


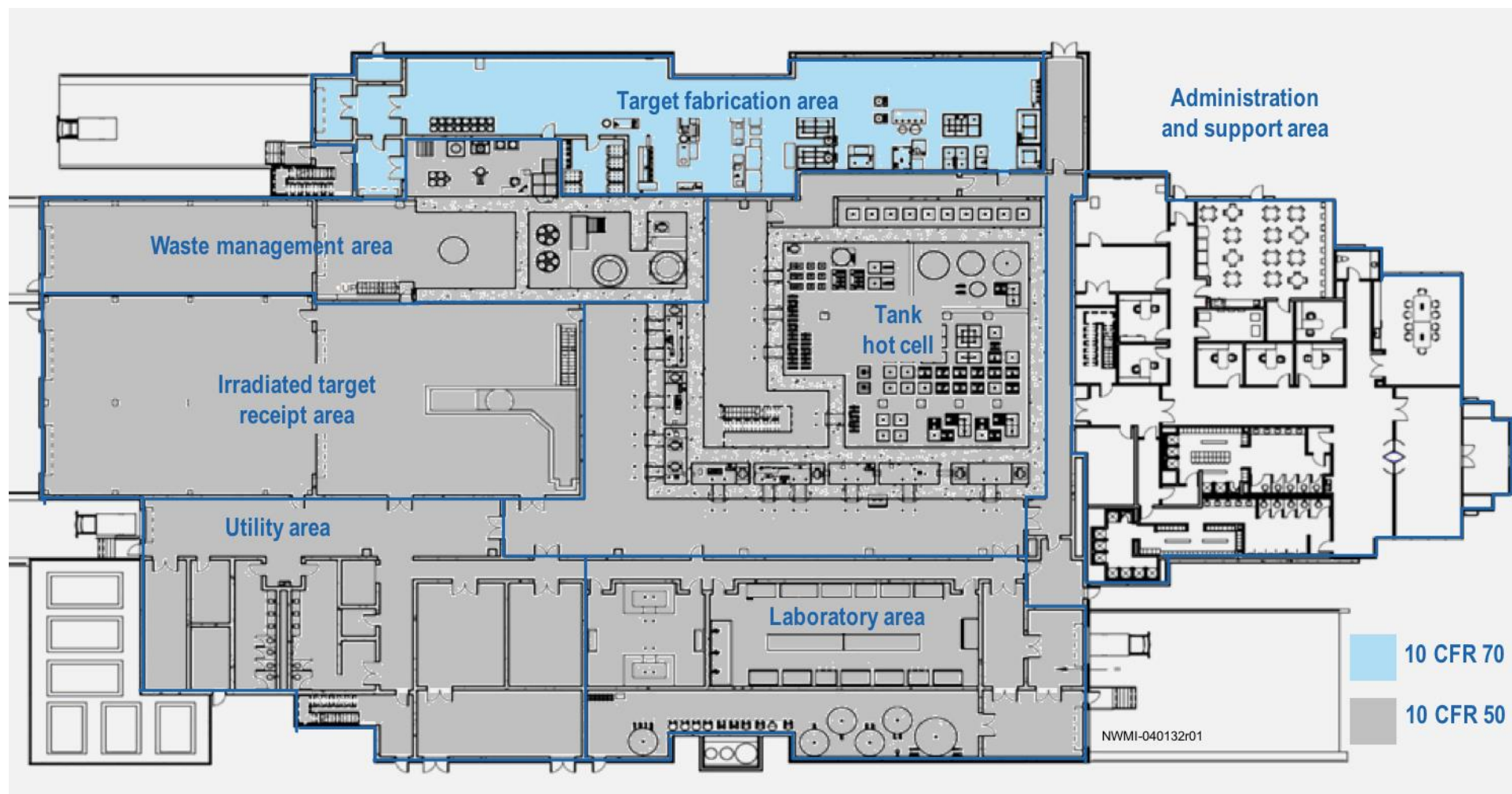
U.S. Nuclear Regulatory Commission Commission Mandatory Hearing



Safety Panel 1 Presentation January 23, 2018

		United States Nuclear Regulatory Commission Official Hearing Exhibit In the Matter of: NORTHWEST MEDICAL ISOTOPES, LLC (Medical Radioisotope Production Facility)	
Docket #: 05000609 Exhibit #: NWMI-005-R-MA-CM01 Admitted: 1/23/2018 Rejected: Other:		Commission Mandatory Hearing Identified: 1/23/2018 Withdrawn: Stricken:	

Radioisotope Production Facility (RPF) Project Overview



- Design based on applicable standards, guides, codes, and criteria and provides reasonable assurance that structures, systems, and components (SSC):
 - Are built and function as designed and required per NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*, Chapter 13.0, “Accident Analysis”
 - Provide acceptable protection of public health and safety and the environment
 - Protect against potential hydrological (water) and seismic damage
- Defense-in-depth design philosophy → Applied from outset of facility design through completion of facility design/construction drawings
- Certain systems and components are considered important-to-safety → Perform safety functions during normal operations or are required to prevent or mitigate consequences of abnormal operational transients or accidents
- Safety-related is applied to items relied on to remain functional during or following a design basis event to ensure that the items provide a safety-related function
- Technical specifications will be developed in the Operating License Application

