SHINE® Medical Technologies

THIS LETTER CONTAINS PROPRIETARY INFORMATION
IN ACCORDANCE WITH 10 CFR § 2.390

January 22, 2019 2019-SMT-0007

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) U.S. Nuclear Regulatory Commission, "Pre-Application Meeting Associated with SHINE Medical Technologies, Inc. Operating License Application," Meeting Notice, January 10, 2019 (ML19010A394)

Meeting Slides for the January 31, 2019 Public Meeting
between SHINE Medical Technologies, Inc. and the NRC

A meeting is scheduled between SHINE Medical Technologies, Inc. (SHINE) and the NRC staff (Reference 1) to familiarize NRC staff with SHINE's medical isotope production facility technology and discuss the organization and content of the SHINE operating license application.

Enclosure 1 provides the non-public (proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's technological overview. In addition to proprietary information, Enclosure 1 contains security-related information which was identified utilizing the guidance contained in RIS 2005-31. Due to the proprietary nature of the discussion, SHINE requests the NRC close the meeting session regarding SHINE's technological overview to the public and withhold Enclosure 1 from public disclosure under 10 CFR § 2.390.

Enclosure 2 provides the public (non-proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's technological overview.

Enclosure 3 provides the non-public (proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's structural design. In addition to proprietary information, Enclosure 3 contains security-related information which was identified utilizing the guidance contained in RIS 2005-31. Due to the proprietary nature of the discussion, SHINE requests the NRC close the meeting session regarding SHINE's structural design to the public and withhold Enclosure 3 from public disclosure under 10 CFR § 2.390.

Enclosure 4 provides the public (non-proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's structural design.

Enclosure 5 provides the SHINE meeting slides for the discussion regarding the organization and content of SHINE's operating license application.

Enclosures 1 and 3 contain both proprietary and security-related information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

Y G01
NRR

THIS LETTER CONTAINS PROPRIETARY INFORMATION
IN ACCORDANCE WITH 10 CFR § 2.390

Enclosure 6 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1 and 3 and the proprietary nature of the discussion surrounding the content of the meeting slides for the subject meeting sessions, pursuant to 10 CFR § 2.390. SHINE requests that the NRC withhold Enclosures 1 and 3 from public disclosure, in their entirety, and close the related meeting sessions to the public, under 10 CFR § 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

If you have any questions, please contact me at 608/210-1735.

Very truly yours,

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosures

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosures 1 and 3)

Enclosures 1 and 3 contain both proprietary and security-related information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

MEETING SLIDES FOR THE JANUARY 31, 2019 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC

SHINE TECHNOLOGY OVERVIEW
PUBLIC VERSION

36 pages follow

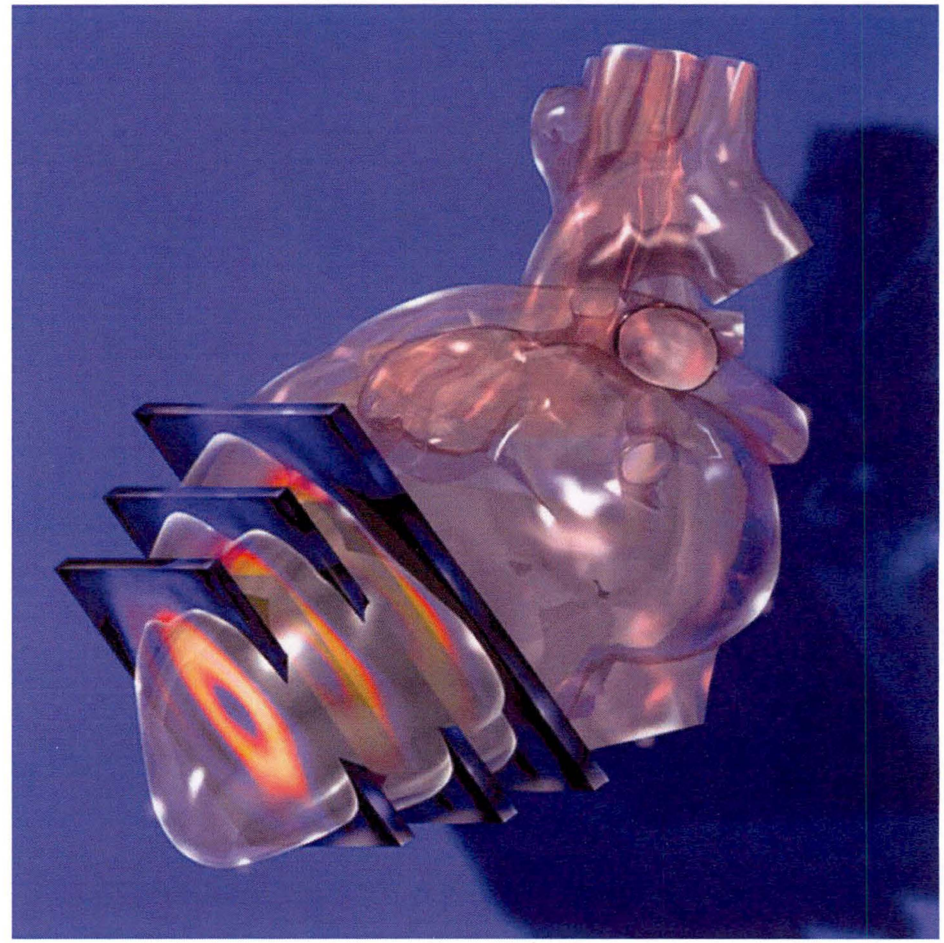
SHINE Technology Overview

Eric Van Abel, Chief Technical Officer

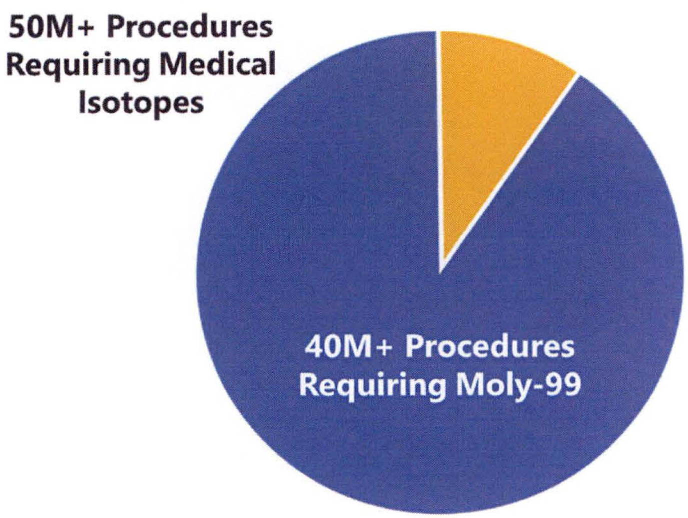
Health. Illuminated.™

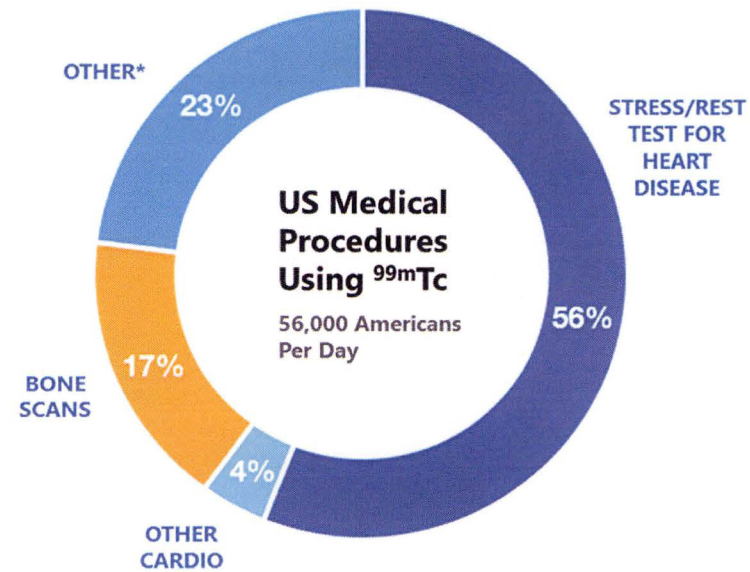
Mission

Dedicated to being the world leader in the safe, clean, affordable production of medical tracers and cancer treatment elements.



