicant should have a plan to monitor start-up and initial operations after the modification to reasonably assure that: • operational and maintenance problems arising from personnel's interactions with the new systems, HSIs, and procedures are identified and addressed • personnel are sufficiently familiar with the new systems, HSIs, and procedures to support safe operations and maintenance • any negative transfer of training from the old removed HSIs to the corresponding new ones was identified and corrected • no new problems are created by coordinating tasks between the remaining old HSIs and new HSIs • no unanticipated negative effects on personnel interaction and teamwork have surfaced	~~N/A,~~ Section 6.0~~5.0~~
12.4.2.2 Modernization Programs Consisting of Many Small Modifications 1. The applicant should assure that each modification follows an HFE program that provides standardization and consistency (1) between old and new equipment, and (2) across the new systems being implemented.	~~N/A,~~ Section 6.0~~5.0~~
2. The applicant should verify that new modifications fulfill a clear operational need, and do not interfere with existing systems. *Additional Information: For example, the auditory alerts in a new HSI should not distract operators from addressing more important alarms.*	~~N/A,~~ Section 6.0~~5.0~~
12.4.2.3 Modernization Programs Consisting of Large Modifications during Multiple Outages 1. Interim configurations may exist for long times (e. g., a refueling cycle), and therefore, applicants should verify that they are acceptable from both engineering and operations perspectives and that they meet regulatory requirements. The applicant's evaluations should include: • PRA evaluations to ensure minimizing high-risk situations • FSAR evaluations to assure defense against design basis accidents • technical-specifications evaluations to determine if changes are needed • defense in depth evaluations to ensure meeting the criteria in RG 1.174	~~N/A,~~ Section 6.0~~5.0~~
2. The applicant should perform task analysis for each interim configuration to verify that any task demands are known and do not degrade personnel performance.	~~N/A,~~ Section 6.0~~5.0~~
3. The applicant should update the HRA to address any unique tasks that may impact risk, as well as any changes to existing tasks due to the interim configuration.	~~N/A,~~ Section 6.0~~5.0~~
4. The applicant should verify that the HSIs needed to perform important tasks (as defined in Section 6) are consistent and standardized. Personnel should not have to use both old and new HSIs for different aspects of the same task.	~~N/A,~~ Section 6.0~~5.0~~
5. The applicant should develop procedures for temporary configurations of systems and HSIs that personnel use when the plant is not shutdown.	~~N/A,~~ Section 6.0~~5.0~~
6. The applicant should develop training for temporary configurations of systems, HSIs, and procedures that personnel can use when the plant is not shutdown.	~~N/A,~~ Section 6.0~~5.0~~

Review Criteria Stated in NUREG-0711, Rev. 3	DI IP Section No. and paragraph
7. The applicant should consider the following aspects of V&V: • HFE Design Verification – Temporary configurations of the systems, HSIs, and procedures that operations and maintenance personnel employ when the plant is not shutdown should be reviewed to verify that their design is consistent with the principles of good HFE design (e.g., conforms to a plant-specific style guide or NUREG-0700). • HSI Task-Support Verification – Temporary configurations of the systems, HSIs, and procedures, which operations and maintenance personnel may use when the plant is not shutdown, should be reviewed to verify that their design supports the intended tasks. – Additional Information: For example, if a temporary configuration of plant systems introduces special monitoring requirements, then the HSIs should give the necessary information. • ISV - Interim configurations should be validated if so warranted by the risk significance of the personnel tasks affected by them.	~~N/A,~~ Section 6.0~~5.0~~
12.4.2.4 Modernization Programs Where both Old and New Equipment are Left in Place 1. The applicant should identify and address negative effects on personnel performance due to control room or HSI clutter resulting from using old and new HSIs in parallel.	~~N/A,~~ Section 6.0~~5.0~~
2. The applicant should identify and address negative effects on personnel performance resulting from the simultaneous presence of parallel alarms.	~~N/A,~~ Section 6.0~~5.0~~
3. The applicant should identify and address negative effects on personnel performance resulting from differences in information from old and new systems on the same parameter or equipment.	~~N/A,~~ Section 6.0~~5.0~~
4. The applicant should identify and address any safety concerns from providing controls that operators can access from two different HSIs. Additional Information: For example, a switch may be installed to select which HSI will control the equipment, thus preventing simultaneous control inputs.	~~N/A,~~ Section 6.0~~5.0~~
12.4.2.5 Modernization Programs Where New Non-functional HSIs are in Place in Parallel with Old Functional HSIs 1. The applicant should evaluate the potential for negative effects on personnel performance due to control room or HSI clutter resulting from having old and new HSIs available in parallel. Where safety concerns are identified, the applicant should take measures to improve the HSIs.	~~N/A,~~ Section 6.0~~5.0~~
2. The applicant should ensure that the non-functional state of HSIs is clearly indicated.	~~N/A,~~ Section 6.0~~5.0~~

