January 11, 2017 SMT-2017-001

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

Meeting Slides for the January 18, 2017 Meeting
between SHINE Medical Technologies, Inc. and the NRC

A meeting is scheduled between SHINE Medical Technologies, Inc. (SHINE) and the NRC's Region II construction inspection staff. Enclosure 1 provides the SHINE meeting slides.

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

Enclosure

cc: Project Manager, USNRC
Environmental Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

MEETING SLIDES FOR THE JANUARY 18, 2017 MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC

53 pages follow

NRC Region II Inspector Meeting

January 18, 2017

Agenda

I. Plant Walkthrough
II. Scope of Planned Design Changes
III. Long-Lead Procurement Items
IV. Design Control and Change Process
V. Quality Assurance Program Implementation During Construction
VI. SHINE Support of NRC Construction Inspections
VII. Management of Regulatory Commitments
VIII. Issues Management Process

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SHINE Medical Technologies, Inc.

I. Plant Walkthrough

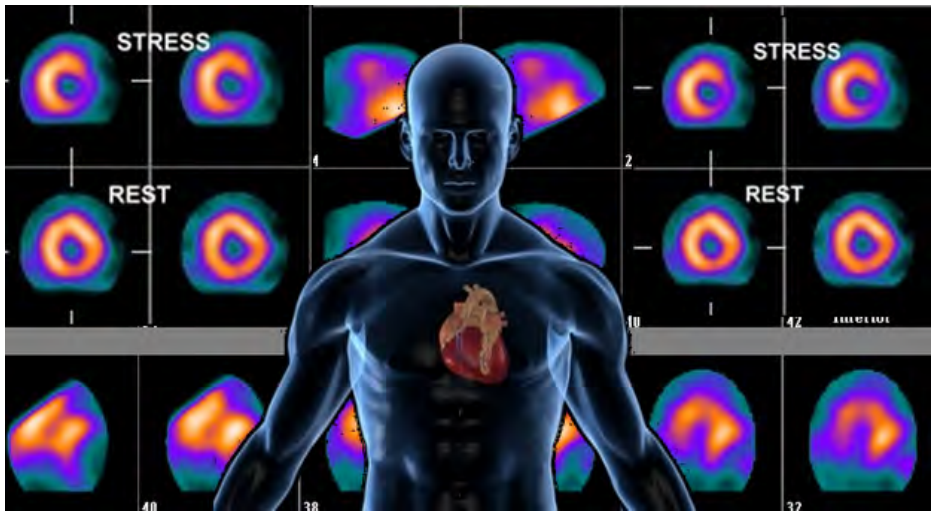
Health. Illuminated.™

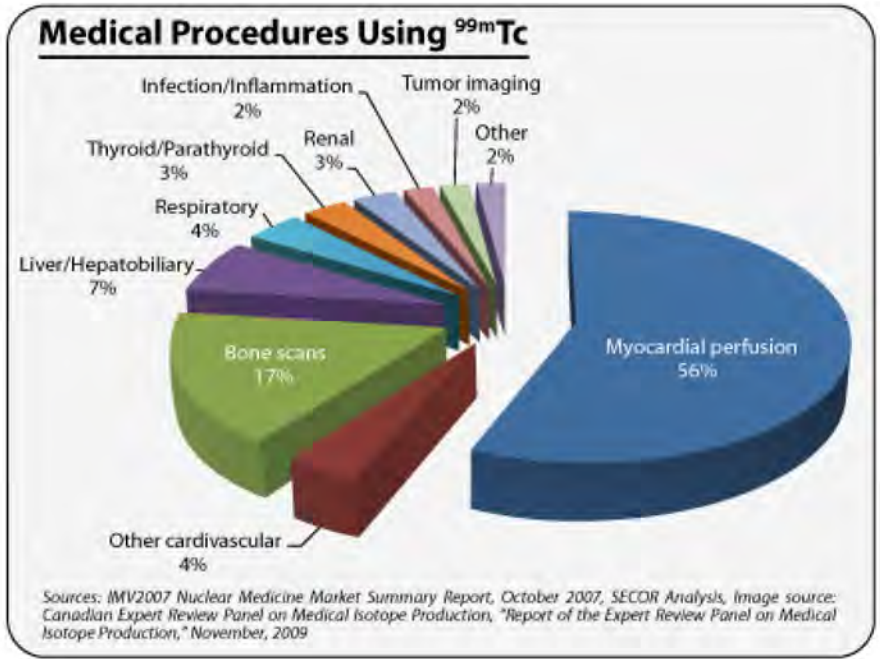
SHINE Medical Technologies, Inc.

- Dedicated to being the world leader in safe, clean, affordable production of medical tracers and cancer treatment elements
- Leading efforts to establish U.S. fission-based medical isotope supply that will fill the gap in supply chain caused by exiting foreign reactors
- Highest priority is safely delivering a highly reliable, high-quality supply of medical isotopes that are required by nearly 100,000 patients globally each day, while maintaining a minimal environmental impact