Medical isotopes enable doctors to diagnose and treat illnesses, such as heart disease and cancer

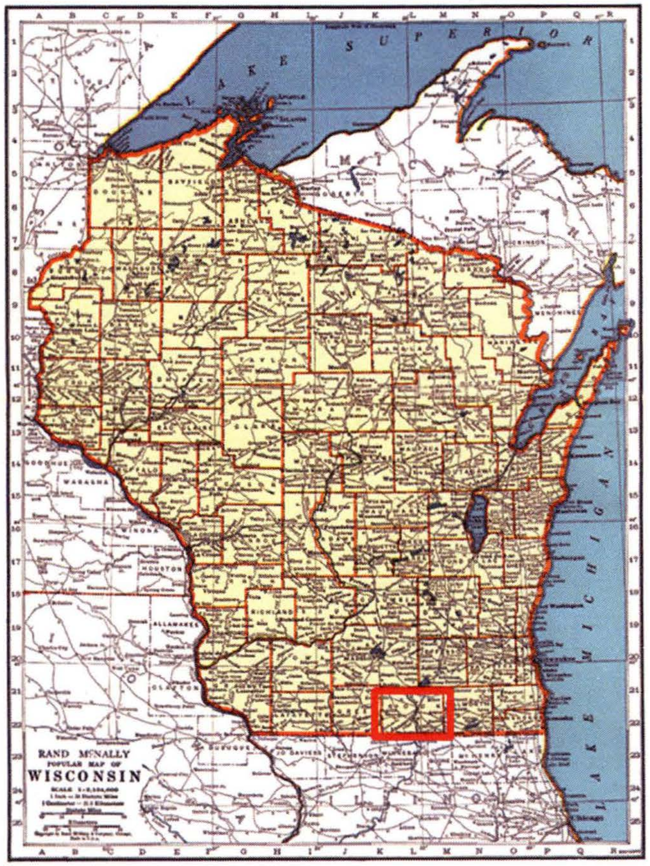




Moly-99 → (Radioactive Decay) → Tc-99m → (Medical Procedure) → Patient Dose

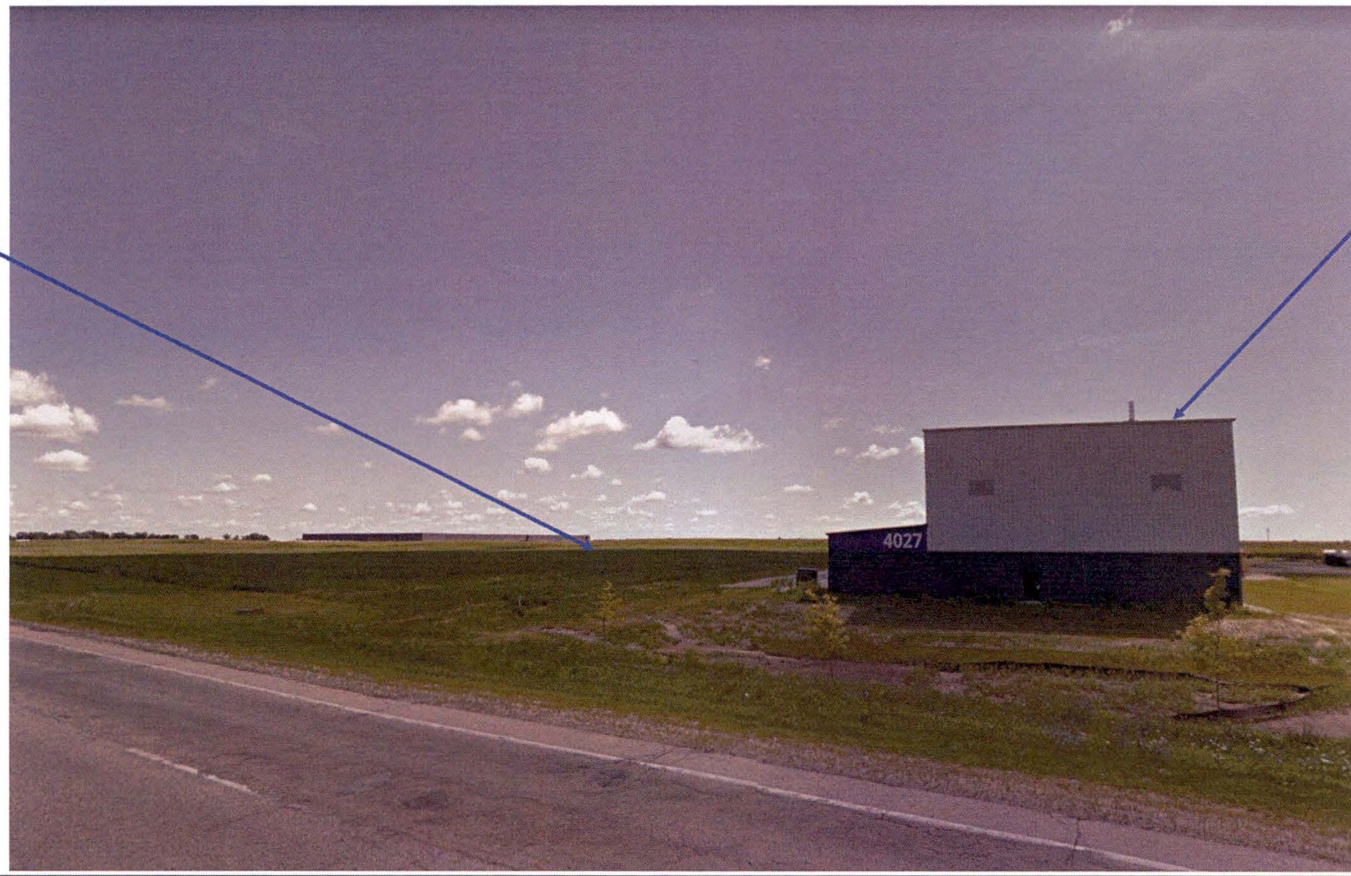
* Other includes liver, respiratory, thyroid / parathyroid, renal, inflammation, tumor imaging, etc.