~~8.0~~9.0 References

~~8.1~~9.1 Source Documents

~~8.1.1~~9.1.1 U.S. Nuclear Regulatory Commission, "Human Factors Engineering Program Review Model," NUREG-0711, Rev. 3, November 2012.

~~8.1.2 U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition — Human Factors Engineering," NUREG-0800, Chapter 18, Rev 2, March 2007.~~

~~8.2~~9.2 Referenced Documents

~~8.2.1~~9.2.1 Human Factors Engineering Program Management Plan, RP-0914-8534.

~~8.2.2~~9.2.2 Human Factors Verification and Validation Implementation Plan, RP-0914-8543.

~~8.2.3 *U.S. Code of Federal Regulations, "Changes, tests and experiments," Section 50.59, Part 50, Title 10, "Energy," (10 CFR 50.59).*~~

~~8.2.4 U.S. Nuclear Regulatory Commission, "Human Factors Engineering Program Review Model," NUREG-0711, Rev. 3, November 2012.~~

HEDs are identified, documented, and resolved throughout the verification and validation process. NuScale begins to record HED's after the completion of Staffing Plan Validation.

The HED resolution process involves evaluation of the HEDs to determine if they require correction, development and evaluation design solutions to address HEDs that must be corrected, and verification that the design solutions have been implemented. These topics are discussed in Reference 8.2.15.

HEDs may not always be resolved; HEDs may be found acceptable after an evaluation in the context of the integrated design. The basis for a decision for accepting an HED without change in the integrated design is documented. It may be based on accepted HFE practices, current published HFE literature, trade-off studies, tests, or engineering evaluations.

5.4.8 HED Process Flow

During ISV testing HEDs are analyzed by the HFEITS team for priority selection and design category placement (e.g., HSI or simulator). Once the HED has been received, a discrepancy entry is created in the HFEITS database and the HED is prioritized as Priority 1, Priority 2, or Priority 3 HEDs according to their importance as follows:

- Priority 1 HEDs have a potential direct or indirect impact on plant safety and are resolved prior to submitting the V&V Results Summary Report.~~before ISV testing is considered complete.~~ HEDs initiated as a result of a performance measure not being met (pass/fail performance measures) are priority 1 HEDs. Cross-cutting issues determined through HED analysis or performance measure analysis are priority 1 HEDs due to their global impact on the HSI design performance.
- Priority 2 HEDs have a direct or indirect impact on plant performance and operability and are resolved before turning over HFE responsibilities to a licensee.~~ the plant design is completed.~~
- Priority 3 HEDs are those that do not fall into priority 1 or priority 2. Priority 3 HEDs are resolved in accordance with QA policy-related programs and processes.~~ do not have to be resolved. If resolution of Priority 3 HEDs is determined to be needed, they are resolved during design implementation~~

The HED is then routed to the appropriate group for resolution. HEDs related to the HSI are sent to the HFE design team, and HEDs related to simulator modeling are sent to the simulator review board. It is possible for HEDs to be routed to both groups.

The HED is then resolved, and the discrepancy entry closed. The HED resolution is reviewed for final closure in the HFEITS database by an HFE review committee. The HED resolution process is depicted in Figure 5-2.

5.0 Human Engineering Discrepancy Resolution

Human engineering discrepancies (HEDs) are identified, documented, and resolved throughout the verification and validation process. NuScale begins to record HEDs after the completion of staffing plan validation.