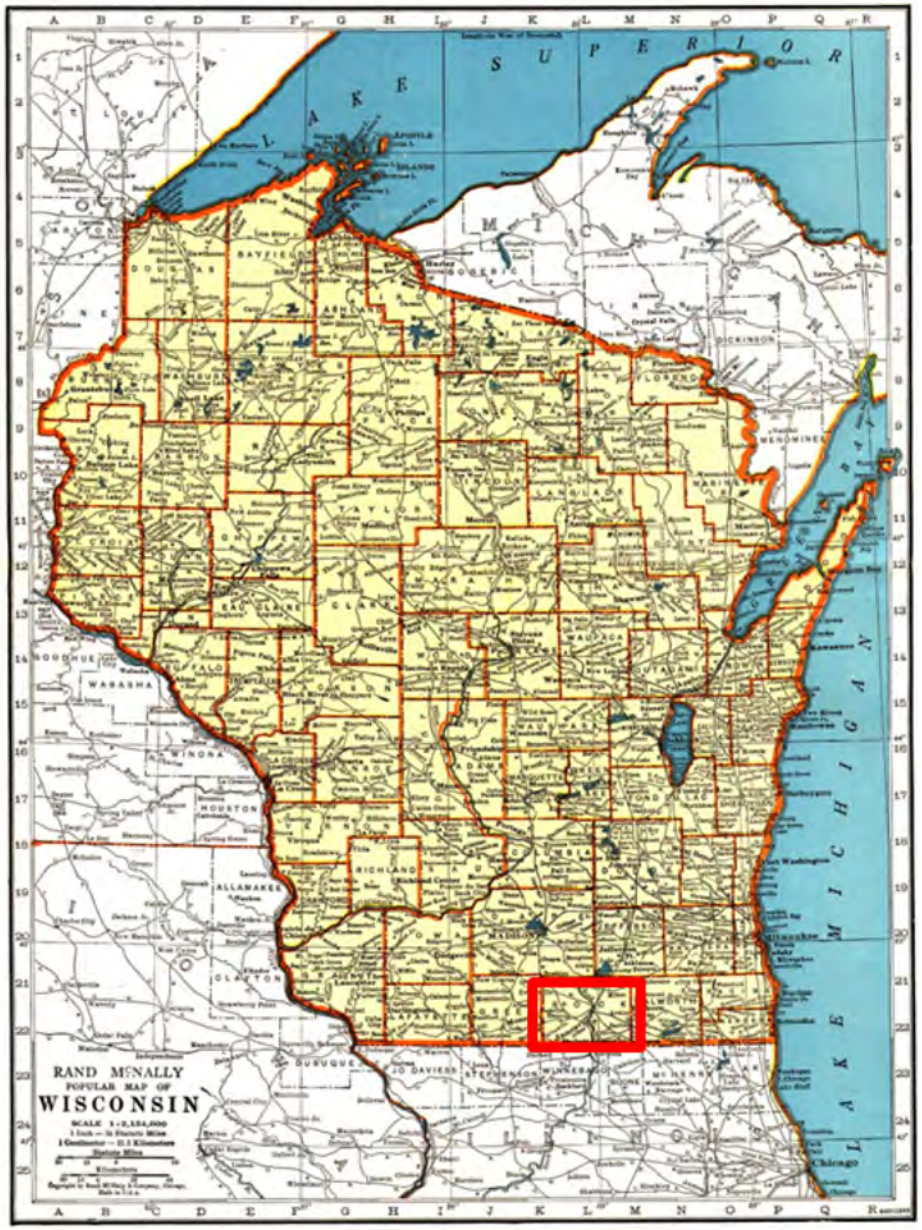
Medical Isotopes

- Molybdenum-99 (Mo-99), the most widely-used medical isotope, decays into technetium-99m, which is used in more than 40 million doses annually
- Mo-99 cannot be stockpiled, which necessitates a reliable and continuous supply
- Stress tests and bone scans most common of dozens of uses
- SHINE's process will also generate iodine-131 and xenon-133