Located in Janesville, Wisconsin



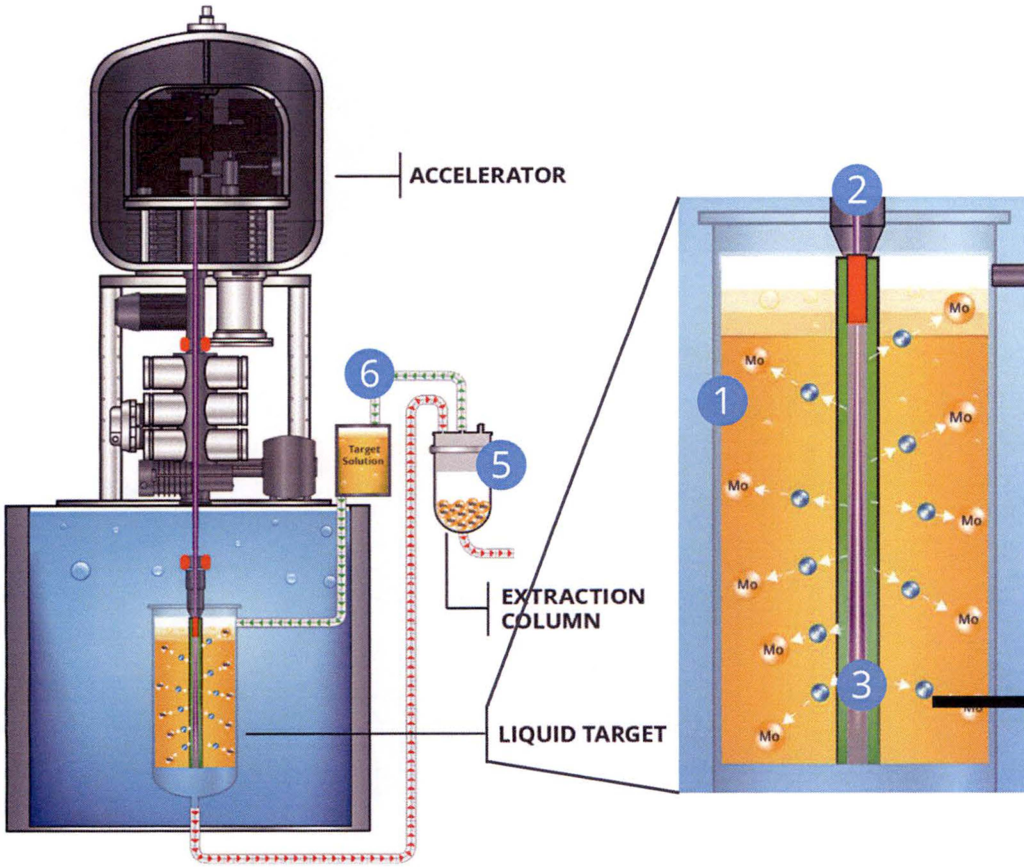
Located in Janesville, Wisconsin

Future SHINE Production Facility

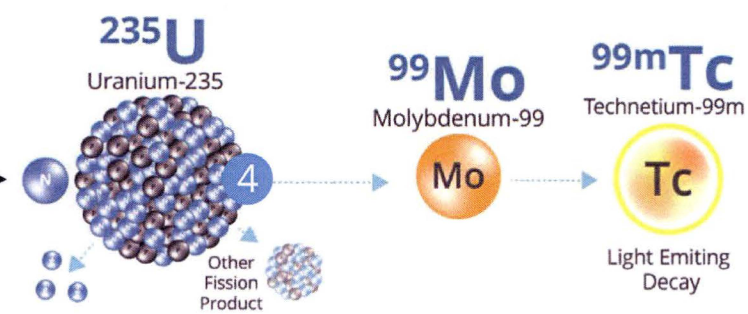


SHINE Building One

SHINE High Level Overview

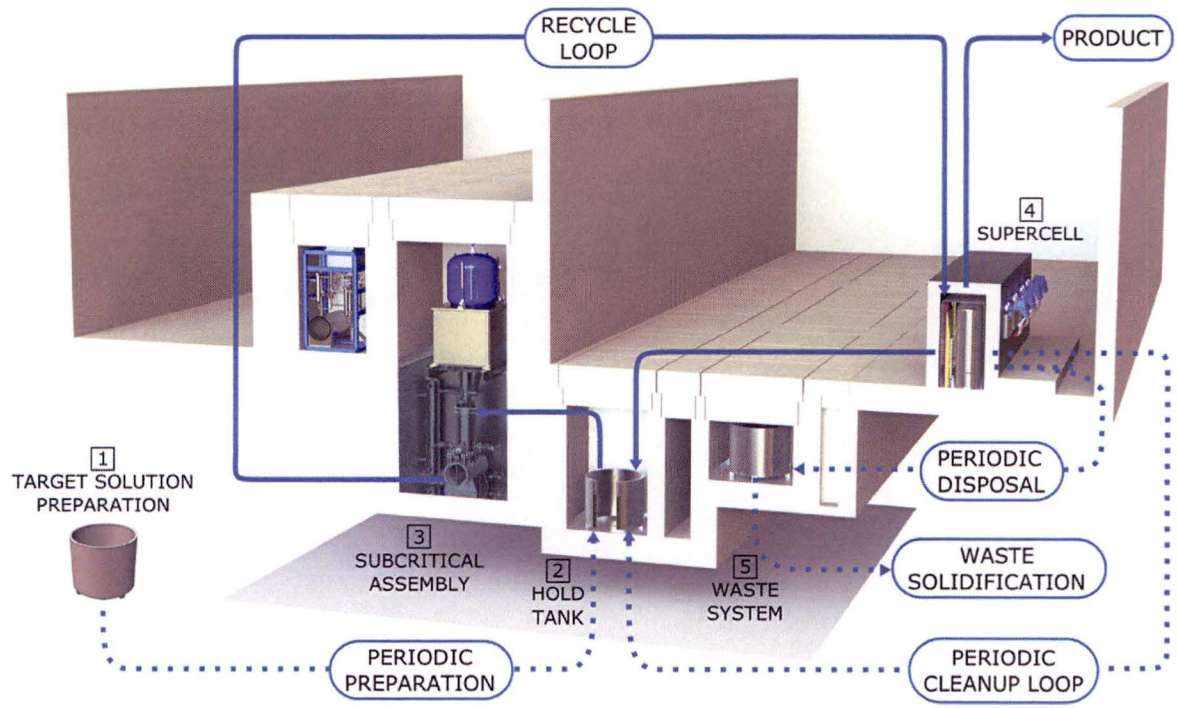


1. LEU is dissolved to form the liquid target
2. Accelerator fires ion beam into tritium gas target chamber
3. Ions from accelerator beam undergo fusion with gas target, freeing neutrons into target solution tank
4. Uranium undergoes fission in target solution tank, producing Mo-99 and other isotopes
5. Mo-99 is captured from the solution via an extraction column
6. The LEU solution is returned to the target solution tank



Process Overview

1. Periodic solution preparation from LEU
2. Solution chemistry check and staging
3. Irradiation for 5.5 days
4. Extraction, purification, QC & packaging
5. Periodic cleanup and solution disposal



Building One

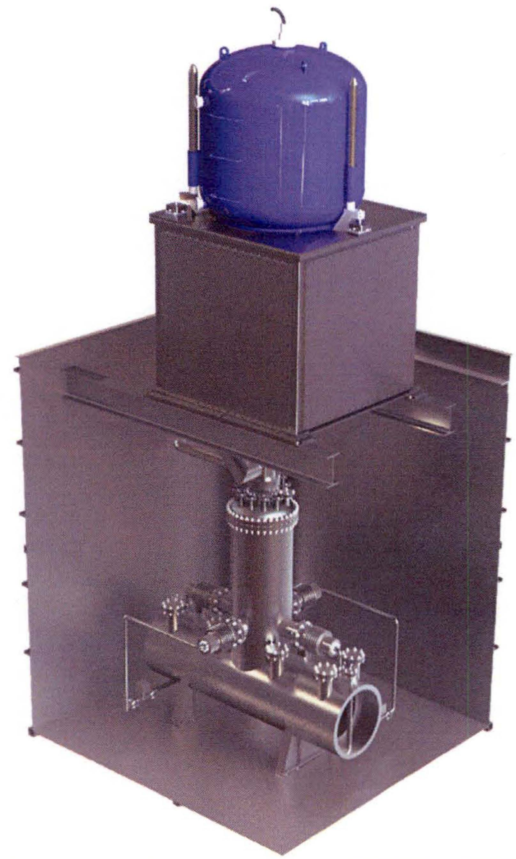
- Construction complete Q1 2018
- Full size accelerator demo currently in-progress
  - Radioactive material license by State of Wisconsin
- Future mockups and prototypes planned
- Future use for employee training and technology development

Top Long-Lead Process Equipment Items

- Supercell
- Neutron Flux Detectors
- Safety I&C System (TRPS/ESFAS)
- Neutron Drivers (Accelerators)
- Thermal Cycle Absorption Process (TCAP) Equipment
- Radioactive Liquid Waste Immobilization System

Technological Approach

- Small systems: Hundreds of times less power than isotope production reactors being used
  - Low source term—helps ensure safety of public and workforce
  - Decay heat per system < 1 kW within 5 hours
  - Minimizes waste nuclide generation compared to reactors
- Low enriched uranium (LEU) reusable target
  - Reduces waste
  - Product compatible with current supply chain
  - Eliminates need for HEU
- Driven by low-energy electrostatic accelerator
  - Eliminates need for HEU
- Multiple units and trains provide operational scalability and flexibility



Safety Philosophy

- Low decay heat, low pressure, low temperature system
  - Minimal stored energy
- Independent units limit common cause failures
- Operator actions are not required for safe response to an accident
- In the event of an upset condition:
  - TSV reactivity protection system (TRPS) initiates trip of system
  - Two completely independent safety-related TSV dump valves open
  - Target solution gravity drains to the TSV dump tank (criticality safe at all uranium concentrations)
  - Hydrogen concentration is maintained below LFL by off-gas system blowers
- Following UPS battery run time, entire plant is passively safe
  - 90 days without cooling: Pool temperature rise is less than approximately 12°F
  - Nitrogen purge system for hydrogen control

Facility Layout – General Arrangement

[

Security-Related Information

]

Facility Layout – General Arrangement

[

Security-Related Information

]

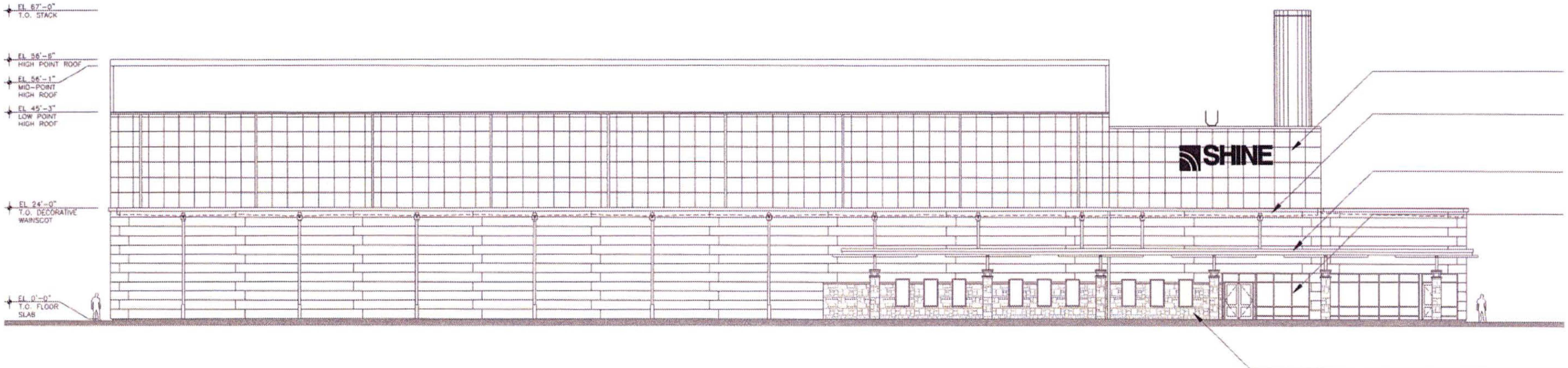
Facility Layout – General Arrangement – Mezzanine

[

Security-Related Information

]

Facility Layout – Elevation and Section Views



WEST BUILDING ELEVATION

Facility Layout – Elevation and Section Views

[

Security-Related Information

]

Facility Layout – Elevation and Section Views

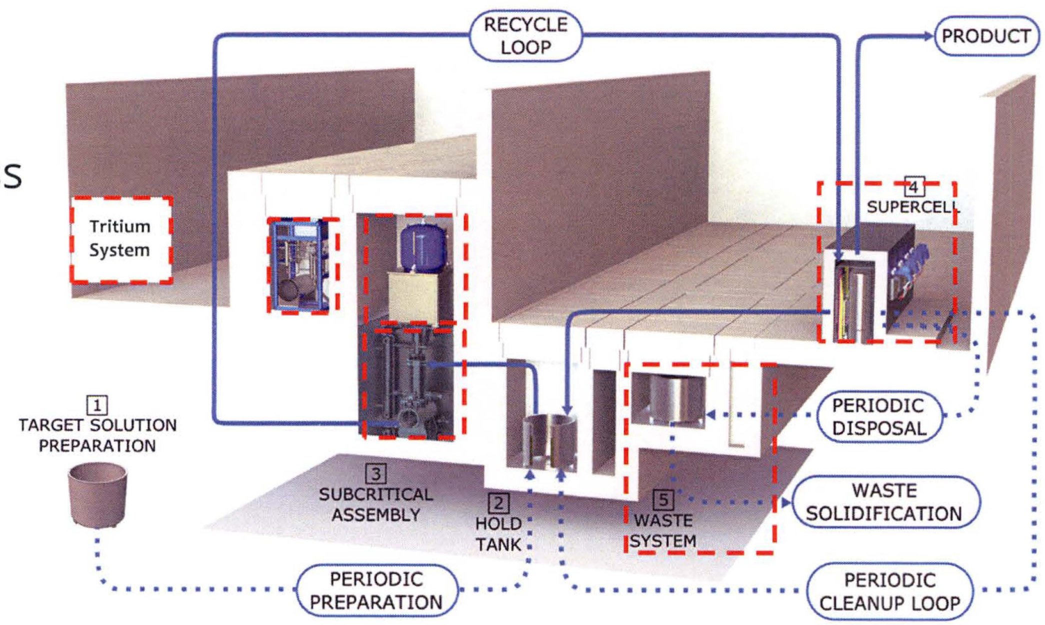
[

Security-Related Information

]

