ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

PRELIMINARY SAFETY ANALYSIS REPORT CHANGES
(MARK-UP)

10 pages follow

- The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
- That ~~the potential for an inadvertent criticality accident is not credible~~all nuclear processes are subcritical, including use of an approved margin of subcriticality;
- That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or
- That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur.

• Nonsafety-related: Those SSCs related to production and delivery of products or services that are not in the above safety classification.

The design bases and design for SHINE facility SSCs are addressed in Sections 3.1 and 3.5.

The SHINE production facility building is designed to withstand severe natural phenomena, including seismic events and tornado missiles. The building exterior wall structure is robust enough to remain intact following the impact of small aircraft, as defined in DOE (1996).

1.2.4.2 Functional Design Bases

1.2.4.2.1 Radiological Safety

A radiation protection program is provided to protect the radiological health and safety of workers and complies with the regulatory requirements in 10 CFR 19, 20, and 70. The Radiation Protection Program meets the requirements of 10 CFR 20, Subpart B, Radiation Protection Programs, and is consistent with the guidance provided in Regulatory Guide 8.2. This program is described in Subsection 11.1.2.

The radiation protection program includes an as low as reasonably achievable (ALARA) program. The facility's commitment to the implementation of an ALARA program is described in Subsection 11.1.3. The objective of the program is to make every reasonable effort to maintain personnel exposures to radiation as far below the dose limits of 10 CFR 20.1201 as is practical. The design and implementation of the ALARA program is consistent with the guidance provided in Regulatory Guides 8.2, 8.13, and 8.29. The operation of the SHINE facility is consistent with the guidance provided in Regulatory Guide 8.10.

Radiation monitoring and surveying are utilized to minimize the occupational dose to personnel. The program equipment and procedures are addressed in Subsection 11.1.4. This includes the use of area radiation monitors, continuous air monitors, the detection and monitoring of gaseous and liquid effluent release streams, control point monitoring, and the use of radiation surveys within the SHINE facility.

Occupational dose is also controlled and minimized through the use of dosimetry and exposure control. This includes the establishment of controlled areas within the facility, the use of access and egress controls, the use of protective clothing and equipment, the monitoring of personnel for exposures through the use of dosimetry and portal monitors, posting of facility areas, and personnel training. Subsection 11.1.5 describes these features and provisions.

1.3 GENERAL DESCRIPTION OF THE FACILITY

The SHINE production facility building consists of an IF, RPF, shipping and receiving area, and other areas that contain various support systems and equipment.

Floor plan and section drawings of the facility showing the arrangements of the major structures and equipment are provided in Figures 1.3-1, 1.3-2, and 1.3-3.

The SHINE facility site layout is provided in Figure 1.3-4. The RCA of the SHINE facility consists of the IF and the RPF (see Figure 1.3-5).

1.3.1 GEOGRAPHICAL LOCATION

The SHINE facility is located on the south side of the City of Janesville corporate boundaries, in Rock County, Wisconsin. The SHINE facility is centered at 42° 37' 26.9" N latitude, and 89° 1' 29.5" W longitude.

1.3.2 PRINCIPAL CHARACTERISTICS OF THE SITE

The SHINE site consists of an undeveloped, approximately 91-acre (ac.) (36.8-hectare [ha]) parcel that has been historically farmed. Safety-related structures are located within a rectangular area located near the center of the property. The region of the SHINE site is entirely contained within Rock County, Wisconsin. The dominant land use in the region is agricultural/ cultivated crops. The northern limits of the City of Beloit are located approximately 3.7 miles (mi.) (6.0 kilometers [km]) to the south. Principal characteristics of the site are further described in Chapter 2.

1.3.3 PRINCIPAL DESIGN CRITERIA, OPERATING CHARACTERISTICS, AND SAFETY SYSTEMS

Safety significant SSCs within the facility ~~are separated into two classifications. The safety-significant SSCs in the IF~~ are classified as safety-related. ~~The safety significant SSCs in the RPF are classified as IROFS.~~ The SHINE facility is licensed under 10 CFR 50. See Subsection 1.2.4.1 for the definition~~s~~ of safety-related ~~and IROFS~~.