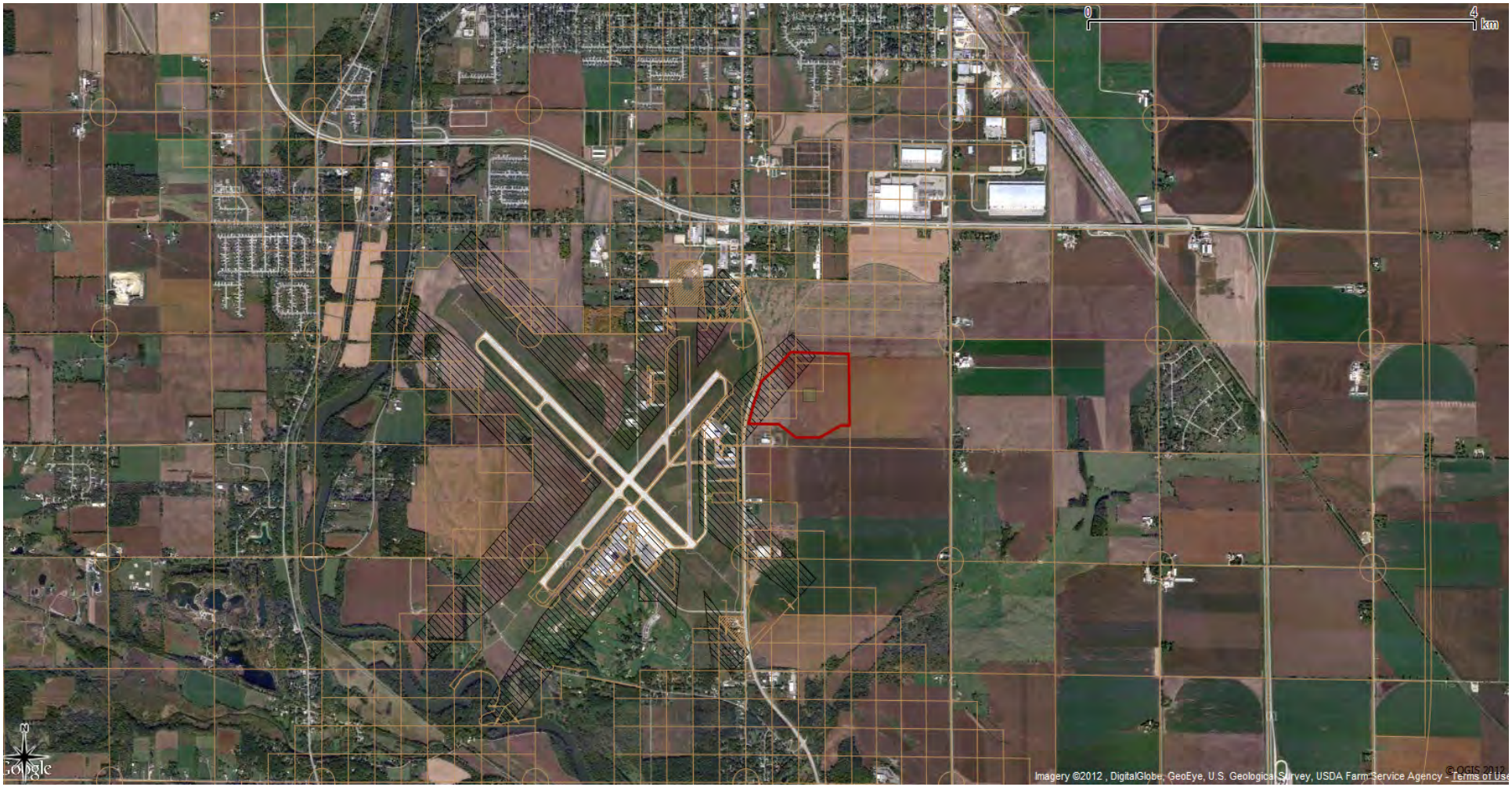




Located in Janesville, Wisconsin

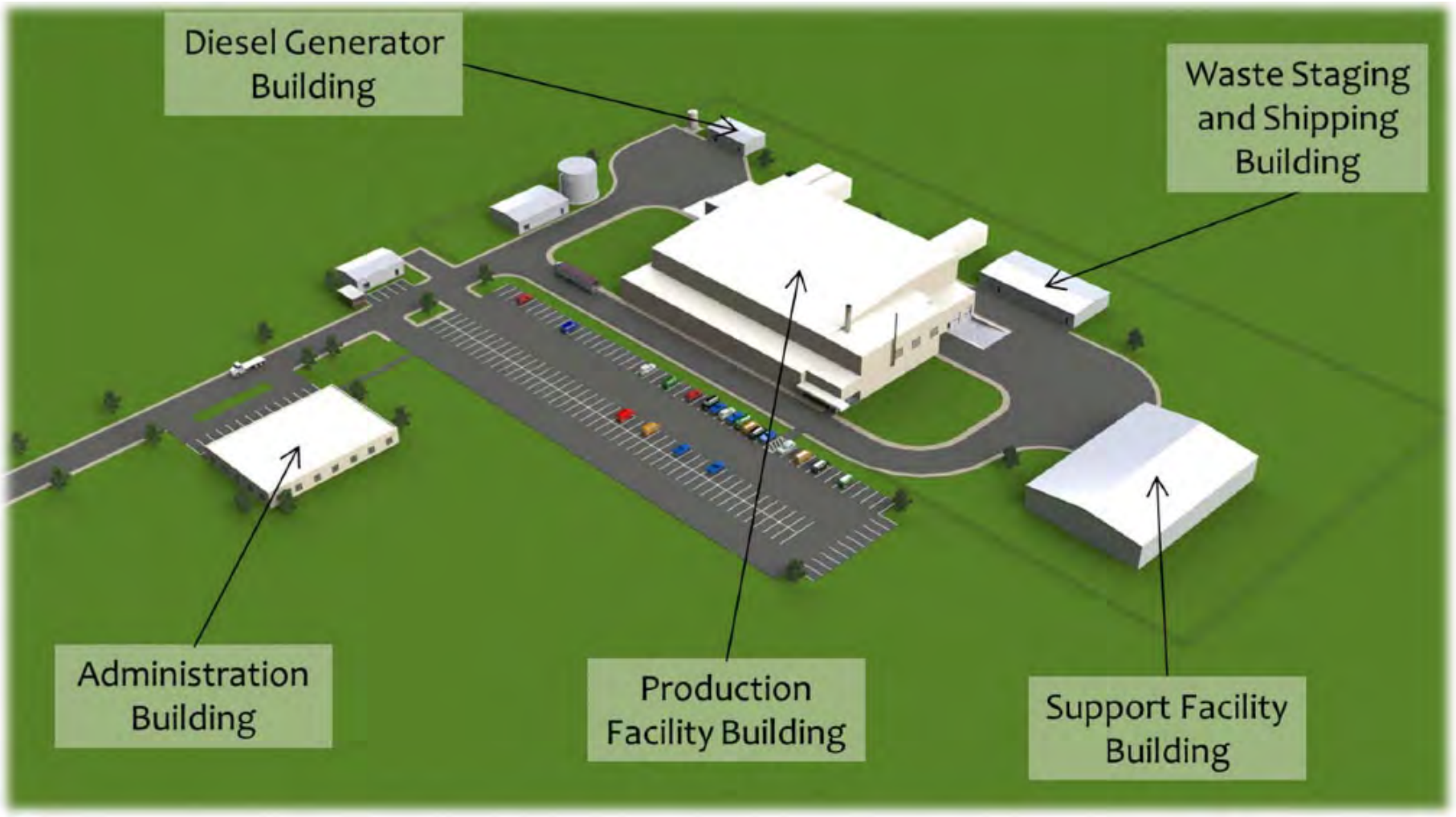


Located in Janesville, Wisconsin

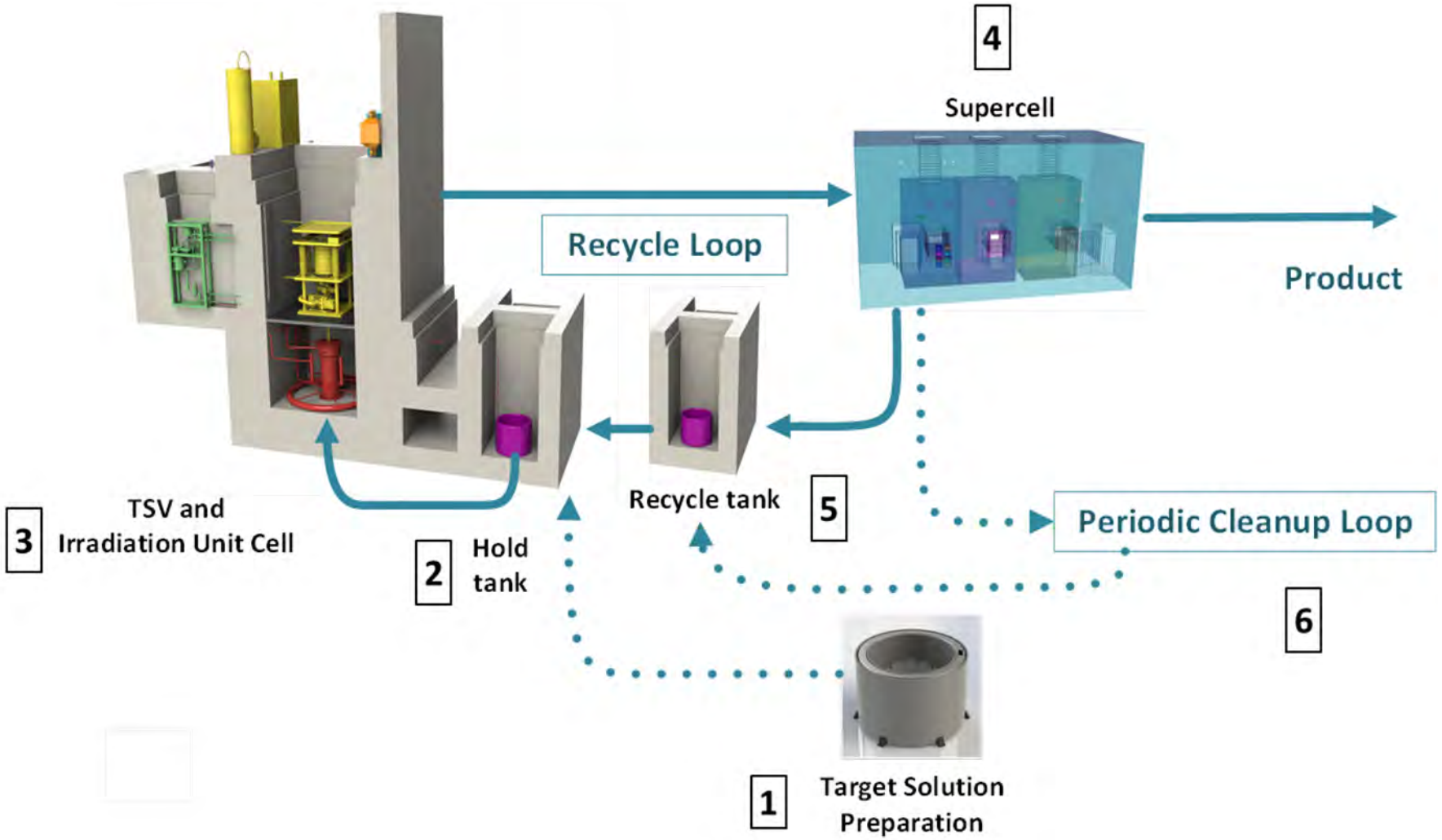


Located in Janesville, Wisconsin

Site Layout


Diesel Generator Building
Waste Staging and Shipping Building
Administration Building
Production Facility Building
Support Facility Building

SHINE Process Overview

