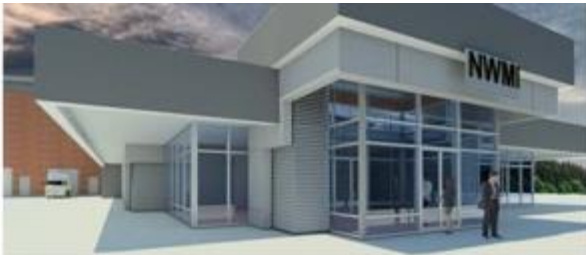


U.S. Nuclear Regulatory Commission Commission Mandatory Meeting



Safety Panel 2 Presentation January 23, 2018

United States Nuclear Regulatory Commission Official Hearing Exhibit	
In the Matter of: NORTHWEST MEDICAL ISOTOPES, LLC (Medical Radioisotope Production Facility)	
Commission Mandatory Hearing	
Docket #: 05000609	Identified: 1/23/2018
Exhibit #: NWMI-006-R-MA-CM01	Withdrawn: Stricken:
Admitted: 1/23/2018	
Rejected:	
Other:	

- NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*, requirements
 - Used integrated safety analysis (ISA) methodologies (per 10 CFR 70 Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material,” and NUREG-1520, *Standard Review Plan for Fuel Cycle Facilities License Applications*)
 - Applied radiological and chemical consequence and likelihood criteria identified in the performance requirements of 10 CFR 70.61
 - Designated items relied on for safety (IROFS) and established management measures to demonstrate adequate safety for the Radioisotope Production Facility (RPF)
- Evaluated RPF in systematic integrated examination, including processes, equipment, structures, and personnel activities, which ensured that all relevant hazards that could result in unacceptable consequences were adequately evaluated and appropriate protective measures were identified
- Evaluated special nuclear material areas through development of criticality safety evaluations (CSE) to identify double contingencies controls to maintain subcriticality

- RPF was evaluated using an ISA process
 - Completed process hazards analysis (PHA)
 - Developed quantitative risk assessments (QRA) to address events and hazards identified in PHA as requiring additional evaluation
- Evaluated accident sequences (qualitatively) to identify likelihood and severity using event frequencies and consequence categories consistent with regulatory guidelines
- Assessed each event with an adverse consequence (involving licensed material or its byproducts) for risk using a risk matrix that enables user(s) to identify unacceptable intermediate- and high-consequence risks
 - Developed IROFS to prevent or mitigate consequences of events
 - Reduced risks acceptable frequencies through preventive or mitigative IROFS

Integrated Safety Analysis Methodology (continued)

- Used event trees analysis (certain circumstances)
 - Provided quantitative failure analysis data (failure frequencies)
 - Quantitatively analyzed an event from its basic initiators to demonstrate that quantitative failure frequencies are highly unlikely under normal standard industrial conditions (i.e., no IROFS required)
- Identified management measures to ensure that the IROFS failure frequency used in the analysis was preserved and IROFS are able to perform intended function(s) when needed
- Translation of IROFS (10 CFR 70) to technical specifications (10 CFR 50) will be developed in the Operating License Application

- Evaluated accident sequences using both qualitative and quantitative techniques
 - Most of quantitative consequence estimates are for releases to an uncontrolled area (public)
 - Worker safety consequence estimates are primarily qualitative
 - As facility final design matures, quantitative worker safety consequence analyses will be performed
- Accidents for operations with special nuclear material (including irradiated target processing, target material recycle, waste handling, and target fabrication), radioactive materials, and hazardous chemicals were analyzed
- Initiating events for analyzed sequences include operator error, loss of power, external events, and critical equipment malfunctions or failures
- Shielded and unshielded criticality accidents assumed to have high consequences to worker if not prevented
- Updated frequency (likelihood) and worker and public quantitative safety consequences will be provided in Operating License Application

- Completed PHA on eight “systems;” 107 nodes were evaluated (PHA tables ~300 pages)
- ~140 accident sequences were identified for additional evaluation; 75 accident sequences were evaluated in QRAs
- 8 QRAs were completed, covering 75 accidents; one QRA addressed chemical accidents

