November 22, 2016 SMT-2016-052

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

References: (1) U.S. Nuclear Regulatory Commission, "SHINE Medical Technologies, Inc. Discussion on Design Changes and Operating License Structure," Meeting Notice, November 15, 2016 (ML16320A607)

Meeting Slides for the December 1st, 2016 Public Meeting between SHINE Medical Technologies, Inc. and the NRC

A meeting is scheduled between SHINE Medical Technologies, Inc. (SHINE) and the NRC staff to discuss SHINE's evaluation of potential structures of the operating license and planned design changes (Reference 1).

Enclosure 1 provides the SHINE meeting slides. The discussion during the meeting could relate to information identified as security-related information based on the guidance contained in Regulatory Information Summary (RIS) 2005-31. Therefore, SHINE requests the NRC close a portion of the meeting if such a discussion is necessary.

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: Administrator, Region III, USNRC
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 DECEMBER 1ST, 2016 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC

31 pages follow

Discussion of Operating License Structure and Design Changes

December 1, 2016

SHINE Operating License Structure Evaluation

- SHINE evaluated two potential licensing structures for the Operating License:
  1) A single facility Operating License for eight utilization facilities and one production facility; and
  2) Individual Operating Licenses for each of the eight utilization facilities and the one production facility.
- SHINE holds a Construction Permit (CPMIF-001) issued pursuant to Sections 103 and 185a of the Atomic Energy Act of 1954, as amended, and 10 CFR Part 50.
  - The permit is structured such that the single Construction Permit allows construction of the eight utilization facilities and one production facility.

Single Facility Operating License

- Administrative efficiencies in maintaining a single license
- Easier to address systems, structures, and components which are shared between, or common to, multiple utilization facilities
- Consistent with the structure of the SHINE Construction Permit, allowing a direct conversion from Construction Permit to Operating License
- Identical utilization facilities and common Technical Specifications minimize challenge of licensing or technical issues related to different portions of facility; promotes standardization

Multiple Facility Operating Licenses

- Added administrative burden in maintaining multiple licenses
- Amending the single Construction Permit into individual Construction Permits could introduce unnecessary delays in the licensing process and add unnecessary project cost

Operating License Structure Evaluation Results

- SHINE has determined that the issuance of a single facility Operating License consisting of eight utilization facilities and one production facility under 10 CFR Part 50 is the preferred approach in the licensing of the SHINE facility.
  - Provides SHINE with administrative efficiencies and standardization among utilization facilities
  - Consistent with the NRC's issuance of a single Construction Permit for the SHINE facility

Design Changes Discussion – Agenda

I. Plant Walkthrough

II. Scope of Planned Design Changes

III. Removal of UREX

IV. Design Control and Change Processes

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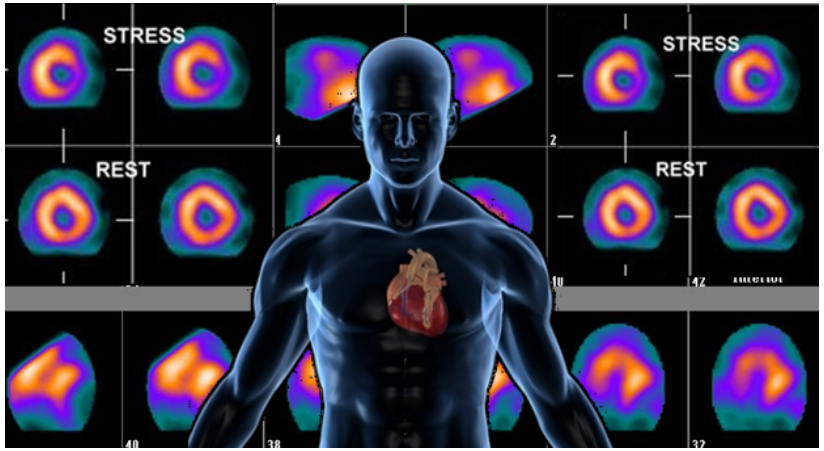
I. Plant Walkthrough