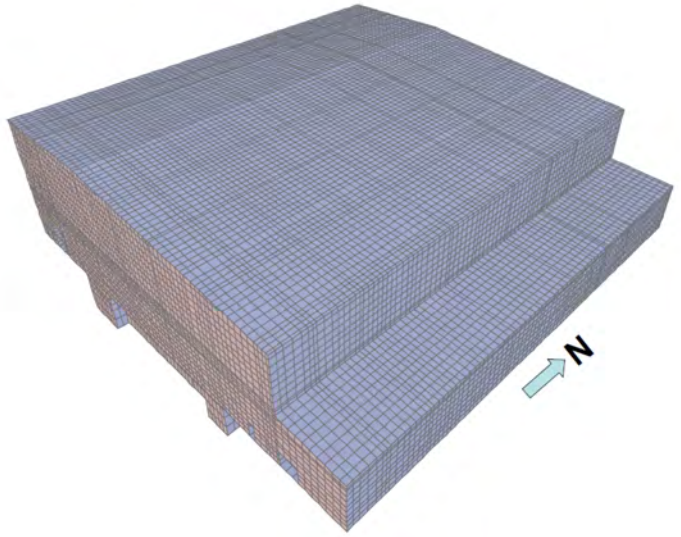


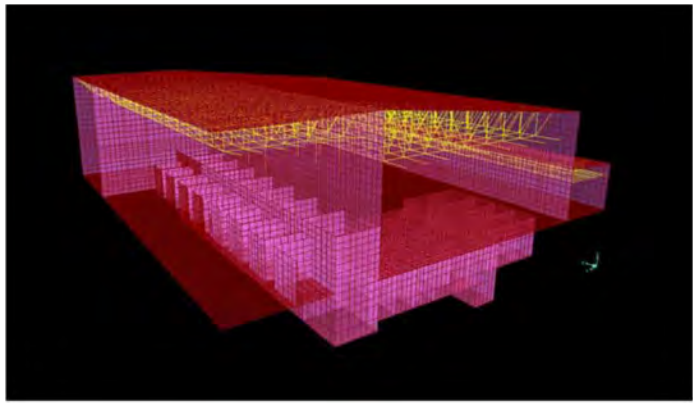
Plant Design

- The SHINE production process consists of an irradiation facility (IF) and a radioisotope production facility (RPF)
- The SHINE IF consists of eight subcritical irradiation units (IUs)
- The RPF is the portion of the SHINE facility used for
  - Preparing target solution
  - Extracting, purifying, and packaging Mo-99
  - Recovering target solution