Major Process Equipment

- Subcritical Assembly and TSV Off-Gas System
- Neutron Driver
- Tritium Purification System
- Extraction and Purification Process
- Supercell
- Radioactive Waste Handling



Subcritical Assembly Overview

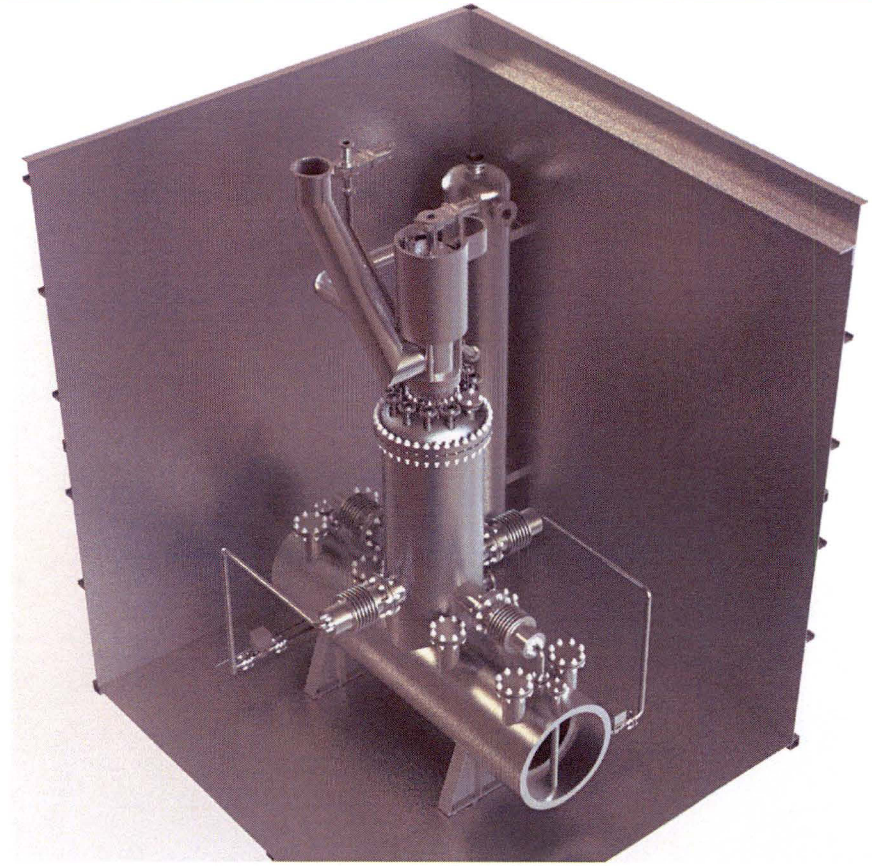
- Hybrid fusion-fission device
  - Accelerator generates fusion neutrons from D-T reaction
  - Subcritical assembly takes fusion neutrons, slows them down, and multiplies them through fission reactions
- Process
  - Fast neutrons created in center of assembly (neutron spark plug)
  - Neutrons pass through [Proprietary Information] multiplier
  - Multiplied neutrons pass into uranium solution in TSV, where they are absorbed by uranium and cause fission
  - Transfer solution to the processing facility for isotope removal

[Proprietary Information]

Subcritical Assembly with Accelerator Target Assembly

Low energy, inherently-safe system

- Key parameters:
  - Pressure: Below atmospheric
  - Target solution: Uranyl sulfate
  - Low temperature: < 212°F
  - Low fluid flow rates: Natural circulation of target solution
  - Reactivity: Subcritical



Subcritical Assembly – Design Summary

[Proprietary Information]

Subcritical Assembly with Accelerator Target Assembly

- Skid-fabricated components
- Safety-related to retain target solution in proper geometry
- Target solution pressure boundary principally constructed of Type 347 stainless steel
- Designed for 100 psig

TSV Offgas System (TOGS)

- The TOGS sweeps gas through the TSV headspace
- Operates during irradiation to remove and recombine hydrogen and oxygen
- Sweep gas passed over catalytic recombiner beds to form water vapor
- Water vapor generated by the TSV and the recombiner beds is condensed and returned to the TSV

[Proprietary Information]

TSV Offgas System (TOGS)

- TOGS general parameters
  - Sweep gas flowrate: [Proprietary Information]
  - Design nominal hydrogen concentration: [Proprietary Information]
  - Liquid return rate: [Proprietary Information]
  - Recombiner materials: [Proprietary Information]
- Safety-related functions to ensure hydrogen concentrations remain acceptable
- Operates on UPSS power for minutes following loss of offsite power to recombine decay hydrogen

Proprietary Information

TOGS Skid

Neutron Driver

- Neutron driver is hydrogen particle accelerator
- Supplied by Phoenix
- 300 kV constant voltage (static)
  - Accelerates hydrogen isotopes to a gas target chamber
- Deuterium-deuterium reaction produces ~1% output
- Deuterium-tritium reaction produces ~100% output
- Neutron source to drive the subcritical chain reactions
- Operation is not safety function
- Turning off accelerator is a safety function
  - Safety-related breakers isolate power feed to accelerator high voltage power supply

[Proprietary Information]

Tritium Purification System (TPS) Overview

- Function: Continuously supply purified tritium (target gas) and deuterium (source gas) to neutron drivers
- Uses Thermal Cycling Absorption Process (TCAP) technology
  - IP Licensed from Savannah River National Laboratory
- Key features
  - Semi-continuous operational mode (batched gas chromatography)
  - 1 TPS serves up to 8 drivers
  - Tritium maintained sub-atmospheric outside of glovebox

[Security-Related Information]

Major TPS Equipment and Functions

- TPS process equipment and main glovebox
  - Remove impurities
  - Separate tritium and deuterium
  - Confine tritium
    - Process equipment normally contains tritium
    - Glovebox confines in the event of a release
- ATIS skids and gloveboxes
  - Distribute gases via headers
  - Interface with neutron drivers and regulate flow to a neutron driver
  - Confine tritium
- Stripper system & air hood
  - Remove residual tritium that enters glovebox atmosphere

[Proprietary Information]

TPS Flow Diagram (Production Facility)

[

Proprietary Information
Security-Related Information

]

Overview of Mo-99 Separation Process

- Target solution transferred from IU cell to hot cells via vacuum lift system
- Mo-99 separated from target solution by extraction column
- [Proprietary Information]
- [Proprietary Information]
- [Proprietary Information]
- Mo-99 solution evaporated and transferred to purification process

[Proprietary Information]

Mo-99 Extraction Equipment

Overview of Mo-99 Purification Process

- Purification via the Low Enriched Uranium (LEU) Modified Cintichem Process
  - Developed by Argonne National Laboratory for the Department of Energy
- Cintichem is a long-established process
  - Used at the Cintichem facility in Tuxedo, NY until 1989
- Process perform by manipulators in hot cell
  - Precipitation and filtration of contaminants
  - Complexation of molybdenum
  - Adsorption and filtration of contaminants on charcoal columns

Supercell

Proprietary Information

- Redundancy is included to handle the 8 irradiation cells and provide flexibility in operations

Proprietary Information

Supercell Design

- Safety function to confine radioisotopes upon release
  - Confinement limits release to stack and to Radioisotope Production Facility (RPF) area
- Provides biological shielding for workers
- Criticality safety controls incorporated

[Proprietary Information]

Waste Treatment

- Waste Stream Overview
  - Three types of radioactive waste:
    - As generated solid radioactive waste, including spent adsorption columns
    - Solidified radioactive waste
    - Gaseous wastes
- Liquid waste is collected in tanks with and without critically-safe geometry, depending on liquid waste stream
  - Size and configuration of liquid waste tanks provide for operational flexibility and reduction in waste source term
  - Liquid waste streams are analyzed and blended to allow for solidification in cement and acceptance at a licensed burial facility
  - Waste streams are solidified in a sealed solidification skid maintained at a slight negative pressure compared to the surrounding Radioisotope Production Facility

Solid Wastes Exported to Storage Drums

[

Proprietary Information

]

Radioactive Liquid Waste Storage System

[

Security-Related Information

]

Radioactive Liquid Waste Immobilization System

- Receives liquid wastes from the plant and solidifies them in a cement-based mixture
- Drums are cured and transported to on-site staging building, prior to offsite shipment
- Waste system is skid-mounted and assembled

[

Proprietary Information

]

Gaseous Waste Treatment

Proprietary Information

ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, INC.