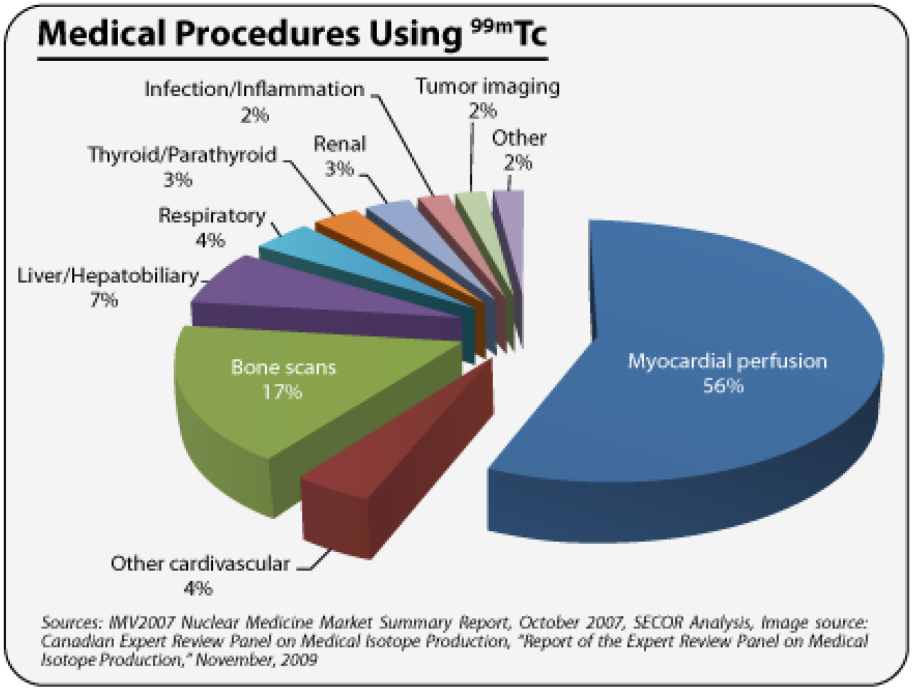
SHINE Medical Technologies, Inc.