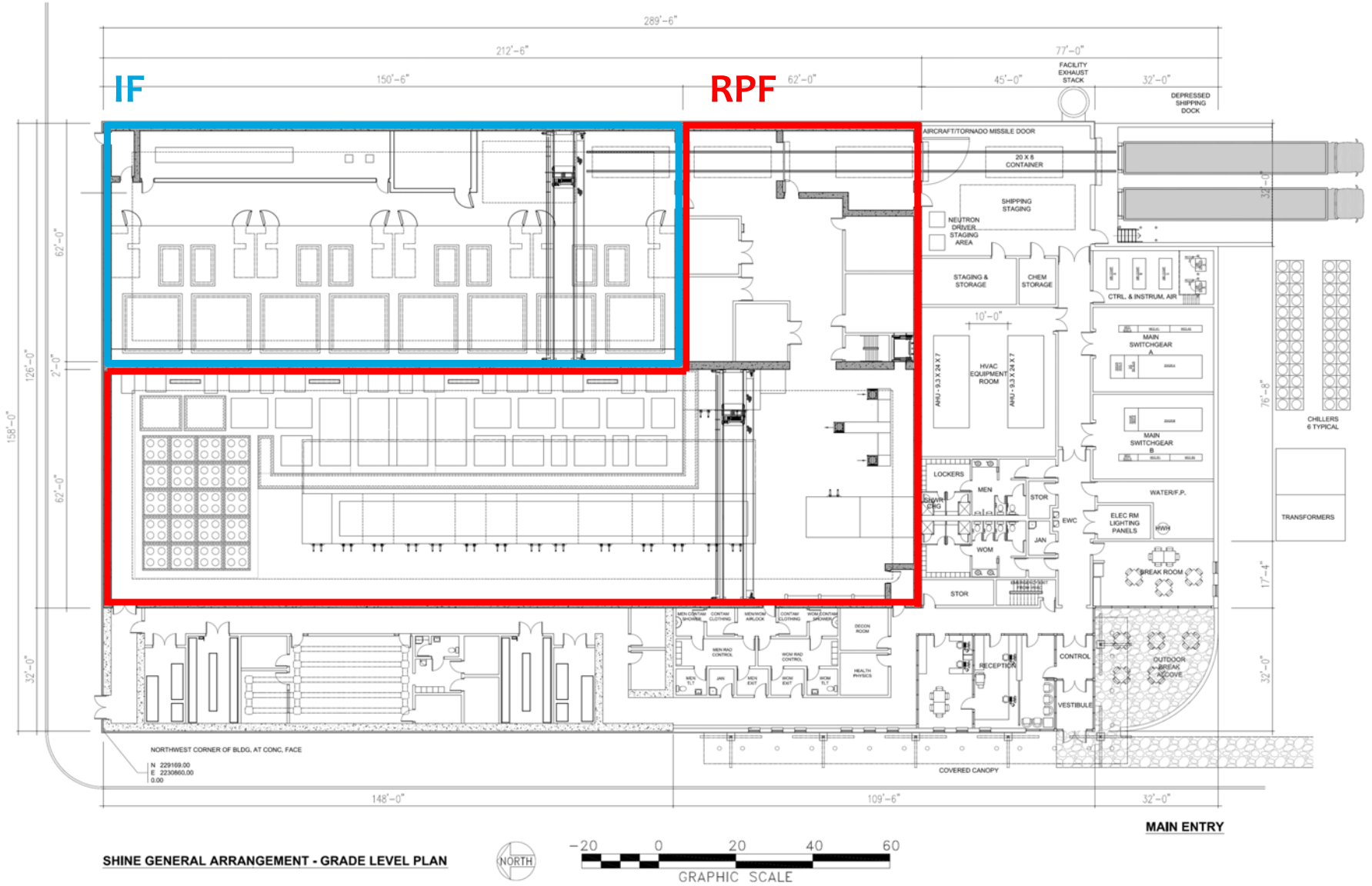
Accident Analysis Summary

- Small systems ensure low source term and decay heat
  - Hundreds of times less power than isotope production reactors currently being used
  - Temperature rise of 12°F (7°C) after 90 days without cooling
- Low temperature and low pressure processes
- Driven by low-energy electrostatic accelerator
  - System must be driven to operate, no criticality
- Main facility building to withstand external events
  - Including seismic, tornado and tornado generated missiles, maximum precipitation and snow load, and aircraft impact
- Maximum hypothetical accident (MHA)
  - Simultaneous release of five gas decay tanks
  - Public (site boundary) TEDE: 82 mrem

