



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS  
WASHINGTON, DC 20555 - 0001**

September 26, 2022

MEMORANDUM TO: Ronald G. Ballinger, Lead  
SHINE License Application Review Subcommittee  
Advisory Committee on Reactor Safeguards

FROM: Vicki M. Bier, Member  
Advisory Committee on Reactor Safeguards

SUBJECT: INPUT FOR ACRS REVIEW OF SHINE OPERATING LICENSE APPLICATION – SAFETY EVALUATION REPORT FOR CHAPTER 7, “INSTRUMENTS AND CONTROL SYSTEMS,” SECTION 7.4.9, “HUMAN FACTORS ENGINEERING”

**Vicki M. Bier**

Digitally signed by Vicki M. Bier  
Date: 2022.09.26 23:48:38  
-04'00'

In response to the Subcommittee’s request, I have reviewed the Nuclear Regulatory Commission (NRC) staff’s safety evaluation report (SER) with no open items (SER Section 7.4.9, “Human Factors Engineering”), and the associated section of the applicant’s final safety analysis report (FSAR) for Chapter 7, “Instruments and Control Systems,” as well as relevant portions of FSAR Chapter 3, “Design of Structures, Systems, and Components,” Chapter 12, “Conduct of Operations,” and Chapter 13, “Accident Analysis.” I also reviewed the SHINE Medical Technologies, LLC (SHINE), Human Factors Engineering Design Checklist and the NRC staff’s “Summary of Audit Related to Human Factors Engineering.” In addition, representatives from SHINE met with the SHINE subcommittee on July 19-20, 2022, to discuss human factors engineering (HFE). The following is my recommended course of action concerning further review of this chapter and the staff’s associated safety evaluation.

### **Background**

Section 7.4.9 of the SER documents the staff’s review of the SHINE HFE program, as presented in Chapters 3, 7, 12, and 13 of the FSAR, and supplemented by the applicant’s responses to staff requests for additional information. It summarizes the staff’s safety review using guidance and acceptance criteria from NUREG-1537, Parts 1 and 2, and the interim staff guidance augmenting NUREG-1537, Parts 1 and 2. In particular, the NRC staff evaluated the sufficiency of the HFE related design aspects and programmatic considerations for the SHINE facility.

R. Ballinger

### **SER Summary**

The SER documents the staff's evaluation of the sufficiency of the SHINE HFE design and programmatic considerations. The NRC staff evaluated the description of outputs and display devices for parameters related to SHINE facility safety, control room alarms, other SHINE facility control room controls and displays of important parameters (not specific to manual protective actions), and how the SHINE human system interfaces support the operator's role in defense in depth. Based on the above evaluations, the NRC staff found that the descriptions and discussions of the HFE are sufficient and meet the applicable regulatory requirements and guidance, and acceptance criteria, for the issuance of an operating license.

### **Concerns**

I did not identify any specific deficiencies in my review. I observed that overall, the application was well documented, and the staff's evaluation thorough. However, staff noted several times that "SHINE had incorporated a human factors engineering program of a limited nature." The fact that this facility is a first-of-a-kind design makes it difficult to put 100% credence in the SHINE assertion that no operator actions are necessary for safety, since unforeseen scenarios could arise. For example, operator action is still credited as part of defense in depth; moreover, operators could conceivably also be involved in errors of commission (e.g., erroneously interrupting automatic safety actions).

I also note that the primary operator interface vendors do not all have extensive experience with human-factors design in the nuclear industry. SHINE uses a checklist (proprietary) to ensure compliance with recommended design guidelines. The checklist appears to be reasonably comprehensive. However, some checklist entries involve subjective judgment (e.g., "Controls and displays are arranged and grouped in a logical manner") and may therefore not provide sufficient guidance to ensure adequate design and acceptance evaluation. This poses a risk that the SHINE HFE design may not fully benefit from the years of experience accumulated by the existing nuclear industry (e.g., through extensive control room design reviews and revision). Just as one example, the control room is laid out in such a manner that both entrances are in the line of sight of the operators, creating a risk of distraction. Therefore, I would have more confidence if SHINE had involved a consultant knowledgeable about HFE for the current nuclear fleet to review the SHINE HFE program and identify possible improvements. However, the limited SHINE HFE program is acceptable, given that operators are not credited with performing essential safety functions in the SHINE licensing basis.

### **Recommendation**

As lead reviewer for SHINE SER Chapter 7, Section 7.4.9, "Human Factors Engineering," I concur with the staff that the HFE related design aspects of the SHINE facility are acceptable, as are the programs for procedures management and for operator training and qualification.

**References**

1. U.S. Nuclear Regulatory Commission, "Human Factors Engineering," Chapter 7, Section 7.4.9, Staff Safety Evaluation Report, July 12, 2022 (ML22193A281).
2. SHINE Medical Technologies, LLC, Application for Operating License Supplement 14, Revision to Final Safety Analysis Report, Chapter 7, "Instruments and Control Systems," January 26, 2022 (ML22034A642).
3. SHINE Medical Technologies, LLC, Application for Operating License Supplement 14, Revision to Final Safety Analysis Report, Chapter 3, "Design of Structures, Systems, and Components," January 26, 2022 (ML22034A638).
4. SHINE Medical Technologies, LLC, Application for Operating License Supplement 14, Revision to Final Safety Analysis Report, Chapter 12, "Conduct of Operations," January 26, 2022 (ML22034A626).
5. SHINE Technologies, LLC, Application for Operating License Supplement 14, Revision to Final Safety Analysis Report, Chapter 13, "Accident Analysis," January 26, 2022 (ML22034A645).
6. SHINE Medical Technologies, LLC FRM 1200-09-03-01, Revision 2, "Human Factors Engineering Design Checklist."
7. U.S. Nuclear Regulatory Commission, NUREG-1537, Part 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," February, 1996.
8. U.S. Nuclear regulatory Commission, "SHINE Medical Technologies, LLC – Summary of Audit Related to Human Factors Engineering (EPID NO. L-2019-NEW-0004)," May 18, 2022 (ML22124A073).

September 26, 2022

SUBJECT: INPUT FOR ACRS REVIEW OF SHINE OPERATING LICENSE APPLICATION – SAFETY EVALUATION REPORT FOR CHAPTER 7, “INSTRUMENTS AND CONTROL SYSTEMS,” SECTION 7.4.9, “HUMAN FACTORS ENGINEERING”

Package No: ML22258A304

Memo Accession No: ML22258A305

Publicly Available Y

Sensitive N

Viewing Rights:  NRC Users or ACRS Only or See Restricted distribution \*via e-mail

<b>OFFICE</b>	<b>ACRS/TSB*</b>	<b>SUNSI Review*</b>	<b>ACRS/TSB*</b>	<b>ACRS*</b>
<b>NAME</b>	CBrown	CBrown	LBurkhart	VBier
<b>DATE</b>	9/16/2022	9/16/2022	9/16/2022	9/26/2022

OFFICIAL RECORD COPY