- 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

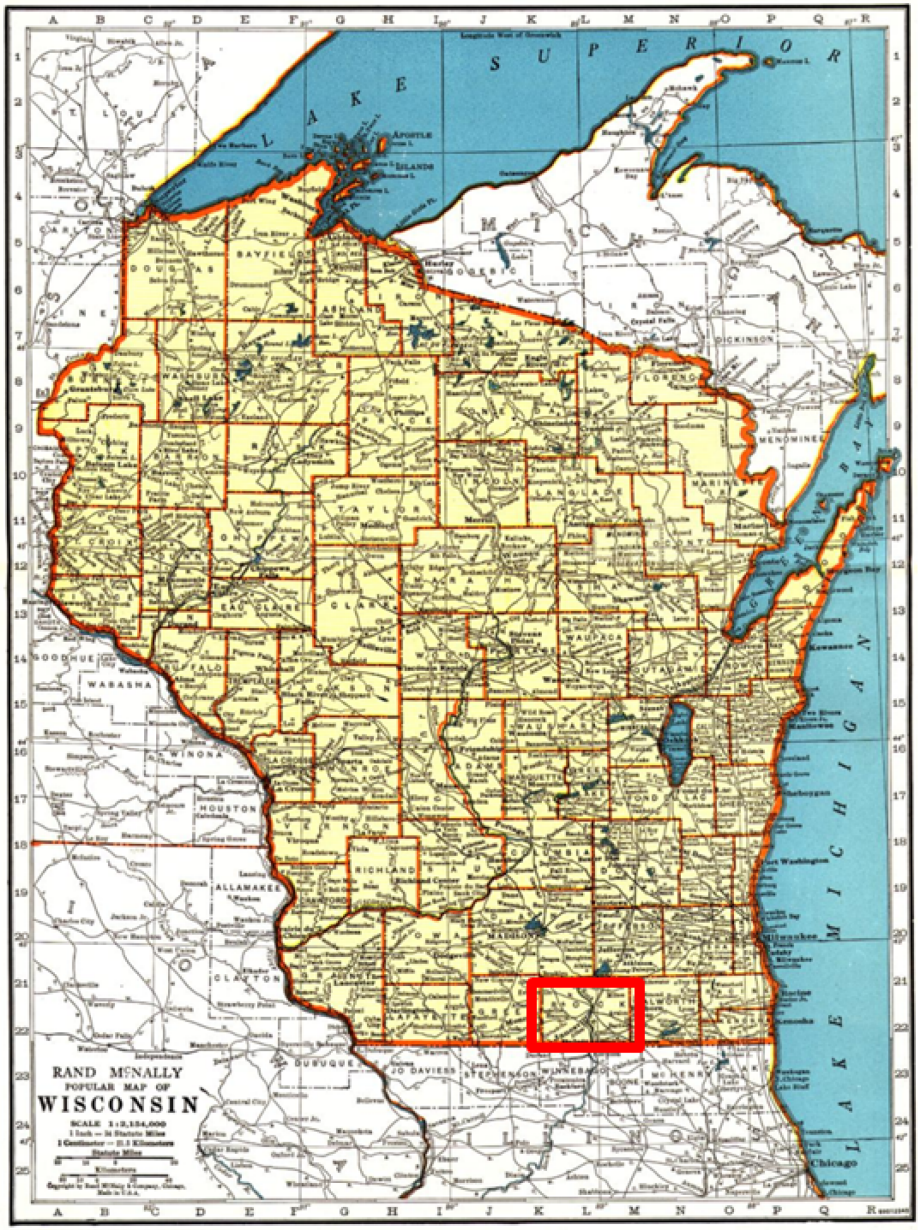
Medical Isotopes

- 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

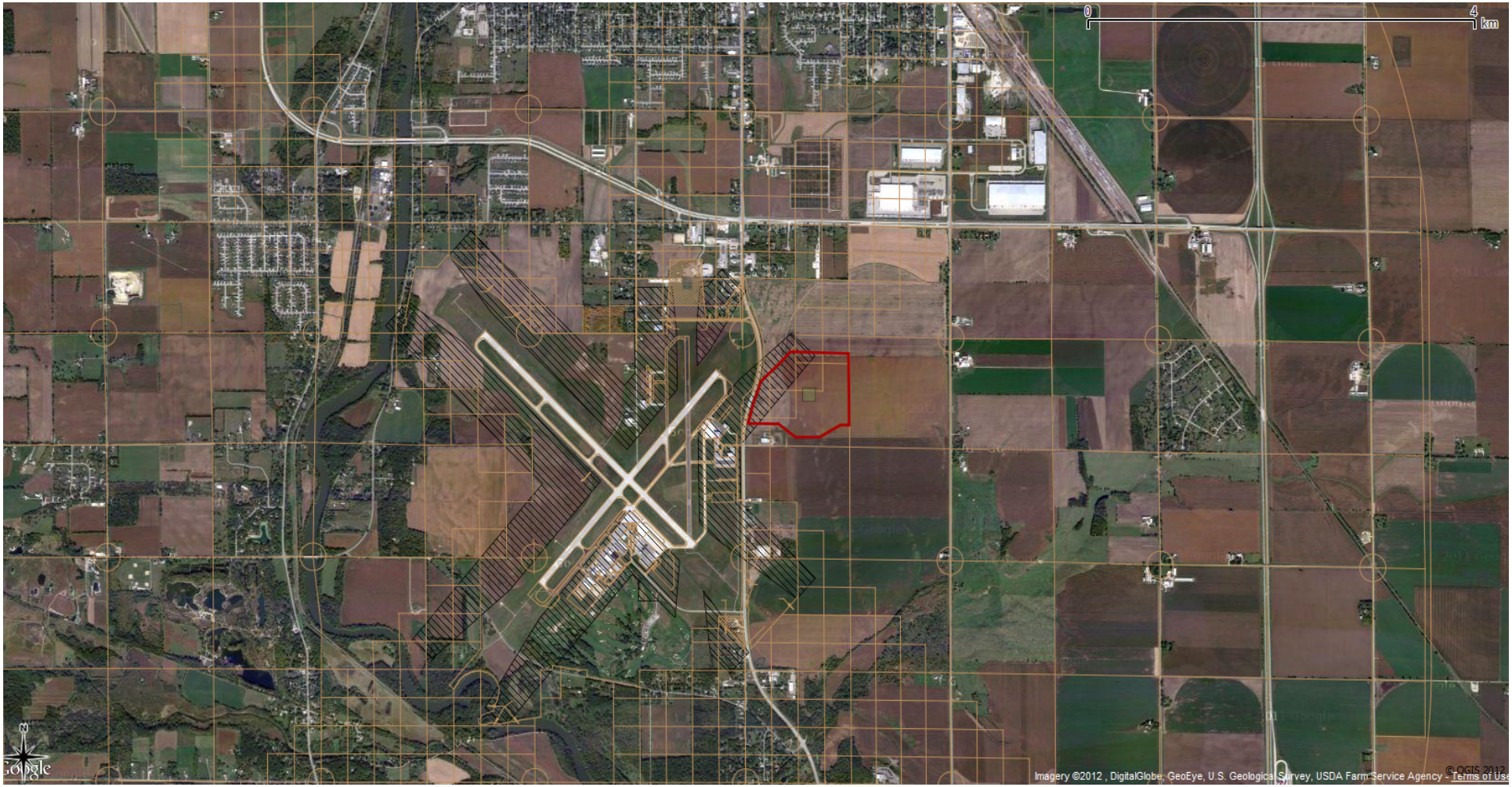




Located in Janesville, Wisconsin

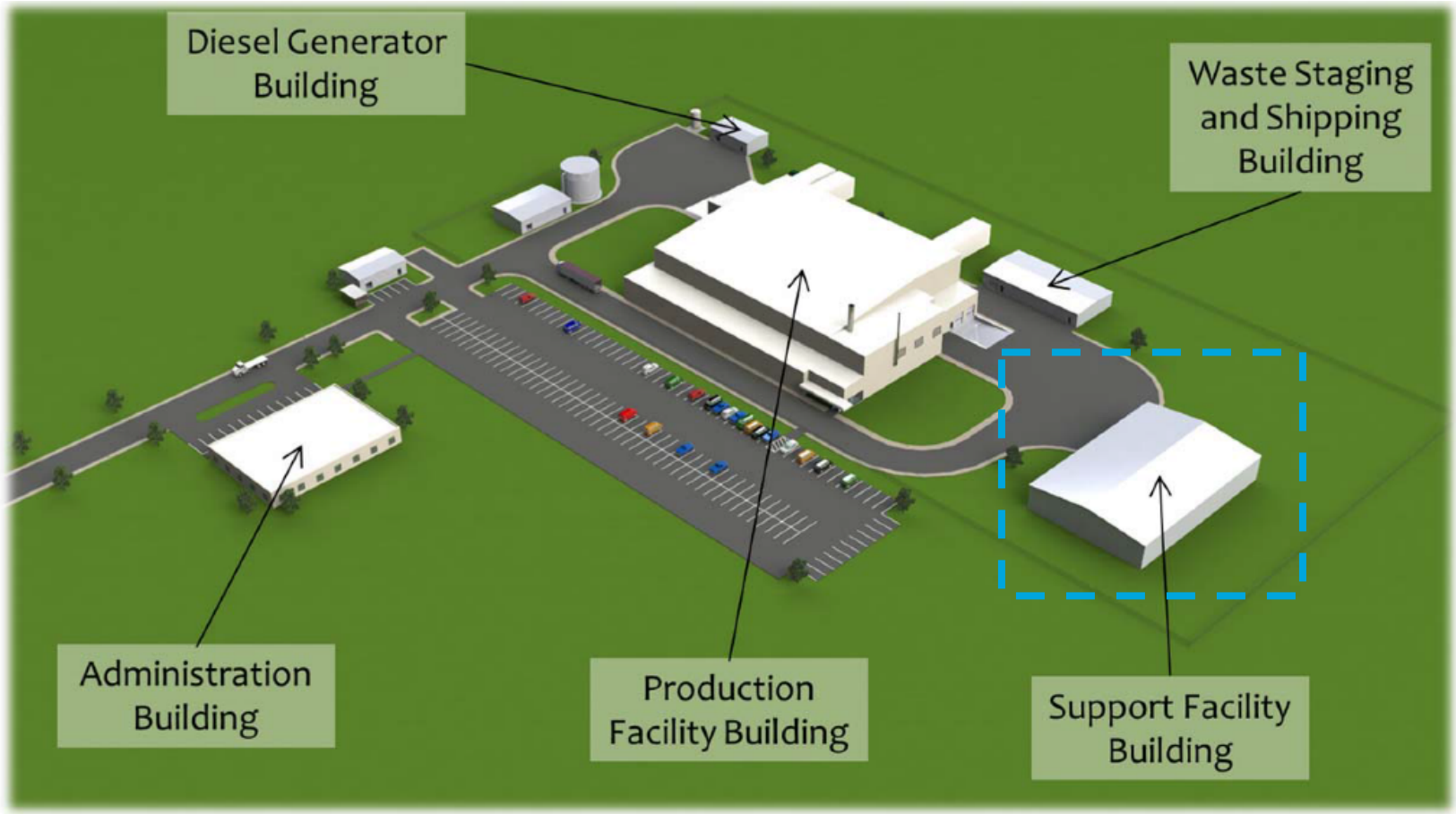


Located in Janesville, Wisconsin

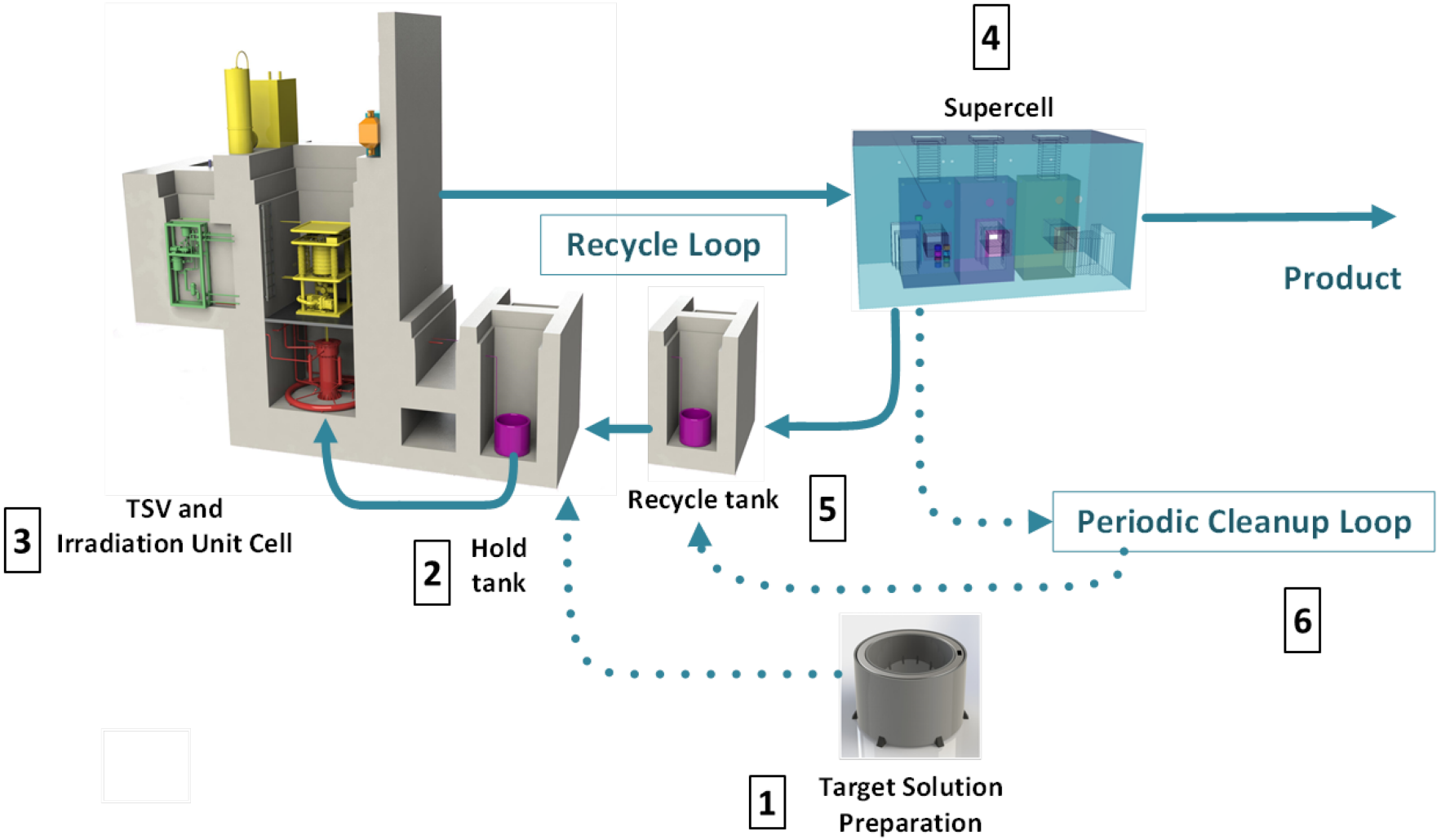


Located in Janesville, Wisconsin

Site Layout


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

SHINE Process Overview

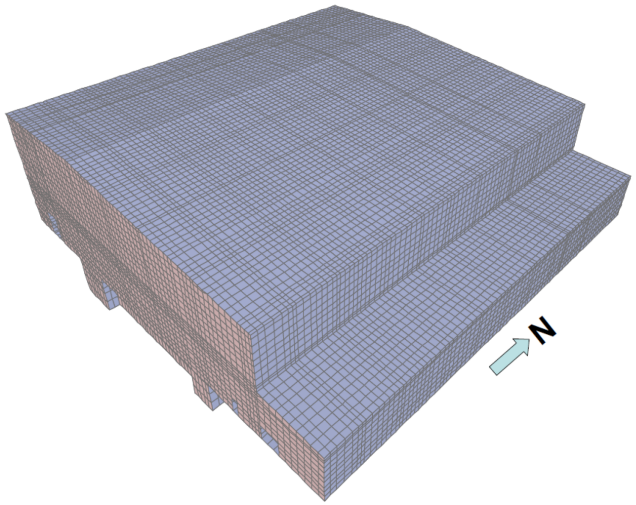