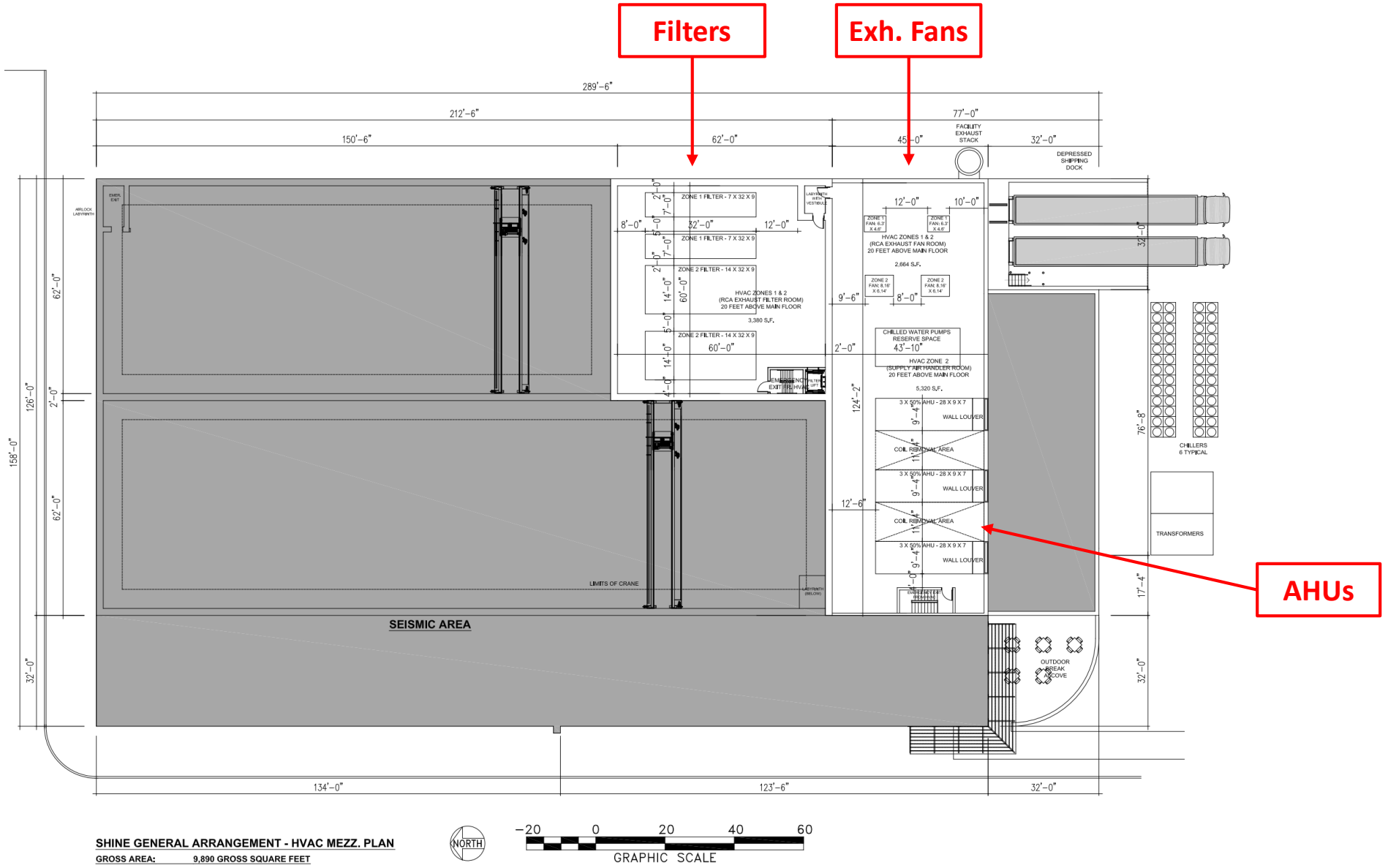




Facility Layout



Facility Layout – Mezzanine Plan



SHINE GENERAL ARRANGEMENT - HVAC MEZZ. PLAN

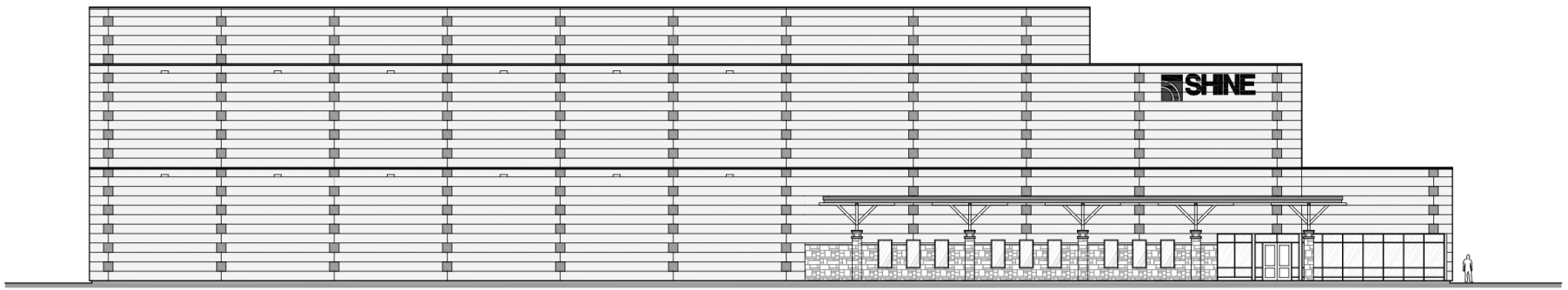
GROSS AREA: 9,890 GROSS SQUARE FEET

NORTH

−20 0 20 40 60

GRAPHIC SCALE

Facility Layout – Elevation View



SHINE PRODUCTION FACILITY - WEST BUILDING ELEVATION

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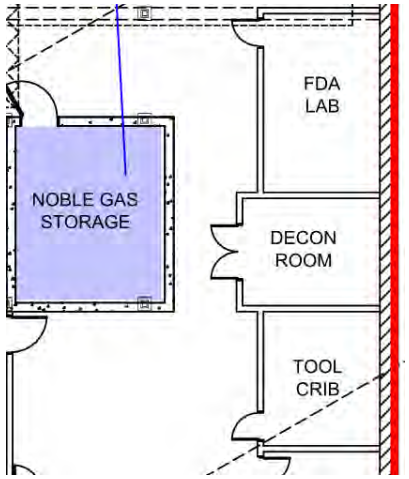
II. Scope of Planned Design Changes

Scope of Planned Design Changes

- SHINE is performing detailed design of the facility
  - Design changes are expected to result
- Design changes revise the preliminary design described in the PSAR
  - One (1) design change of the process technology expected (UREX, discussed later)
  - Other design changes as part of detailed design
    - Incorporation of NRC/ACRS considerations (e.g., exhaust filter train location)
    - Down-selects of design as indicated in the PSAR (e.g., post-LOOP hydrogen recombination)
    - Improvements to safety (e.g., relocation of noble gas handling equipment to below grade vault)
    - Results of detailed engineering work (e.g., updated heat exchanger sizing)
    - Optimizations for construction (e.g., re-arrangement of tank vaults to minimize rebar detail work)

LWPS and PCLS Equipment



Original Noble Gas Storage Location

Planned Design Changes and Construction

- Design change impact on construction inspection
  - Detailed design will produce final design documents stored in SHINE Records repository
    - Available to NRC inspectors
  - Construction is performed following "issued for construction" design packages
  - Documentation will be provided to inspectors in the form of complete packages and specific documents, as needed
  - Changes to the design as described in the PSAR will be tracked
    - Design control process and change control processes govern design
    - Processes compare final design to PSAR
    - Markup of changes is developed for incorporation into draft FSAR/as-submitted FSAR

UREX Removal Evaluation

- SHINE is currently working to remove the UREX process and associated systems from the plant design
  - Removal of UREX system, uranyl nitrate preparation system, thermal denitration system
  - Reduced size Target Solution Cleanup hot cell is retained
- UREX being removed due to certainty on waste disposal and reduced concerns on product purity
- Waste streams volumes expected to be reduced
  - SHINE currently estimates waste target solution, upon final disposal, will be Class B or Class A depending on final isotope partitioning
  - If any GTCC is produced, it is required to be taken by DOE under the American Medical Isotopes Production Act (AMIPA)
- Change will improve safety
  - Eliminates potential accident sequences
  - Simplifies design; reduces the number of unit processes handling fission products and SNM
  - Eliminates red oil potential
  - Reduces maintenance worker dose (ALARA) by reducing number of components requiring servicing

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III. Long-Lead Procurement Items

Long-Lead Procurement Items

- SHINE has identified the long lead procurement items below
- The currently scheduled date to start procurement for each is shown
  - 40 Ton 62’ span Irradiation Facility crane
    - Procurement start: 5/2017
  - 15 Ton 62’ span RPF crane
    - Procurement start: 5/2017
  - Class 1E UPS/Batteries
    - Procurement start: 5/2017
  - Structural steel
    - Procurement start: 6/2017
- SHINE will not begin procurement of items for the facility until necessary procurement and Part 21 procedures and processes are in-place

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IV. Design Control and Change Process

Design Control and Change Processes

- Design control and design change control processes are part of the SHINE Configuration Management program
- The processes maintains consistency between
  - Design requirements
  - Physical configuration
  - Facility documentation
- Implement the design control requirements of the SHINE QAPD

