


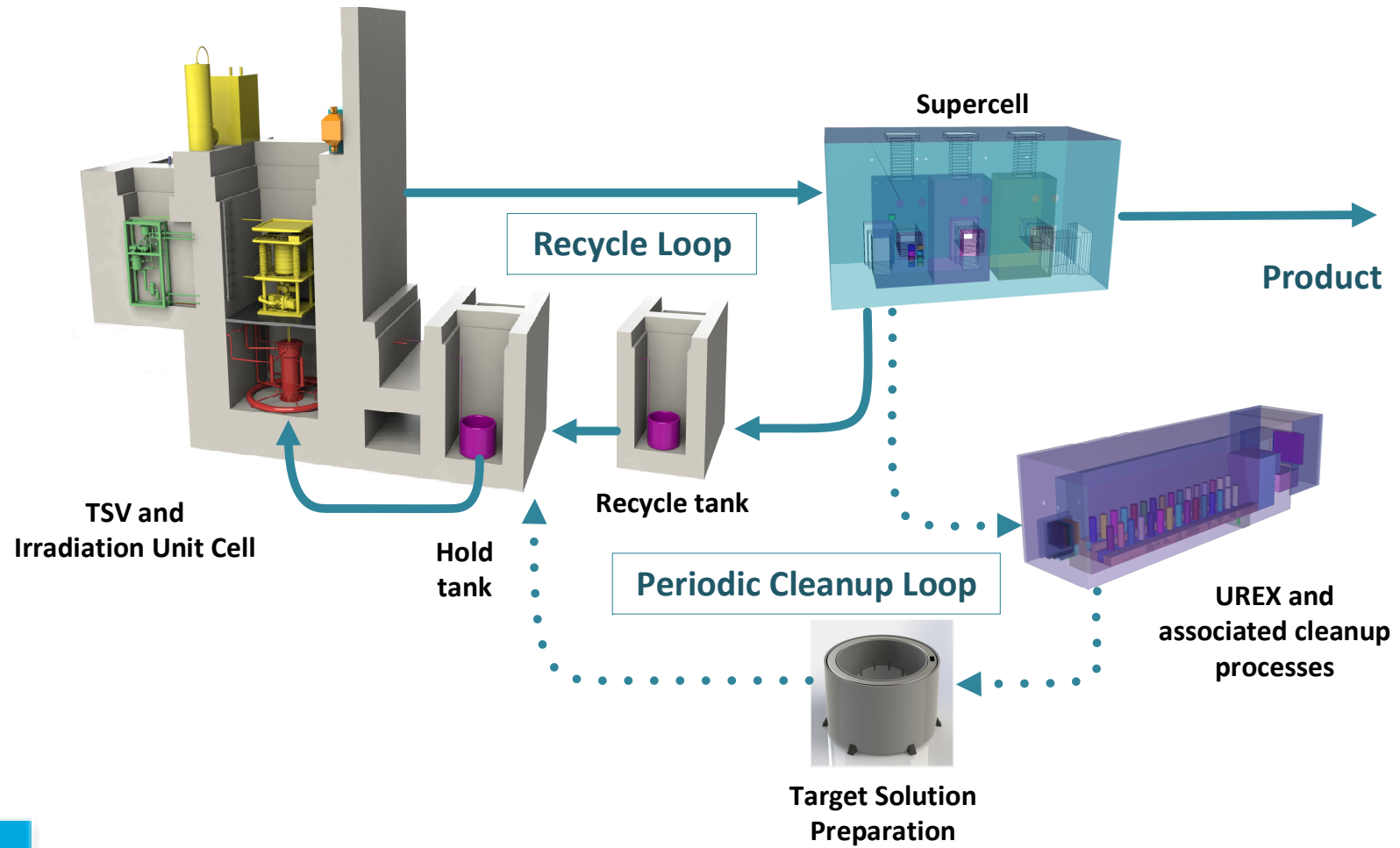
United States Nuclear Regulatory Commission Official Hearing Exhibit		
In the Matter of: SHINE MEDICAL TECHNOLOGIES, INC. (Medical Radioisotope Production Facility)		
	Commission Mandatory Hearing	
	Docket #:	05000608
	Exhibit #:	SHN-027-MA-CM01
	Admitted:	12/15/2015
	Rejected:	
Other:		Identified: 12/15/2015
		Withdrawn:
		Stricken:

Exhibit SHN-027



Commission Mandatory Hearing
SHINE Construction Permit Application
Safety – Panel 1
Facility
December 15, 2015

SHINE Process Overview



Design of Structures, Systems, and Components

- Certain structures, systems, and components (SSCs) are designated safety-related because they are relied upon to perform safety functions during normal operation or design basis events
 - SSCs must be able to perform their design basis functions during normal operation and under required accident conditions
- SSCs that are determined to have safety significance are designed, fabricated, and tested commensurate with the criteria set forth in ANSI/ANS-15.8 (“Quality Assurance Program Requirements for Research Reactors”)



Safety-Related SSC Definition

- Safety-related SSCs are those SSCs that are relied upon to remain functional during normal conditions and during and following design basis events to assure:
 1. The integrity of the primary system boundary;
 2. The capability to shutdown the target solution vessel (TSV) and maintain the target solution in a safe shutdown (SSD) condition;
 3. The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;
 4. That all nuclear processes are subcritical, including use of an approved margin of subcriticality;
 5. That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or
 6. That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur



Seismic Design and Quality Levels

- Plant SSCs are designed to withstand the effects of the design basis earthquake (DBE) if they perform a safety-related function or if necessary to ensure they do not degrade the function and performance of a safety-related SSC
- SHINE Quality Levels (QLs):
 - QL-1: Safety-related SSCs are designated as QL-1 in the Quality Assurance Program Description (QAPD), and the full measure of the QAPD is applied to these SSCs
 - QL-2: Selected SSCs that support or protect the safety function of safety-related equipment are designated QL-2, and quality elements are applied commensurate with the importance to safety
 - QL-3: Nonsafety SSCs that do not support or protect the safety function of safety-related SSCs are designated QL-3



Design of Structures, Systems, and Components

- Single failure criterion is applied to safety systems
 - Sufficient redundancy and independence that a single failure of an active component does not result in loss of capability to perform its safety function
 - A single failure, in conjunction with initiating event, does not result in the loss of the system's ability to perform its safety function
- SHINE system designs based on defense-in-depth practices, with preference for engineered and passive controls over administrative controls