MEETING SLIDES FOR THE JANUARY 31, 2019 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC

SHINE STRUCTURAL DESIGN
PUBLIC VERSION

32 pages follow

SHINE Structural Design

Abbey Donahue, P.E., Structural Engineering Manager
Christopher Hewitt, P.E., Senior Project Manager, Simpson, Gumpertz & Heger

Health. Illuminated.™

Structural Agenda

- Update on design and construction method of the building
- Safety-Related building envelope
- Seismic methodology discussion
- Aircraft impact methodology discussion
- Overview of other structural loads

Design Updates

- Return to traditional cast-in-place construction
  - SHINE developed a pre-cast building design based on the presentation May 2018
  - Pre-cast building design adequately protected the facility against:
    - Wind
    - Snow
    - Tornado
    - Seismic
    - Heavy rain / flooding
    - Aircraft Impact
  - The complexity of the construction of the pre-cast building did not yield the expected construction cost or schedule, so the pre-cast design was retired

The Safety-Related Structure

- Structural design of the safety-related structure is complete
  - Design Criteria and Methodology:
    - DC-2016-1001, Rev. 0 - Structural Design Criteria For SHINE Medical Main Production Facility
    - SL-011476, Rev. 2 - Seismic Analysis Methodology
  - Calculations supporting design:
    - CALC-2017-1000, Rev. 0 - SHINE Facility Structural Design
    - CALC-2017-1001, Rev. 0 - Evaluation of Aircraft and Tornado Impact
    - CALC-2017-1002 , Rev. 0 - SHINE Facility Truss Evaluation
    - CALC-2012-10359, Rev. 2 - Determination Of Strain-Dependent Soil Properties
    - CALC-2018-06920, Rev. 0 - Soil-Structure Interaction Analysis (SASSI) and Response Spectra Generation

Design Criteria

- SHINE uses general design criteria to ensure that the SSCs within the facility demonstrate adequate protection against the hazards present
  - The design criteria are selected to cover:
    - Quality standards;
    - Analyses and design for meteorological, hydrological, and seismic effects;
    - Provisions to avoid or mitigate the consequences of fires, explosions, and other manmade or natural conditions;
    - System response to anticipated transients and potential accidents;
    - Redundancy for subcritical assembly protective and safety features;
    - Inspection, testing, and maintenance of safety SSCs; and
    - The basis for SSC operability and availability
  - These general design criteria have been developed to meet the guidance provided in NUREG-1537, Parts 1 and 2, and the associated interim staff guidance

The Safety-Related Structure

[

Security-Related Information

]

The Safety-Related Structure - Mezzanine

[

Security-Related Information

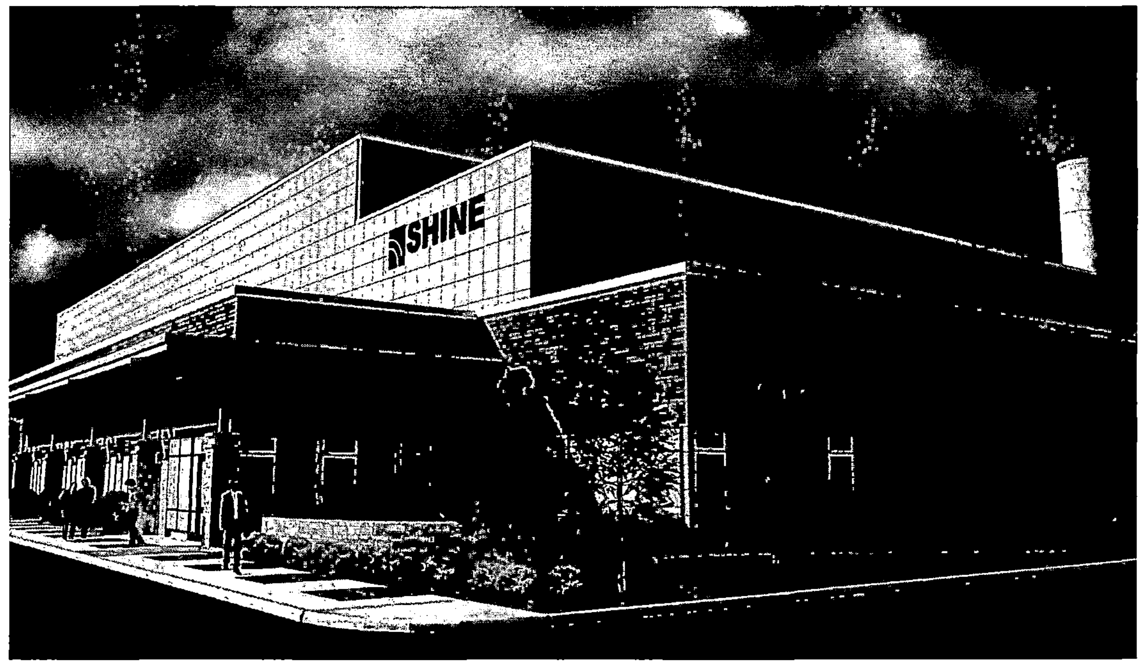
]

The Safety-Related Structure

- Subgrade Design
  - The design basis seismic event provides the dominant forces on the subgrade elements
  - A Soil-Structure Interaction (SSI) analysis is performed using SASSI2010 to determine the seismic load effects on the structure during a seismic event
- Superstructure Design
  - The aircraft impact provides the dominant forces on the superstructure elements
    - Local response evaluation confirms that the aircraft will not penetrate the structure
    - Global response evaluation confirms that the energy imparted onto the structure will not cause excessive deformations or a large-scale failure

Key Structural Considerations

- Designed to survive an aircraft impact as a design-basis condition due to proximity to Janesville airport
- Partially embedded structure was required to be designed for soil-structure interaction effects
- Building arrangement has evolved since the PSAR submittal for efficiency in performance and construction
- Main production facility building structure design package is complete
- Final load checks, incorporating vendor data, will be performed at completion of construction prior to placing the building into service



Building Arrangement

[

Security-Related Information

]

Building Arrangement – Ground Floor

[

Security-Related Information

]

Building Arrangement – Mezzanine

[

Security-Related Information

]

Building Arrangement

[

Security-Related Information

]

Seismic Analysis

- For the PSAR:
  - Building was first designed using a fixed-base seismic time-history analysis model in SAP2000.
  - Soil-structure interaction (SSI) analysis was performed in parallel in SASSI.
  - Nodal accelerations from the time-history analysis were compared to the nodal accelerations of the SSI analysis.
  - A scale factor was applied to the SAP2000 seismic results to amplify the fixed base time history analysis results based on a comparison to best-estimate SSI results.
  - The SAP2000 model forces are post-processed (code checked) to confirm compliance with code requirements for concrete .

From PSAR

"**3.4.2.6.4.5 Earthquake Load**
A time history analysis is conducted on a fixed-base model...
Directional masses and accelerations for each joint are extracted from the fixed-base model. The directional masses for each joint are multiplied by the corresponding accelerations in order to obtain nine seismic force terms. Seismic design forces are increased by a factor derived by a ratio of SSI accelerations to design accelerations in order to envelope the SSI seismic design forces."

Seismic Analysis

- For the FSAR:
  - A 3D building model was developed in SAP2000.
  - The model's stiffness and seismic mass characteristics were converted to an identically numbered SASSI model.
  - Soil properties were added to the model to explicitly represent best-estimate, lower-bound, and upper-bound soil cases, as well as a cracked concrete best estimate evaluation.
  - Seismic time history analysis was performed in SASSI to produce maximum static accelerations at each node from all soil cases.
  - The maximum SASSI nodal accelerations were applied directly in the SAP2000 model on a equivalent static basis. Linear elastic soil springs, derived in accordance with ASCE 4, are applied to the equivalent static model.
  - The SAP2000 model forces are post-processed (code checked) to confirm compliance with code requirements for concrete.

Seismic Analysis

- Reasons for Change:
  - Building configuration was sufficiently mature to allow for a more precise modeling approach
  - Direct application of seismic data is less prone to error
  - Both approaches are accepted by NUREG-1537 and guidance in IAEA 1347
  - More accurately captures the below grade building response
  - Overall, the seismic analysis performed for the FSAR is more robust than the analysis that was performed for the PSAR.
  - The resulting design envelopes seismic demand from all applicable soil cases and ensures adequate protection of equipment and nuclear safety.

From IAEA 1347

> "**6.1.4. Soil structure interaction**
>
> The dynamic response of the coupled model of soil and structure needs to be evaluated taking into account the behaviour of the soil region around the foundation and of the seismic waves propagating into it. If SSI effects are deemed to cause beneficial effects, then the analyses may be carried out without incorporating SSI."