Overview of processes

- Process for requesting, screening, evaluating, and approving (or rejecting) design changes relative to the PSAR
  - Applies only to design changes, not generation of additional details of the design
- Ensures that design changes receive appropriate technical and management review to
  - Ensure safety and environmental impacts are fully understood
  - Assess impacts on the licensing basis and licensing documents
  - Evaluate overall benefits and consequences of the change

Licensing Basis Documents Reviewed during Design Process

- Licensing basis is reviewed, including but not limited to:
  - PSAR, including the Environmental Report (ER)
  - SHINE RAI Responses
  - NRC Safety Evaluation Report (SER) and Environmental Impact Statement (EIS) related to Construction Permit (CP)
- Effect of proposed change on these documents is determined and evaluated
- Markup of affected draft FSAR/as-submitted FSAR sections is created
- Issues Management Report (IMR) is used to track the implementation of any changes to the draft FSAR/as-submitted FSAR
- SHINE CP is reviewed
  - If a change is required, an Amendment Request would be prepared and submitted to the NRC
- Licensing basis review form is reviewed and approved

Conclusions

- Design control and change processes ensures that potential deviations from the approved design are appropriately reviewed and approved
  - Effects on safety and the environment
  - Licensing basis effects
  - Overall effects on the facility design, construction, and operation
- Design packages consolidate affected documents to facilitate a comprehensive review
- Change control process ensures that design requirements, physical configuration, and facility documentation remain consistent

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V. Quality Assurance Program Implementation During Construction

Why Do We Have A QA Program?

Our Stakeholders

- Clients
- Management
- The public, and
- Regulatory agencies

Quality Assurance Program

QUALITY ASSURANCE IS ABOUT…

RAISING THE PERFORMANCE BAR !

How We Raise the Bar

- Good procedures that are followed
- Work planning
- Repetition
- Constant improvement
- Problem identification
- Procurement Control
- Records Management
- Oversight Programs

QAPD/Procedures

- Comply with ANS/ANSI 15.8
- Use the guidance and best practices from various industry standards to develop implementing procedures
- Applied in a graded approach consistent with importance to safety and reliability
- Use extensive QA experience in nuclear industry on what works and what doesn't work well
- Train personnel to the established practices and procedures
- Measure performance regularly
- Continually look for value-added improvements

QA Program Implementation

- SHINE QAPD is the top-level document
- QAPD requirements are passed down to suppliers
- Supplier Qualification process in place
- QC will be performed by independent Constructor QC Inspectors
- SHINE QA will review qualifications of QC Inspectors
- SHINE will have a QC Manager to oversee Contractor QC activities
- SHINE QA/QC will review Constructor QA/QC Procedures
- SHINE QA performs oversight/assessment of QA program implementation

Quality Mode

- Items must be of specified Quality
- Quality is achieved by employees with the knowledge, skills, experience, training and motivation to do the job right
- Persons who manage, perform and verify work contribute to an integrated, cost effective and efficient quality management system to produce a quality product.
- SHINE QAPD lines up with ANS/ANSI 15.8 Criteria

The QA Program Overriding QA Principle

FOR EVERY REQUIREMENT, THERE MUST BE DOCUMENTATION OF HOW THAT REQUIREMENT IS MET

Section 2.1 Organization
Section 2.2 Quality Assurance Program

Section 2.1

- Organizational structure, responsibilities and authority
- Sr. Management expectations for quality
- Responsibilities and interfaces defined and documented
- Freedom/authority of QA to ID, report and verify correction of problems

Section 2.2

- Establishment of program and procedures
- Assessments of QA program adequacy and effectiveness
- Indoctrination and training
- Designation of qualifications and experience

Section 2.3 Design Control

- Design inputs translated into designs
- Design interfaces identified and controlled
- Design adequacy verified by qualified “independent”
- Design changes controlled same as original
- Design analyses sufficiently detailed
- Construction matches design
- Computer programs and software
- Configuration management
- Commercial grade dedication

Section 2.4 Procurement Document Control
Section 2.5 Procedures Instructions and Drawings

Section 2.4

- Procurement documents are clear, accurate with proper requirements
- Design bases and other requirements translated into procurement documents
- Suppliers have QA programs consistent with scope
- Procurement documents developed/reviewed by various SMEs
- Changes controlled/distributed as original design
- Detailed content

Section 2.5

- Activities affecting quality prescribed and performed in accordance with documented instructions, procedures or drawings
- Reference to quantitative or qualitative acceptance criteria to determine prescribed activities have been satisfactorily accomplished

Section 2.6 Document Control
Section 2.7 Control of Purchased Items and Services

Section 2.6

- The most current information available in documents
- Controlled document (CD) identification and distribution
- ID responsibility for preparation, review, approval and distribution of CDs
- Review of CDs for adequacy, completeness and proper approval
- Change control – changes reviewed and approved as original

Section 2.7

- Assure Items/Services comply with procurement documents
- Source and bid evaluation
- Evaluation of objective evidence of quality furnished by supplier
- Supplier qualification process
- Source inspection, audit and examination
- Methods of acceptance (C of Cs, receipt inspection, testing)
- Control supplier nonconformances (notify/evaluate/disposition)

Section 2.8 Identification and Control of Items
Section 2.9 Control of Special Processes

Section 2.8

- Ensure correct and acceptable items are used and installed
- ID from initial receipt and fabrication up to installation and use
- Physical Marking or physical separation or procedural control
- ID limited shelf life items
- Maintenance of markings during duration and storage conditions

Section 2.9

- Special Processes that control/verify quality (Welding, Heat Treating, NDE)
- Performed by qualified personnel, using qualified procedures
- In accordance with specified requirements
- Proper conditions, environment and equipment
- Calibration requirements, acceptance criteria, codes and standards

Section 2.10 Inspections

- In-process and final inspections
- Inspections planned and executed
- Characteristics and methods identified
- Performed by qualified personnel
- Cannot inspect ones own work
- Acceptance criteria and authority defined
- Hold points and who may waive
- Sampling – process defined, statistical methods
- Nonconformance system

Section 2.11 Test Control
Section 2.12 Control of Measuring and Test Equipment

Section 2.11

- Test requirements and acceptance criteria
- Provided by the responsible design organization
- Documented test plans and procedures
- Results evaluated by responsible authority
- Determination that requirements satisfied