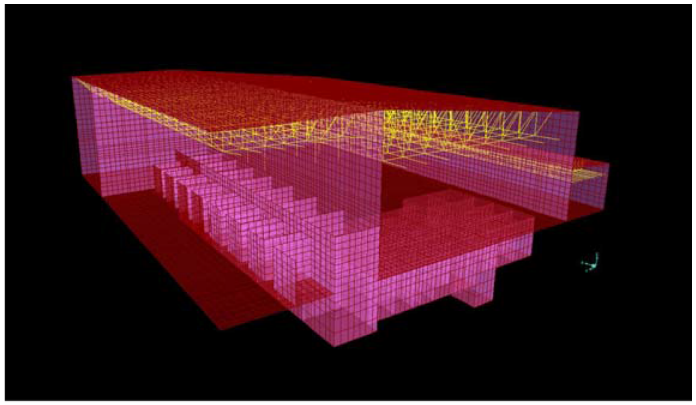
Plant Design

- 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

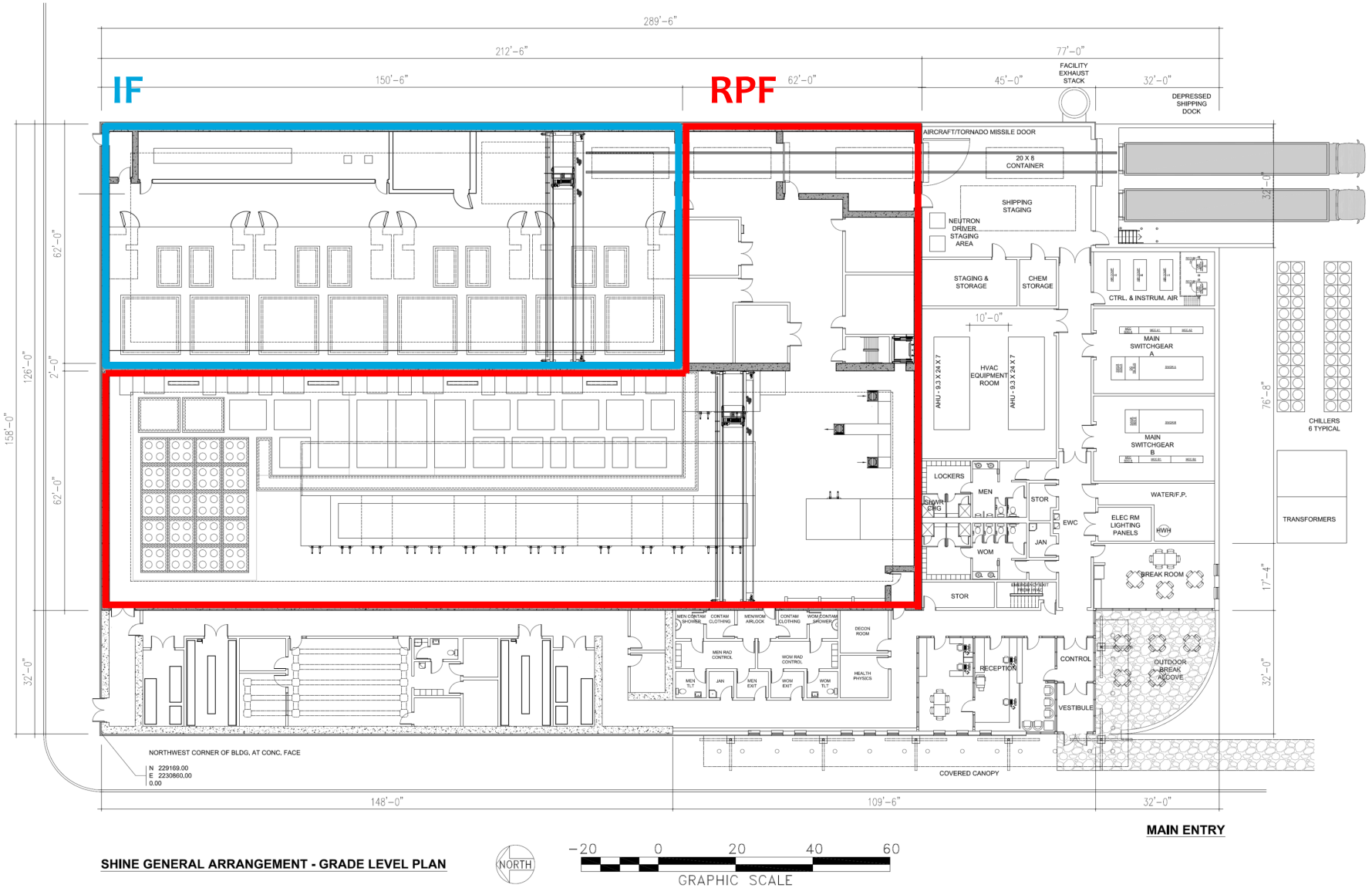
Accident Analysis Summary

- 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

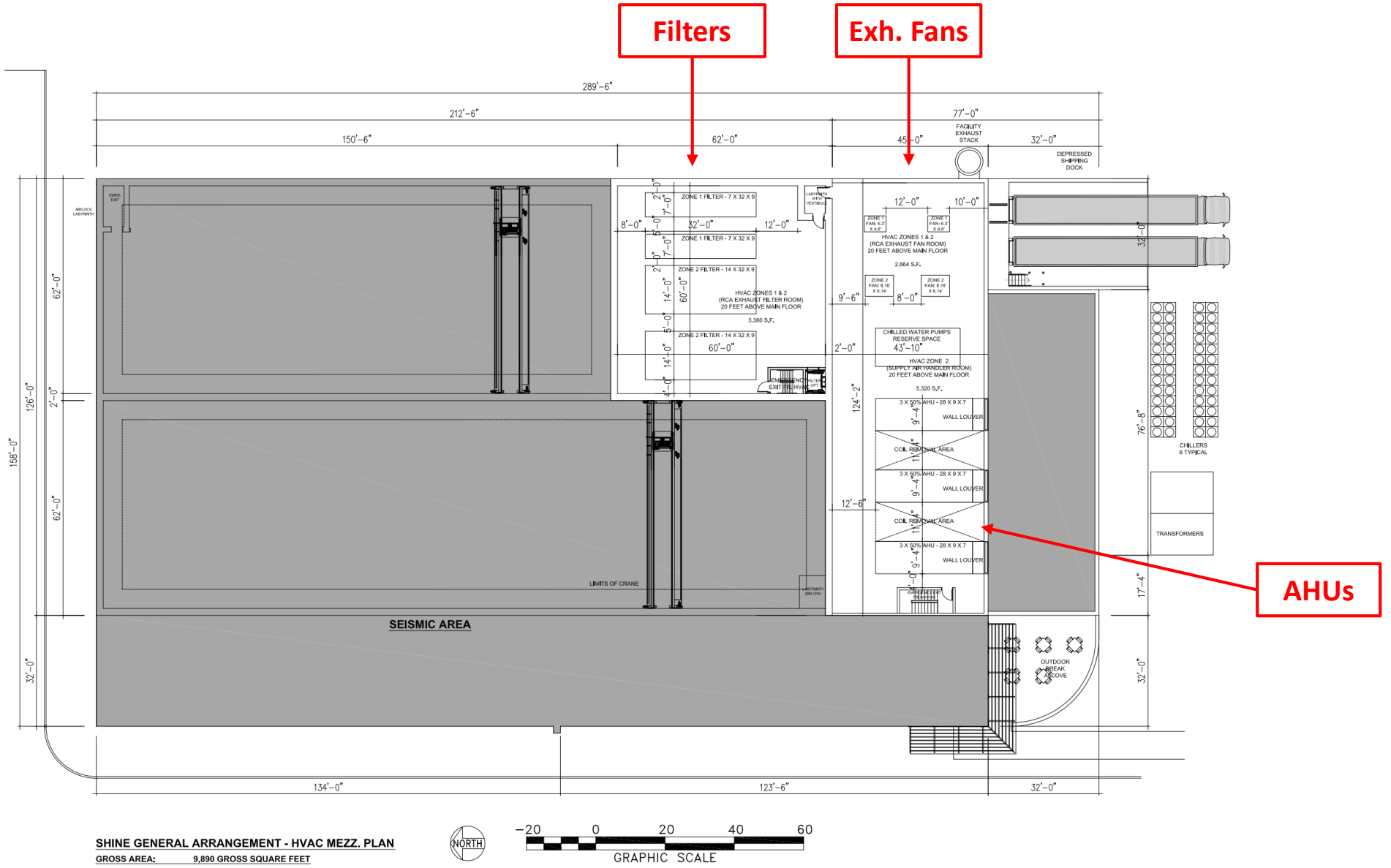




Facility Layout without UREX



Facility Layout – Mezzanine Plan



SHINE GENERAL ARRANGEMENT - HVAC MEZZ. PLAN

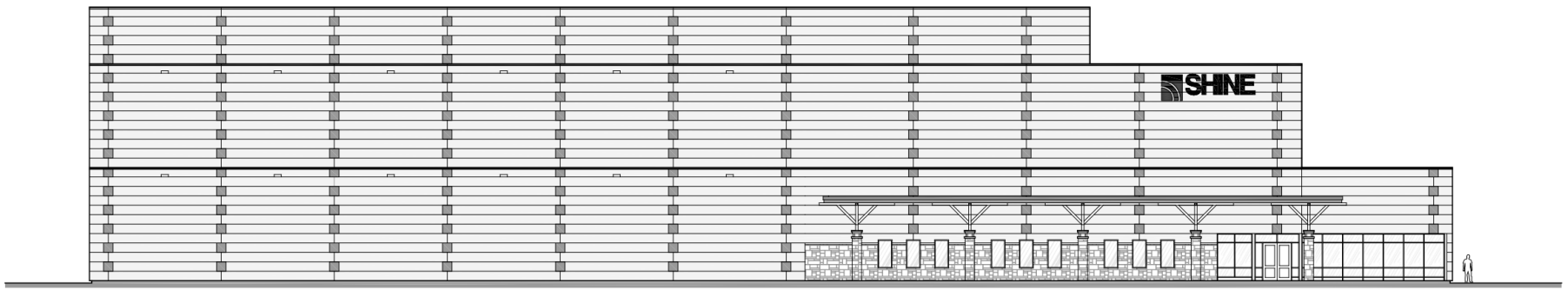
GROSS AREA: 9,890 GROSS SQUARE FEET

NORTH

−20 0 20 40 60

GRAPHIC SCALE

Facility Layout – Elevation View