HEDs may not always be resolved; HEDs may be found acceptable after an evaluation in the context of the integrated design. The basis for a decision for accepting an HED without change in the integrated design is documented. It may be based on accepted HFE practices, current published HFE literature, trade-off studies, tests, or engineering evaluations. HEDs are identified in the V&V process during

- task support verification (Section 3.2)
- HFE design verification (Section 3.3)
- ISV (Section 4.0)

HFE issues and HEDs are identified and tracked in the HFEITS database. The HFEITS database is available to any member of the HFE team and identification of issues is part of the NuScale corporate culture. The HFEITS database is maintained until fuel load.

A sampling of HEDs found during the V&V process will be discussed in the V&V RSR HED evaluation documentation section and include information on the potential cumulative effects of HEDs observed and samples of HEDs which may have shown an indication of broader issues seen during testing.

5.1 HED Design Solution Implementation

During ISV testing, HEDs are analyzed by the HFEITS team for priority selection and design category placement (e.g., HSI or simulator). Once the HED has been received, a discrepancy entry is created in the HFEITS database and the HED is prioritized as Priority 1, Priority 2, or Priority 3 HEDs according to their importance as follows:

- Priority 1 HEDs have a potential direct or indirect impact on plant safety and are resolved ~~before ISV testing is considered complete~~prior to submittal of the V&V Results Summary Report. HEDs initiated as a result of a performance measure not being met (pass or fail performance measures) are Priority 1 HEDs. Cross-cutting issues determined through HED or performance measure analyses are also Priority 1 HEDs due to their global impact on the HSI design performance.
- Priority 2 HEDs have a direct or indirect impact on plant performance and operability and are resolved before ~~the plant design is completed~~turning over HFE program responsibilities to a licensee.
- Priority 3 HEDs are those that do not fall into Priority 1 or Priority 2. Priority 3 HEDs ~~do not have to be resolved. If resolution of Priority 3 HEDs is determined to be needed, they are resolved during design implementation~~are resolved in accordance with QA policy-related programs and processes.

Evaluation of aspects of the facility that are not simulated (e.g., LCSs) but are relevant to the overall HFE program includes

- a walkdown to confirm conformance to the documentation approved by the HFE team (results of HFE analyses, style guides, etc.) and to human factors V&V conclusions.
- a subject matter expert review of suitability of use of operating procedures for LCSs.
- a subject matter expert evaluation of training material used for MCR, TSC, RSS, EOF, and LCS human-system interfaces.

Where the evaluation cannot confirm that the as-built HSIs, procedures, and training design are the same as or equivalent to the planned design, an HED is generated and tracked as discussed below.

18.11.2.3 Verification that Human Factors Engineering Issues in Issue Tracking System are Addressed

RAI 18-46

~~Human factors engineering issues~~HEDs found during design implementation activities are documented, evaluated, and tracked by the licensee performing these activities. The HEDs are tracked in the licensee's QA policy related programs and processes.~~as HEDs in the human factors engineering issues tracking system (see Section 18.1).~~ The HEDs from earlier HFE program elements and those generated during human factors V&V activities are addressed as follows:~~closed prior to ISV. Human engineering discrepancies generated during human factors V&V that do not affect ISV acceptance criteria or conclusions and HEDs generated after completion of V&V are resolved during design implementation. Some HEDs may not be resolved during HFE program activities and may be on-going due to anticipated technology or other advancements; however, these HEDs are closed prior to completion of design implementation.~~

RAI 18-46

- All HEDs affecting the ISV are closed prior to the ISV.
- All priority 1 HEDs are closed prior to submitting the V&V Results Summary Report.
- All Priority 2 and any new priority 1 HEDs are closed prior to turning over HFE program responsibility to the licensee.
- All Priority 3 HEDs open at the time the HFE program responsibility is turned over to the licensee and any Priority 1 and 2 HEDs identified after turnover are tracked and resolved in accordance with the licensee's programs and processes.

18.11.2.4 Addressing Important Human Actions

Important human actions are identified, addressed, and tracked as described in Section 18.6, and are incorporated into the HSI design as described in Section 18.7.