1.3.3.1 Principal Design Criteria

Design criteria for the facility are addressed in Section 3.1. Design criteria for systems and components are addressed in Section 3.5.

1.3.3.2 Operating Characteristics

The IUs are operated in a batch mode with an approximate week-long operating cycle. An operating cycle includes the following steps: receipt of uranyl sulfate target solution from the RPF, transfer to the TSV, operation of the subcritical assembly at full power for approximately 5.5 days, shut down, and transfer of the irradiated target solution to the RPF for isotope extraction. During the full power operation of the subcritical assembly system, the target solution is maintained in a subcritical state.

3.5.1.1 Nuclear Safety Classifications for SSCs

Certain SSCs of the SHINE facility are considered SR because they perform safety functions during normal operations or as required to prevent or mitigate the consequences of abnormal operational transients or accidents. The purpose of this section is to classify SSCs according to the safety function they perform. In addition, design requirements are placed upon such equipment to ensure the proper performance of safety function, when required. A listing of these SSCs and their safety classifications are provided in Table 3.5-1.

SHINE uses a modified definition from 10 CFR 50.2 “Definitions” to develop the definition of SR SSCs, where appropriate.

3.5.1.1.1 Safety-related SSCs

Those SSCs that are relied upon to remain functional during normal conditions and during and following design basis events to assure:

a. The integrity of the primary system boundary;
b. The capability to shutdown the target solution vessel (TSV) and maintain the target solution in a safe shutdown (SSD) condition;
c. The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
d. That ~~the potential for an inadvertent criticality accident is not credible~~all nuclear processes are subcritical, including use of an approved margin of subcriticality;
e. That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or
f. That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur.

3.5.1.1.2 NSR SSC

Nonsafety-related SSCs are those SSCs related to production and delivery of products or services that are not in the above safety classification.

3.5.1.2 Quality Assurance (Quality Group Classifications for SSCs)

Quality assurance requirements may be found in the SHINE QAPD.

The SHINE QAPD has been developed in accordance with ANSI/ANS 15.8-R2005 (ANSI/ANS, 2005), “Quality Assurance Program Requirements for Research Reactors,” and provides the following graded approach to quality.

3.5.1.2.1 QL-1

This quality level shall implement the full ~~requirements of the QAPD in accordance with an approved Quality Assurance Plan (QAP). This quality level shall be applied to SR~~

~~SSCs~~measure of the QAPD and shall be applied to safety-related SSCs and to safety-related activities.

3.5.1.2.2 QL-2

This quality level ~~shall apply to NSR quality activities performed by the licensee, that are deemed necessary by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements~~is applied to selected SSCs and activities intended to support or protect the safety function of safety-related equipment. Quality Assurance Program elements are applied to an extent that is commensurate with the item's importance to safety. Implementing documents establish program element applicability.

3.5.1.2.3 QL-3

This quality level is applied to nonsafety-related SSCs and activities and does not support or protect the safety function of safety-related SSCs or activities. However, the performance of QL-3 SSCs and activities may be important to ensuring customer requirements are met, or operational or mission-related goals such as throughput, cost, or schedule are achieved. Controls, appropriate for the application, are applied to SSCs and activities using the SHINE Quality Assurance Program for efficiency to avoid the creation and use of a separate or redundant management system. The controls on these SSCs and activities do not impact QL-1 or QL-2 SSCs and activities or the regulatory basis of the facility.

3.5.2 SEISMIC CLASSIFICATION

Plant SSCs important to safety are designed to withstand the effects of a design basis earthquake (DBEQ) (see Section 3.4) and remain functional if they are necessary to assure:

1. The integrity of the primary system boundary;
2. The capability to shutdown the TSV and maintain the target solution in a safe shutdown condition;
3. The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
4. That ~~the potential for an inadvertent criticality accident is not credible~~all nuclear processes are subcritical, including use of an approved margin of subcriticality;
5. That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area;
6. That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur; or
7. They do not degrade the function and performance of any SR SSC.

Plant SSCs, including their foundations and supports, that are designed to remain functional in the event of a DBEQ are designated as Seismic Category I, as indicated in Table 3.5-1.

Structures, components, equipment, and systems designated SR (see Section 3.5.1.1 for a definition of safety classes) are classified as Seismic Category I.