Section 2.12

- Tools, gages, other M&TE used for activities affecting quality controlled
- Calibration periods, adjusted/maintained to recognized standards
- At regular intervals and when suspect
- Procedures identify or reference accuracy
- Segregation and non-use of out-of-calibration M&TE, with status indication
- Corrective action process, including back-check
- Handling, storage, environmental controls
- Not applicable to commercial equipment (rulers, tapes, levels)

Section 2.13 Handling, Storage and Shipping
Section 2.14 Inspection, Test and Operating Status

Section 2.13

- Ensure items to be used/installed are not damaged
- Prevention of damage, loss or deterioration
- In accordance with procedures, drawings, specifications or instructions
- Special containers, environments and other protective measures
- Special handling tools and equipment which must be tested and inspected according to procedures
- Marking and labeling

Section 2.14

- The status of inspection and test activities shall be identified
- Items that have not passed the required inspections and tests are not inadvertently installed, used, or operated

Section 2.15 Control of Nonconforming Items
Section 2.16 Corrective Actions

Section 2.15

- Identification on item or container
- Documentation (NCRs, inspection forms)
- Control (segregation, tags, locks, blocks)
- Evaluation (responsibility, authority, expertise)
- Disposition and reexamination
- Rework, repair, use-as-is, reject dispositions

Section 2.16

- Conditions adverse to quality identified promptly and corrected as soon as practicable
- Correction in accordance with design requirements
- For significant conditions adverse to quality, the cause of the condition determined and corrective action taken to preclude recurrence
- The identification, cause, and corrective action for significant conditions adverse to quality documented and reported to management
- Completion of corrective actions verified

Section 2.17 Quality Assurance Records
Section 2.18 Assessments

Section 2.17

- Furnish documentary proof that items/activities meet specified requirements
- Identified, generated, authenticated, maintained and final disposition Id'd
- Receipt control
- Classification (permanent or nonpermanent) with retention periods
- Storage - requirement for dual or single
- Retrieval

Section 2.18

- Assessments performed to verify compliance to requirements, performance criteria and effectiveness of programs/procedures
- Assessments performed to procedures/checklists
- Qualified and independent assessors
- Reported/reviewed by responsible management
- Scheduling, preparation, performance, reporting, response and follow-up

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VI. SHINE Support of NRC Construction Inspections

SHINE Support of NRC Construction Inspections

- SHINE intends to maintain frequent communications with the NRC into the Construction Phase
  - The SHINE Licensing Manager will be the point of contact for the NRC's RII Construction Project Manager
  - Continue weekly phone calls with NRR Project Manager
  - As recommended in the May 26, 2016 Public Meeting, SHINE will participate in weekly teleconferences with NRR and RII Construction Project Management staff
- To support the NRC's construction inspections, SHINE intends on establishing/maintaining an access-controlled electronic reading room
  - Access provided to NRC
  - Electronic reading room to include pertinent licensing basis documents (e.g., construction schedules, procedures, QAPD) and specific documents to satisfy formal inspection document requests
- SHINE will provide NRC inspectors with work space at the SHINE offices and at the construction site

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VII. Management of Regulatory Commitments

Management of Regulatory Commitments

- SHINE Procedure 2200-01-02, "Regulatory Commitment Management," defines the responsibilities and process for management of Regulatory Commitments
  - Identification of Regulatory Commitments in incoming/outgoing correspondence
  - Tracking of Regulatory Commitments
  - Revising Regulatory Commitments
  - Documenting completion and closure of Regulatory Commitments
- SHINE tracks Regulatory Commitments in the Certrec Action Tracking System, ensuring each Regulatory Commitment is assigned an Owner and a Due Date

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VIII. Issues Management Process

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Issues Management Process

- The SHINE Corrective Action Program is implemented via Procedure 2200-01-01, "Issues Management," defining the process for identifying and documenting issues, and developing and implementing appropriate corrective actions
  - SHINE's Issues Management Process applies to work performed by SHINE and its contractors, and addresses all aspects of the business (e.g., design, procurement, construction, operations, quality, ES&H, facilities)
- SHINE uses the Certrec Action Tracking System to administer the Issues Management Process
- To date, SHINE has initiated approximately 500 Issues Management Reports (IMRs), dating back to 2013

Issues Management Process

- IMR Initiation
  - IMRs are initiated upon discovery of an issue, or at the first opportunity the initiator has to initiate the IMR
  - Individuals are encouraged to initiate an IMR on any issue without fear of retribution for identifying the issue
  - If the initiator believes it is necessary, 2200-01-01 includes provisions for an IMR to be initiated anonymously
- IMR Screening
  - IMRs are screened by the IMR Committee
    - Classification as a Significant Condition Adverse to Quality (SCAQ), a Condition Adverse to Quality (CAQ), or Condition Not Adverse to Quality (NCAQ)
    - Assignment of a Significance Level (i.e., SL-1, SL-2, SL-3, SL-4, or SL-5)
    - Determination of whether the issue requires any regulatory notification or report
    - Assignment of a Responsible Department and an IMR Due Date
    - Assignment of appropriate Action(s) (i.e., Improvement Action, Corrective Action, Condition Evaluation, Apparent Cause Evaluation, or Root Cause Evaluation) to address issue and corresponding Due Date

Issues Management Process

- IMR Action Completion
  - Actions assigned under IMRs are required to be completed by the Assigned To Individual prior to the assigned Due Date
  - Completion of the assigned Action is required to be documented in the Certrec Action Tracking System, including any relevant documents which support completion of the Action
  - The Responsible Manager, upon a satisfactory review of the relevant information supporting completion of the assigned Action, takes the Action to a "Complete" status
- IMR Closure
  - Upon completion of the Action(s) assigned under a specific IMR, the Responsible Manager conducts a final review of the IMR prior to closure
    - For IMRs classified as a Significant Condition Adverse to Quality, the Response Manager is required to acquire IMR Committee concurrence prior to closure
  - Closure of an IMR by the Response Manager requires verification of assigned Actions having been completed and any regulatory reporting requirements having been met

Issues Management Process

- IMR Process Management Assessment
  - The Licensing Manager performs an annual Management Assessment to confirm the effectiveness of the Issues Management Process