Structural Analysis Model Configuration

[

Security-Related Information

]

Structural Analysis Model Configuration

[

Security-Related Information

]

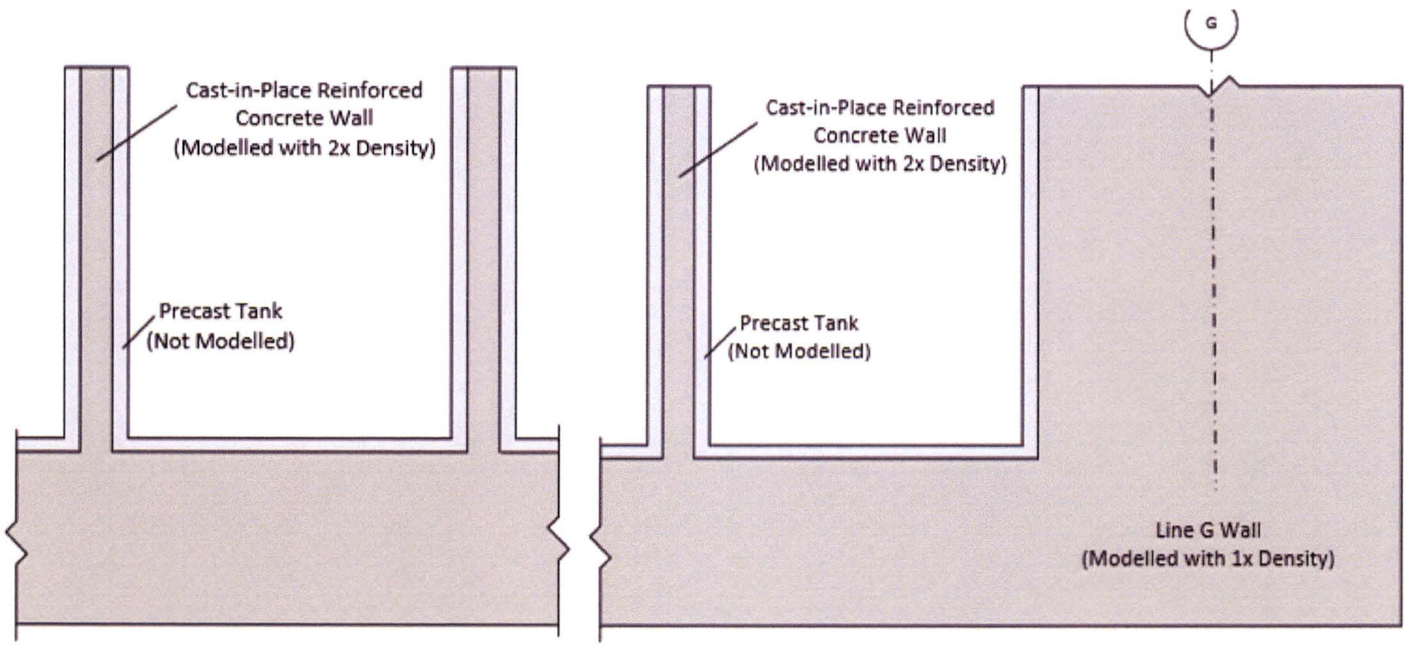
Structural Analysis Model Configuration

[

Security-Related Information

]

Precast Vaults as Stay-in-place Forms

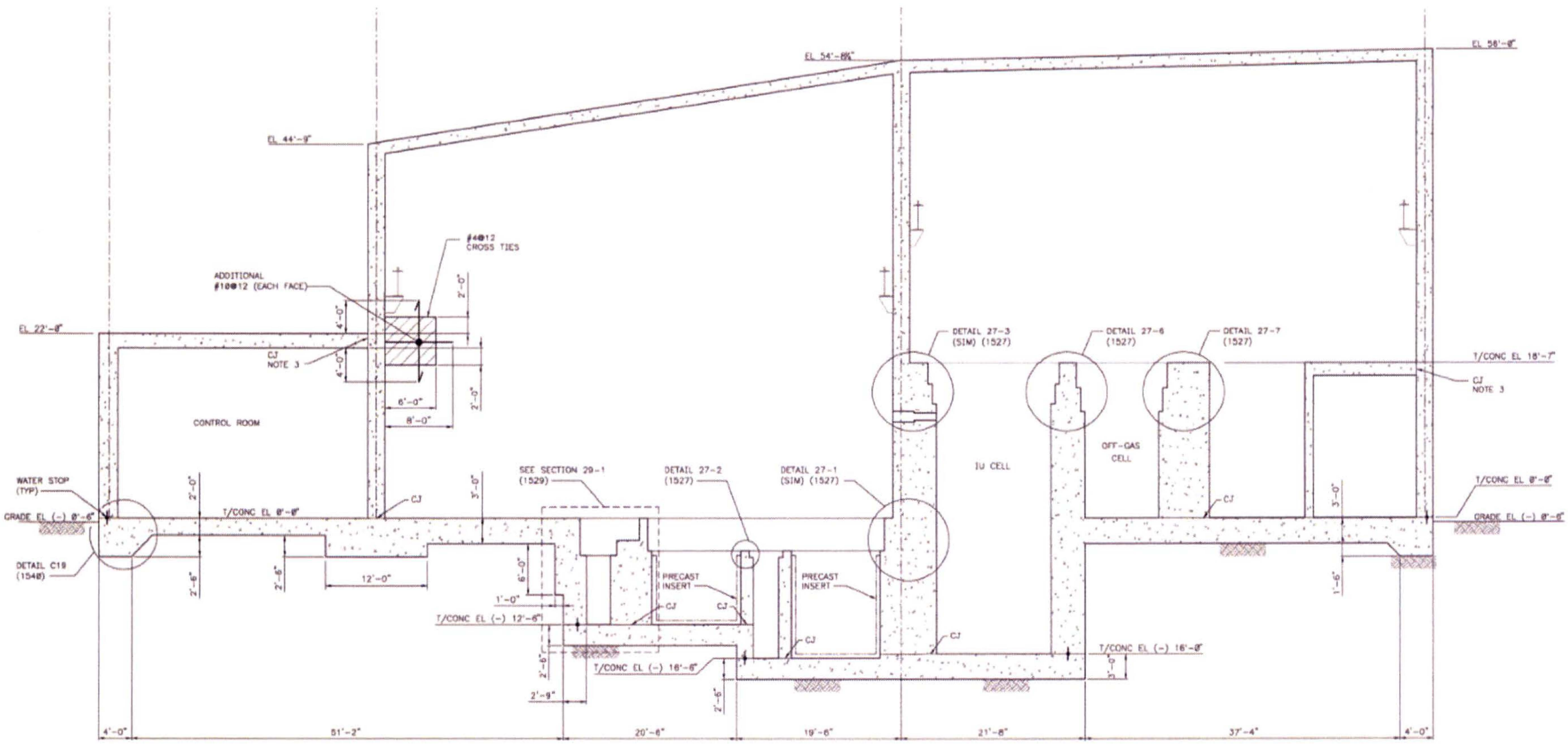


Precast Vaults as Stay-in-place Forms

[

Security-Related Information

]



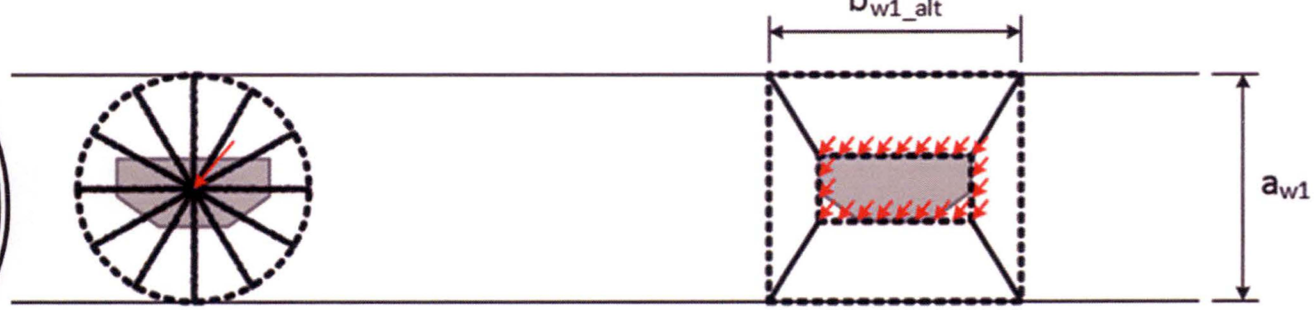
SECTION 10
SCALE: ¼" = 1'-0"

Impact Analysis

- Controlling load effect for most of the superstructure
  - Evaluated as a Design Basis Load, per ACI 349-13 Acceptance Criteria
  - Evaluation of Aircraft Impact Effects based on Energy Balance Approach (DOE-STD-3014, 2006)
  - Aircraft Characteristic Unchanged from PSAR
  - Global Evaluation Similar to PSAR, aside from ACI 349 code year. Outer Building Walls to Remain Cast in Place Concrete. Details of Evaluation Expanded to Address All Cases. Additional Refinement in Analysis Reduced Need for Shear Ties.
  - Global Impact Evaluation of Roof Refined to Credit Deck as Scab Plate
  - Design of Interior Missile Barriers Added
  - Representative reinforcing bar patterns were reported in the PSAR but are not reported in FSAR. Bar patterns are provided in supporting design calculations and drawings.