SSCs co-located with Seismic Category I systems are reviewed and supported in accordance with II over I criteria. This avoids any unacceptable interactions between SSCs.

SSCs that must maintain structural integrity post-DBEQ, but are not required to remain functional are Seismic Category II.

All other SSCs that have no specific NRC regulated requirements are designed to local jurisdictional requirements for structural integrity and are Seismic Category III.

All Seismic Category I SSCs are analyzed under the loading conditions of the DBEQ and consider margins of safety appropriate for that earthquake. The margin of safety provided for safety class structures, components, equipment and systems for the DBEQ are sufficient to ensure that their design functions are not jeopardized. For further details of seismic design criteria refer to Section 3.4.

Table 3.5-1 System Classifications
(Sheet 2 of 4)

System Name	System Code	Highest Safety Classification Within System Scope[a]	Seismic Classification[b]	Quality Group
Uranyl Nitrate Conversion System	UNCS	SR	Category I	QL-1
Target Solution Cleanup (UREX)				
Thermal Denitration				
Production Facility Biological Shield System	PFBS	SR	Category I	QL-1
Radioactive Drain System	RDS	SR	Category I	QL-1
Radioactive Liquid Waste Evaporation and Immobilization	RLWE	SR	Category I	QL-1
Aqueous Radioactive Liquid Waste Storage	RLWS	SR	Category I	QL-1
RCA Material Handling Systems	RMHS	SR	Category I	QL-1
Facility Control Room	FCR	SR	Category I	QL-1
Other Facility Systems and Components				
Hot Cell Fire Detection and Suppression System	HCFD	NSR	Category II	QL-2
Facility Instrument Air System	FIAS	NSR	Category III	QL-2
~~Facility Control Room~~	~~FCR~~	~~NSR~~	~~Category III~~	~~QL-2~~
Stack Release Monitoring	SRM	NSR	Category III	QL-2
Facility Fire Detection and Suppression	FFPS	NSR	Category III	QL-2
Neutron Driver Assembly System	NDAS	NSR	Category III	QL-2
Primary Closed Loop Cooling System	PCLS	NSR	Category II	QL-2
Primary Closed Loop Cooling and Light Water Pool Makeup System	MUPS	NSR	Category III	~~QL-2~~QL-3
Health Physics Monitors	HPM	NSR	Category III	~~QL-2~~QL-3
TSV Process Control System	TPCS	NSR	Category II	QL-2
Normal Electrical Power Supply System	NPSS	NSR	Category II	QL-2
Inert Gas Control	IGS	NSR	Category III	QL-2
Material Handling	MHS	NSR	Category II	QL-2
Solid Radioactive Waste Packaging	SRWP	NSR	Category II	QL-2

Table 3.5-1 System Classifications
(Sheet 3 of 4)

System Name	System Code	Highest Safety Classification Within System Scope[a]	Seismic Classification[b]	Quality Group
Material Control and Accountability System	MCAS	NSR	Category III	~~QL-2~~QL-3
Organic Liquid Waste Storage and Export	OLWS	NSR	Category II	QL-2
Radioisotope Process Facility Cooling System	RPCS	NSR	Category III	QL-2
Moly Isotope Product Packaging System	MIPS	NSR	Category III	QL-2
Standby Diesel Generator System	SDGS	NSR	Category II	QL-2
Radiologically Controlled Area (RCA) Ventilation Zone 3	RVZ3	NSR	Category III	QL-2
Facility Ventilation Zone 4	FVZ4	NSR	Category III	QL-2
Facility Integrated Control System	FICS	NSR	Category III	QL-2
Facility Potable Water System	FPWS	NSR	Category III	~~QL-2~~QL-3
Facility Compressed Air System	FCAS	NSR	Category III	~~QL-2~~QL-3
Facility Breathing Air System	FBAS	NSR	Category III	QL-2
Facility Inert Gas System	FIGS	NSR	Category III	QL-2
Facility Welding System	FWS	NSR	Category III	~~QL-2~~QL-3
Facility Roof Drains System	FRDS	NSR	Category III	~~QL-2~~QL-3
Facility Sanitary Drains System	FSDS	NSR	Category III	~~QL-2~~QL-3
Facility Data and Communications System	FDCS	NSR	Category III	QL-2
Facility Lightning Protection System	FLPS	NSR	Category III	~~QL-2~~QL-3
Facility Demineralized Water System	FDWS	NSR	Category III	~~QL-2~~QL-3
Facility Chilled Water Supply and Distribution System	FCHS	NSR	Category III	QL-2
Facility Acid Reagent Storage and Distribution System	FARS	NSR	Category II	QL-2
Facility Alkaline Reagent Storage and Distribution System	FLRS	NSR	Category II	QL-2