SHINE PRODUCTION FACILITY - WEST BUILDING ELEVATION

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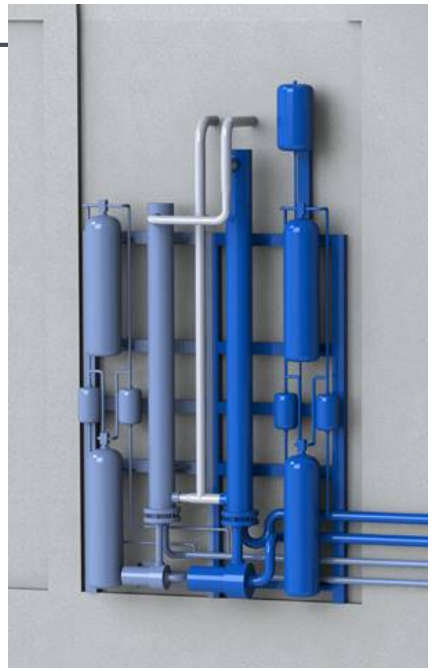
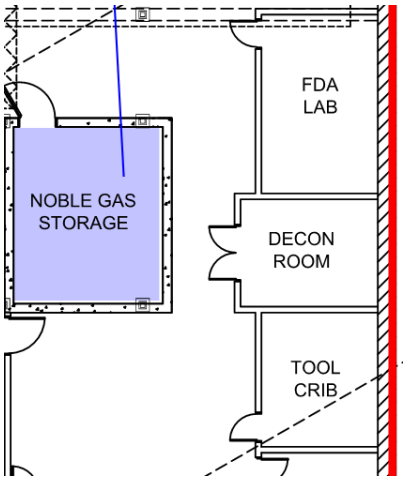
II. Scope of Planned Design Changes

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 available 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

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III. Removal of UREX

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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 would 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

UREX Removal Evaluation (cont.)

- Target solution is recovered in the process for reuse without UREX
  - Solution is recovered for continued irradiations until no longer within specifications
  - Target solution cleanup is not required for nuclear behavior of subcritical assembly, accident analysis, or criticality safety
- Additional hot cell capacity is being planned for cleanup of uranium solution directly
  - Target Solution Cleanup hot cell
  - Provides option for treatment through design modification in the operating plant
  - Sized to allow flexibility in internal arrangement
- Planned capability to:
  - Remove precipitating species to reduce crud
  - Install, operate, and remove selective ion exchange columns

UREX Removal Evaluation (cont.)

- The UREX process separated the uranium from a raffinate mixture that contained fission products and plutonium
- Without UREX, bulk fission products and transuranics stay in the target solution
  - Pu has minimal neutronics effect
  - Pu is not specifically removed
  - Similar to various other radioactive isotopes in solution, some is removed along with Mo-99 during weekly extraction
    - Buildup in solution of Pu is not substantially different from preliminary design

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IV. Design Control and Change Processes

Design Control and Change Processes

- Design control and design change control processes are part of the SHINE Configuration Management program
- The processes maintain 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