Impact Analysis

GLOBAL IMPACT ANALYSIS



(a) Model A
Circular fan yield line for concentrated load

(b) Model B
Yield line for distributed loads along the impact footprint

Impact Analysis

ROOF IMPACT ANALYSIS

Concrete Roof Deck Sized to Prevent Perforation
(thinner than was provided in the PSAR, which was size for both perforation and spalling)

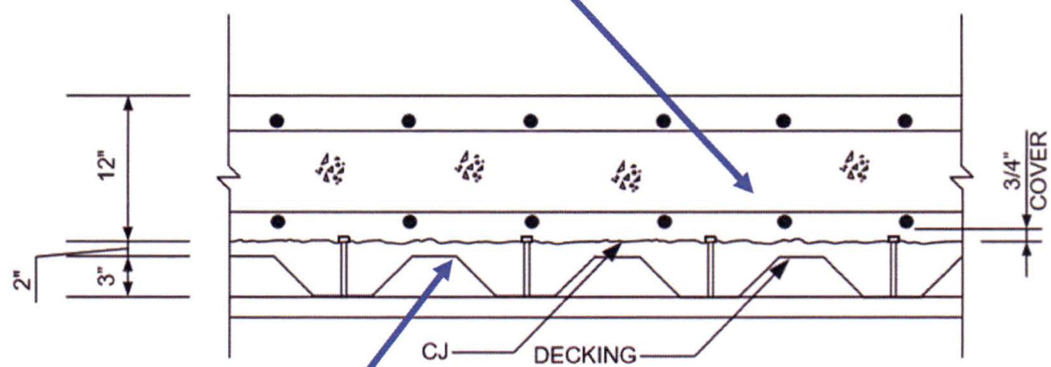
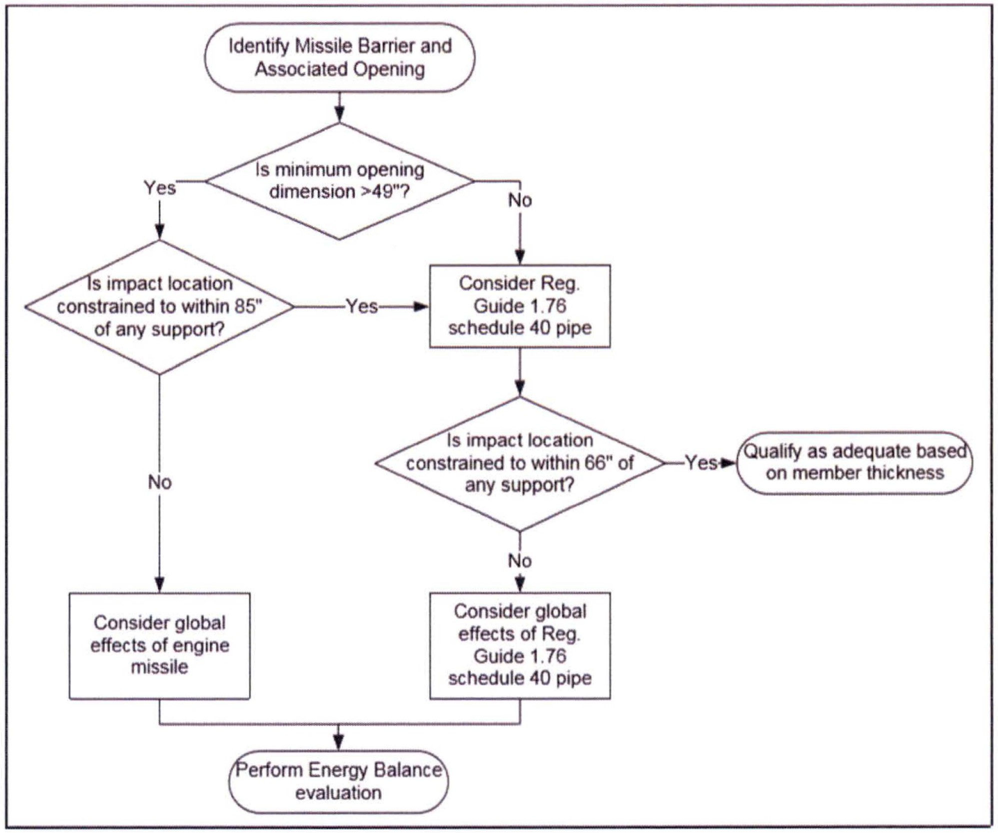


Illustration of Main Building Roof

Metal Decking
Credited as a Scab
Plate to Contain Spalls

Impact Analysis

INTERIOR BARRIER IMPACT ANALYSIS



Impact Analysis

[

Proprietary Information
Security-Related Information

]

Impact Analysis

[

Proprietary Information

]

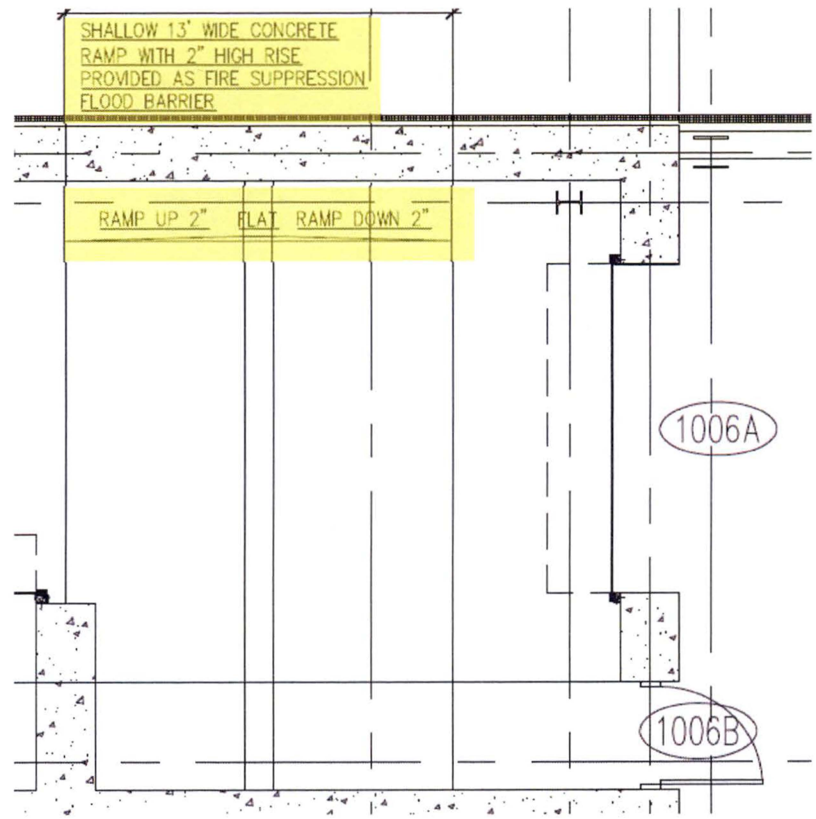
[

Proprietary Information

]

Other Details / Substantive Changes to Chapter 3

- 3.3.1.1.2 Compartment Flooding from Fire Protection Discharge
  - Entrances to Radiological Area Provided with Ramps and/or thresholds to contain expected volume of firefighting water in the event of a fire.



Other Details / Substantive Changes to Chapter 3

- 3.4.2.6.4.6 Crane Load
  - ASME NOG-1 Criteria Being Applied to Crane Procurement and Evaluation
    - Vendor Procurement In Parallel with Construction
    - Seismic Decoupling Criteria of ASME NOG-1 Being Credited In Design

- 3.4.2.6.4.7 Soil Pressure
  - PSAR analysis demonstrated stability with only resistance from at-rest pressure
  - FSAR Stability Analysis requires engagement of 60% of the soil's passive pressure capacity to meet required factor of safety against sliding
  - Outer building walls are sized to accommodate the soil pressure demand required for stability

Summary

- Structural design of the main production facility is in substantial alignment with PSAR commitments, with some minor updates to approach, as noted
- Facility building structure design is complete and complies with the guidance provided in NUREG-1537

ENCLOSURE 5

SHINE MEDICAL TECHNOLOGIES, INC.

MEETING SLIDES FOR THE JANUARY 31, 2019 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC

SCOPE OF THE SHINE MEDICAL TECHNOLOGIES, INC. OPERATING LICENSE APPLICATION

21 pages follow

Scope of the SHINE Medical Technologies, Inc. Operating License Application

Jeff Bartelme, Licensing Manager

Health. Illuminated.™

SHINE Operating License Application – Application Components

I. General Information to be Submitted with the Application

II. Final Safety Analysis Report

III. Programs/Plans to be Submitted with the Application

Health. Illuminated.™

General Information to be Submitted with the Application

Health. Illuminated.™

General Information

- SHINE will provide a standalone enclosure as part of the Operating License Application containing the following general and financial information:
  - Applicant Information [10 CFR § 50.33(a), (b), (c), and (d)(3)]
  - Scope of Application Request [10 CFR § 50.33(e)]
  - Financial Qualification of the Applicant and Stockholder Relationships [10 CFR § 50.33(f)]
    - With appropriate reference to Chapter 15 of the FSAR, as applicable
  - Decommissioning Funding Assurance [10 CFR § 50.33(k)(1)]
    - With appropriate reference to Section 15.3 of the FSAR
  - Fee Information [10 CFR § 50.30(e)/10 CFR § 170.21]
  - Classified Information Agreement [10 CFR § 50.37]

Overview of the Final Safety Analysis Report

Health. Illuminated.™

Final Safety Analysis Report – Format and Content

- The FSAR is being developed following the format and content guidance provided in NUREG-1537 and the Interim Staff Guidance augmenting NUREG-1537
- SHINE is updating the content provided in the Preliminary Safety Analysis Report (PSAR) to reflect the detailed design of the SHINE facility in the FSAR
  - The FSAR is also being updated to incorporate applicable SHINE responses to PSAR requests for additional information (RAIs) (including Regulatory Commitments) and considerations resulting from the review by the Advisory Committee on Reactor Safeguards

Final Safety Analysis Report Overview

- Chapter 1: The Facility
  - No significant organization or content changes from the PSAR
- Chapter 2: Site Characteristics
  - No significant organization or content changes from the PSAR
- Chapter 3: Design of Structures, Systems, and Components
  - SHINE-specific general design criteria have been described, replacing the discussion of the interpretation and application of the 10 CFR Part 50, Appendix A general design criteria provided in the PSAR. System-specific safety functions have been moved to the applicable FSAR Chapters and are no longer discussed in Chapter 3.
  - The definition of safety-related has been updated to align with the ANSI/ANS-15.8 definition of "safety-related items."