Table 3.5-1 System Classifications
(Sheet 4 of 4)

System Name	System Code	Highest Safety Classification Within System Scope[a]	Seismic Classification[b]	Quality Group
Facility Salt Reagent Storage and Distribution System	FSRS	NSR	Category II	QL-2
Facility Organic Reagent Storage and Distribution System	FORS	NSR	Category II	QL-2
Cathodic Protection System	CPS	NSR	Category III	~~QL-2~~QL-3
Emergency Lighting System	ELTG	NSR	Category II	QL-2
Facility Grounding System	FGND	NSR	Category III	QL-2
Lighting System	LTG	NSR	Category III	~~QL-2~~QL-3
Process Facility Wet Vacuum System	PFWV	NSR	Category III	QL-2
Process Facility Sampling System	PFSS	NSR	Category III	~~QL-2~~QL-3
Continuous Air Monitoring System	CAMS	NSR	Category III	~~QL-2~~QL-3

a) Safety classification accounts for highest classification in the system. Systems that are classified as safety-related may include both safety-related and nonsafety-related components. Only safety-related components will be used to satisfy the safety functions of the system, whereas nonsafety-related components can be used to perform non-safety functions. For example, there are nonsafety-related components, such as fans, within the safety-related ventilation systems that perform nonsafety-related functions.

b) Seismic category may be locally revised to account for II over I design criteria and in order to eliminate potential system degradation due to seismic interactions.

Acronyms and Abbreviations

Acronym/Abbreviation	Definition
10 CFR	Title 10 of the Code of Federal Regulations
ANS	American Nuclear Society
ANSI	American National Standards Institute
IF	irradiation facility
~~IROFS~~	~~item relied on for safety~~
ISA	Integrated Safety Analysis
IU	irradiation unit
LCO	limiting condition of operation
LSSS	limiting safety system setting
LWPS	light water pool system
NGRS	noble gas removal system
PCLS	primary closed loop cooling system
PSB	primary system boundary
PVVS	process vessel vent system
RCA	radiologically controlled area
RPF	radioisotope production facility
RVZ1	RCA ventilation system Zone 1
RVZ2	RCA ventilation system Zone 2
SHINE	SHINE Medical Technologies, Inc.
SL	safety limit
SNM	special nuclear material
TOGS	TSV off-gas system
TSV	target solution vessel

15.2 FINANCIAL ABILITY TO OPERATE THE SHINE FACILITY

The class of license SHINE is applying for will be a Class 103 license per 10 CFR 50.22 (for commercial and industrial facilities). Additional future applications will be for the ~~production facility~~ operating license for one production facility and eight utilization facilities under 10 CFR 50, receipt, possession and use of source material under 10 CFR 40, byproduct material under 10 CFR 30, and special nuclear material under 10 CFR 70. SHINE expects to request an Operating License (OL) for a term of 30 years.

SHINE is providing information that demonstrates that the company possesses or has reasonable assurance of obtaining the funds necessary to cover estimated facility operation costs for the period of the license. These are the estimates provided for total annual operating costs for each of the first 5 years of operation of the facility. Pursuant to 10 CFR 50.33(f)(2), the sources of funds to cover these costs will be funded from the expected revenues associated with the sale of molybdenum-99 (Mo-99) and other radioisotopes produced by the facility. SHINE expects that such revenue will be significantly more than the operating costs incurred. The latest financial statements of the company will be provided as part of the evidence of financial solvency and the ability to fund the facility.

Table 15.2-1 represents the budgetary estimate of operating costs for the first 5 years of the SHINE facility and the expected revenues from the production and sale of Mo-99 and other radioisotopes.