- SSCs are classified as safety-related and non-safety-related:
 - **Safety-related** is a classification applied to items relied on to remain functional during or following a postulated design basis event to ensure:
 - Integrity of facility infrastructure
 - Capability to shut down the RPF and maintain the facility in a safe shutdown condition
 - Capability to prevent or mitigate consequences of postulated accidents identified through accident analyses that could result in potential off-site and worker exposures comparable to applicable guideline exposures set forth in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61 (d) "Performance Requirements"
 - Operation of RPF without undue risk to the health and safety of workers, the public, and environment to meet 10 CFR 20, "Standards for Protection Against Radiation," normal release or exposure limits for radiation doses and applicable limits for chemical exposures
 - **Safety-related items relied on for safety (IROFS)** – SSCs identified through accident analyses as required to meet the performance requirements of 10 CFR 70.61(b), (c), and (d)
 - **Safety-related Non-IROFS** – SSCs that provide reasonable assurance that the RPF can be operated without undue risk to the health and safety of workers, the public, and environment, and includes SSCs to meet 10 CFR 20 normal release or exposure limits
 - **Non-safety-related** – SSCs related to production and delivery of products or services that are not in the above safety classifications

- **Quality Level (QL) 1** will implement the full measure of the NWMI Quality Assurance Program Plan (QAPP) and will be applied to safety-related SSC IROFS, including items in which failure or malfunction could directly or indirectly result in a condition that adversely affects workers, the public, and/or environment, as described in 10 CFR 70.61
 - Items to prevent nuclear criticality accidents (e.g., preventive controls and measures to ensure that under normal and credible abnormal conditions, all nuclear processes are subcritical)
 - Items credited to withstand credible design-bases external events (e.g., seismic, wind)
 - Items to prevent degradation of structural integrity (e.g., failure or malfunction of facility)
- **QL 2** will be applied to non-QL 1 safety SSCs
 - QAPP is important to acceptability and suitability of item or service to perform as specified (e.g., SSCs to meet 10 CFR 20 normal release or exposure limits, fire protection systems, safeguards and security systems, material control and accountability systems)
- **QL 3** will include non-safety-related quality activities that are deemed necessary to ensure manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements

- SSCs identified as IROFS will be designed to satisfy general seismic criteria to withstand effects of natural phenomena without loss of capability to perform their safety functions
- Seismic classification methodology used complies with ASCE 7, Chapter 11 (*Seismic Design Criteria*) and Regulatory Guide 1.29 (*Seismic Design Classification*)
 - Demonstrates capability to function during and after vibratory ground-motion associated with safe-shutdown earthquake conditions
- Methodology classifies SSCs into three categories:
 1. Seismic Category I (C-I):
 - Applies to IROFS and those SSCs required to support shut down of the RPF and maintain the facility in a safe shutdown condition from both functionality and integrity perspective
 2. Seismic Category II (C-II):
 - Applies to SSCs designed to prevent collapse under the safe-shutdown earthquake from an integrity perspective
 - SSCs are classified as C-II to preclude structural failure during a safe-shutdown earthquake, or where interaction with C-I items could degrade the functioning of a safety-related SSC to an unacceptable level or could result in an incapacitating injury to occupants of the main control room
 3. Non-seismic (NS):
 - NS SSCs are those that are not classified seismic C-I or C-II

System Safety/Seismic Classification/Quality Level Summary

System Safety and Seismic Classification and Associated Quality Level Group

System name (code)	Highest safety classification	Seismic classification	Quality level group
Facility structure (RPF)	IROFS	C-I	QL-1
Target fabrication (TF)	IROFS	C-I	QL-1
Target receipt and disassembly (TD)	IROFS	C-I	QL-1
Target dissolution (DS)	IROFS	C-I	QL-1
Mo recovery and purification (MR)	IROFS	C-I	QL-1
Uranium recovery and recycle (UR)	IROFS	C-I	QL-1
Waste handling (WH)	IROFS	C-I	QL-1
Criticality accident alarm (CA)	IROFS	C-I	QL-1
Radiation monitoring (RM)	IROFS	C-I	QL-1
Standby electrical power (SEP)	IROFS	C-I	QL-1
Normal electrical power (NEP)	SR	C-I	QL-1
Process vessel ventilation (PVV)	IROFS	C-I	QL-1
Facility ventilation (FV) ^c	IROFS	C-I/II	QL-1/2
Fire protection (FP)	SR	C-II	QL-2
Plant and instrument air (PA)	NSR	C-II	QL-2
Emergency purge gas (PG)	IROFS	C-I	QL-1
Gas supply (GS)	NSR	C-II	QL-2
Process chilled water (PCW)	IROFS	C-I	QL-1
Facility chilled water (FCW)	NSR	C-II	QL-2
Facility heated water (HW)	NSR	C-II	QL-2
Process steam	IROFS	C-I	QL-1
Demineralized water (DW)	NSR	C-II	QL-2
Chemical supply (CS)	IROFS	C-I	QL-1
Biological shield (BS)	IROFS	C-I	QL-1
Facility process control (FPC)	SR	C-II	QL-2

IROFS = items relied on for safety.

NSR = non-safety related.

RPF = Radioisotope Production Facility.

SR = safety-related (not IROFS).

Questions?

Exhibit NWMI-005-R