Final Safety Analysis Report Overview (cont.)

- Chapter 4a2: Irradiation Facility Description
  - Modified the material of construction of the target solution vessel to Type 347 stainless steel
  - Added detailed discussion of the nuclear design
  - Added discussion on the thermal-hydraulic analysis and the transient nuclear analysis
- Chapter 4b: Radioisotope Production Facility Description
  - Added discussion of the Uranium Receipt and Storage System (URSS)
  - Removed discussion of the Uranyl Nitrate Conversion System (UNCS), including the Uranium Extraction (UREX) and Thermal Denitration (TDN) subsystems (systems removed from the design of the SHINE facility)

Final Safety Analysis Report Overview (cont.)

- Chapter 5a2: Irradiation Facility Cooling Systems
  - Added discussion of the Process Chilled Water System (PCHS), a closed loop cooling system that rejects heat to the atmosphere by use of air-cooled chillers
- Chapter 5b: Radioisotope Production Facility Cooling Systems
  - No significant organization or content changes from the PSAR
- Chapter 6a2: Irradiation Facility Engineered Safety Features
  - No significant organization or content changes from the PSAR
- Chapter 6b: Radioisotope Production Facility Engineered Safety Features
  - Added discussion of the Nitrogen Purge System (N2PS) (new system)
- Chapter 7: Instrumentation and Control Systems
  - Chapter written to align with the format and content guidance provided in the draft Chapter 7 Interim Staff Guidance, describing SHINE's use of the Rock Creek Innovations, LLC Highly Integrated Protection System (HIPS) for safety-related I&C systems

Final Safety Analysis Report Overview (cont.)

- Chapter 8a2: Irradiation Facility Electrical Power Systems
  - No significant organization or content changes from the PSAR
- Chapter 8b: Radioisotope Production Facility Electrical Power Systems
  - No significant organization or content changes from the PSAR
- Chapter 9a2: Irradiation Facility Auxiliary Systems
  - No significant organization or content changes from the PSAR
- Chapter 9b: Radioisotope Production Facility Auxiliary Systems
  - Removed discussion of the Noble Gas Removal System (NGRS) (system removed from the design of the facility)
  - Added discussion of the Vacuum Transfer System (VTS) (new system)
- Chapter 10: Experimental Facilities
  - Chapter remains not applicable to the SHINE facility

Final Safety Analysis Report Overview (cont.)

- Chapter 11: Radiation Facility Protection Program and Waste Management
  - No significant organization or content changes from the PSAR
- Chapter 12: Conduct of Operations
  - Appendix 12A, 12B, 12C, and 12D removed from Chapter
- Chapter 13a2: Irradiation Facility Accident Analyses
  - Updated accident sequences based on the results of the Integrated Safety Analysis
  - Modified the dose analysis consequence limit to 500 mrem total effective dose equivalent (TEDE) to members of the public offsite
- Chapter 13b: Radioisotope Production Facility Accident Analyses
  - Updated accident sequences based on the results of the Integrated Safety Analysis
  - Modified the dose analysis consequence limit to 500 mrem TEDE to members of the public offsite
  - New RPF MHA, resulting from removal of the NGRS storage tanks from the design of the facility

Final Safety Analysis Report Overview (cont.)

- Chapter 14: Technical Specifications
  - Chapter rewritten to provide brief discussion of the development of the Technical Specifications
- Chapter 15: Financial Qualifications
  - Discussion of the financial ability to decommission the facility addresses the detailed decommissioning cost estimate performed by SHINE, as well as an indication of the method chosen to provide funds for decommissioning
- Chapter 16: Other License Considerations
  - Chapter remains not applicable to the SHINE facility
- Chapter 17: Decommissioning and Possession Only License Amendment
  - Chapter remains not applicable to the SHINE facility
- Chapter 18: Highly-Enriched to Low-Enriched Uranium Conversion
  - Chapter remains not applicable to the SHINE facility

Programs/Plans to be Submitted with the Operating License Application

Health. Illuminated.™

Environmental Report Supplement

- SHINE will submit the Supplement to the Applicant's Environmental Report – Operating License Stage as part of the Application, consistent with the requirements in 10 CFR § 51.53(b)
- The Supplement will discuss matters that differ or that reflect new information since the publication of the Final Environmental Impact Statement by the NRC
  - The level of detail for each new or different matter will be similar in level of detail to that considered by the NRC Staff in the Final Environmental Impact Statement

Emergency Plan

- SHINE will submit the Emergency Plan as part of the Application, consistent with the requirements in 10 CFR § 50.34(b)(6)(v)
- The Emergency Plan is being developed to conform to the requirements of 10 CFR Part 50, Appendix E, following the guidance of:
  - Regulatory Guide 2.6, "Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities," Revision 2
  - ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors"
  - NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors"
  - ANSI/ANS-8.23-2007, "Nuclear Criticality Accident Emergency Planning and Response"

Operator Training Programs

- SHINE will submit the Operator Requalification Program as part of the Application, consistent with the requirements in 10 CFR § 50.34(b)(8)
  - While not explicitly required by regulation, SHINE will also submit the Initial Operator Training Program as supplemental application content, in order for the NRC Staff to meet the acceptance criteria provided in Section 12.10b of the Interim Staff Guidance Augmenting NUREG-1537, Part 2
- The Operator Training Programs are being developed to conform to the requirements of 10 CFR Part 55, as they pertain to the SHINE facility, following the guidance of ANSI/ANS-15.4-2016, "Selection and Training of Personnel for Research Reactors"
  - The Operator Requalification Program specifically is being developed to conform to the requirements of 10 CFR § 55.59, as they pertain to the SHINE facility
  - Additional consideration for the content requirements and areas for review/acceptance criteria described in Parts 1 and 2 of the Interim Staff Guidance augmenting NUREG-1537

Technical Specifications

- SHINE will submit proposed Technical Specifications as part of the Application, consistent with the requirements in 10 CFR § 50.36(a)(1)
- The Technical Specifications are being developed following the guidance of 10 CFR § 50.36 and ANSI/ANS-15.1-2007, "The Development of Technical Specifications for Research Reactors"

Quality Assurance Program Description (QAPD)

- SHINE will submit a Quality Assurance Program Description (QAPD) as part of the Application, consistent with the requirements in 10 CFR § 50.34(b)(6)(ii)
- The QAPD has been developed following the guidance of ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors"

Physical Security Plan

- SHINE will submit a Physical Security Plan as part of the Application, consistent with the requirements in 10 CFR § 73.67(c)(1)
- The Physical Security Plan is being developed following the guidance of Regulatory Guide 5.59, "Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance," Revision 1, and the additional physical security requirements discussed with NRC Staff at an April 6, 2017 closed meeting
- SHINE will submit the Physical Security Plan under separate cover, consistent with the requirements of SHINE's NRC-approved Safeguards Information protection program

Material Control and Accounting (MC&A) Plan

- SHINE will submit a Material Control and Accounting (MC&A) Plan as part of the Application, consistent with the requirements in 10 CFR § 74.41
- The MC&A Plan is being developed following the guidance of the September 2013 *Draft for Comment* version of NUREG-2159, "Acceptable Standard Format and Content for the Material Control and Accounting Plan Required for Special Nuclear Material of Moderate Strategic Significance"
  - SHINE has also reviewed the NRC Staff responses to public comments on the proposed rule and associated draft guidance (ML18061A050) and considered applicable NRC Staff responses in the MC&A Plan

Integrated Safety Analysis (ISA) Summary

- SHINE will submit an Integrated Safety Analysis (ISA) Summary as part of the Application, consistent with the requirements in 10 CFR § 70.65(b)
- The ISA Summary is being prepared using the guidance described in NUREG-1513, "Integrated Safety Analysis Guidance Document," and NUREG-1520, "Standard Review Plan (SRP) for Fuel Cycle Facilities License Applications," Revision 2

ENCLOSURE 6

SHINE MEDICAL TECHNOLOGIES, INC.

MEETING SLIDES FOR THE JANUARY 31, 2019 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC

AFFIDAVIT OF JAMES COSTEDIO

2 pages follow

SHINE® Medical Technologies

AFFIDAVIT OF JAMES COSTEDIO

STATE OF WISCONSIN)
) ss.
COUNTY OF ROCK)

I, James Costedio, Vice President of Regulatory Affairs and Quality of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission (NRC) and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial and financial information submitted in the public meeting slides provided by letter 2019-SMT-0007 with enclosures and the related meeting discussion. SHINE requests that the confidential information contained in Enclosures 1 and 3, and the related meeting discussion, be withheld from public disclosure in their entirety.

2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.

3. Pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.

   a. The information sought to be withheld from public disclosure contained in Enclosures 1 and 3, and the related meeting discussion, is owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.

   b. The information sought to be protected in Enclosures 1 and 3, and the related meeting discussion, is not available to the public to the best of my knowledge and belief.

c. The information contained in Enclosures 1 and 3, and the related meeting discussion, is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial financial information, commercial information, or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.

d. The proprietary information sought to be withheld from public disclosure in Enclosures 1 and 3, and the related meeting discussion, includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope production facility, process and system locations, and process details. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings. Public disclosure of the information in Enclosures 1 and 3, and the related meeting discussion, would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality.

e. Public disclosure of the information in Enclosures 1 and 3, and the related meeting discussion, would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.

f. The information contained in Enclosures 1 and 3, and the related meeting discussion, is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on January 18, 2019.

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, Inc.