Qualitative Risk Assessment Documents

Radioisotope Production Facility Preliminary Hazards Analysis

Radioisotope Production Facility Integrated Safety Analysis Summary

Chemical Safety Process Upsets

Process Upsets Associated with Passive Engineering Controls Leading to Accidental Criticality Accident Sequences

Criticality Accident Sequences that Involve Uranium Entering a System Not Intended for Uranium Service

Criticality Accident Sequences that Involve High Uranium Content in Side Waste Stream

Facility Fires and Explosions Leading to Uncontrolled Release of Fissile Material, High- and Low-Dose Radionuclides

Radiological Accident Sequences in Confinement Boundaries (including Ventilation Systems)

Administratively Controlled Enrichment, Mass, Container Volume, and Interaction Limit Process Upsets Leading to Accidental Criticality Accident Sequences

Receipt and Shipping Events

Evaluation of Natural Phenomenon and Man-Made Events on Safety Features and Items Relied on for Safety

- Monte Carlo N-Particle Transport Code: MCNP 6.1, Continuous Energy ENDF/B- VII.1 Cross-Section
- Define operation/process to identify range of parameters to be validated
- 92 criticality safety experiments were selected that adequately match uranium enrichment, geometry, moderator, reflector, and neutron energy
- Define area of applicability (AoA) of the validation
- Analyzed data
 - Determined bias and bias uncertainty
 - Identified trends in data → No trends were identified
 - Test for normal or other distribution and select statistical method for data treatment
 - Identify and support subcritical margin – Margin of subcriticality (MoS) of 0.05 Δk
 - Calculate USL – 0.9240

- Used “first principles” as bases for equipment design and process area layouts
 - Geometry constraints (e.g., pencil tank diameters)
 - Tank array spacing (conservative)
 - Transition from “safe-geometry” process equipment to less-restricted waste staging and processing equipment was considered
- Evaluations and analysis
 - MCNP code validation and upper subcritical limits for all areas of applicability
 - Defined operation/process to identify range of parameters
 - 92 criticality safety experiments
 - Defined area of applicability
 - Project-specific single-parameter criticality limits for U enrichment, forms, and basic geometries
- Criticality safety evaluations (CSE)
 - Normal operating conditions described
 - Criticality hazard evaluation
 - Contingency analysis
 - Double contingency controls

Criticality Safety Evaluation Documents

Irradiated Target Handling and Disassembly

Irradiated Low-Enriched Uranium Target Dissolution

Molybdenum-99 Recovery

Low-Enriched Uranium Target Material Production

Target Fabrication Uranium Solution Processes

Target Finishing

Target and Can Storage and Carts

Hot Cell Uranium Purification

Liquid Waste Processing

Solid Waste Collection, Encapsulation, and Staging

Offgas and Ventilation

Target Transport Cask and Drum Handling

Analytical Laboratory

Calculations

- *Single Parameter Subcritical Limits for 20 wt% ^{235}U - Uranium Metal, Uranium Oxide, and Homogenous Water Mixtures*
- *Irradiated Target Low-Enriched Uranium Material Dissolution*
- *55-Gallon Drum Arrays*
- *Single Parameter Subcritical Limits for 20 wt% ^{235}U – Low-Enriched Uranium Target Material*
- *Target Fabrication Tanks, Wet Processes, and Storage*
- *Tank Hot Cell*

Accident Sequences Evaluated

- Spill and Spray Accidents – Radiological and Criticality (Section 13.2.2)
- Dissolver Offgas Accidents -- Radiological (Section 13.2.3)
- Leaks into Auxiliary Systems – Radiological and Criticality (Section 13.2.4)
- Loss of Electrical Power Accidents (Section 13.2.5)
- Natural Phenomena Accidents (Section 13.2.6)
- Other Accidents (Section 13.2.7)
- Accidents with Hazardous Chemicals (Section 13.3)

Accident-Initiating Events

- Criticality accident
- Loss of electrical power
- External events (meteorological, seismic, fire, flood)
- Critical equipment malfunction
- Operator error
- Facility fire (including explosion)
- Any other event potentially related to unique facility operations

Questions?

Exhibit NWMI-006-R

