GENERAL ATOMICS

nordion

Update

General Atomic's Proprietary Selective Gas Extraction Process at the University of Missouri Research Reactor

June 2, 2016

Project Team

General Atomics (GA)

Target and Reactor Systems Design and Manufacturing

- Trusted resource of high-technology systems
- Experts in nuclear fuel cycle, including uranium mining and processing
- Experts in reactor design: TRIGA® research reactors in operation around the world for over 50 years
- Developer of LEU technology utilizing novel reusable target design

University of Missouri Research Reactor (MURR)

Premium Reactor Operator and Research Center

- 10 megawatt facility; largest university research reactor in the United States
- Operates 52 weeks per year
- 35+ years of successful and innovative radiopharmaceutical R&D and collaborations with industry
- Strong record of regulatory compliance (NRC, FDA, DOT)
- Experts in volume radiochemical processing and international shipping
- Nordion's partner in supply of TheraSphere for over 20 years

Nordion

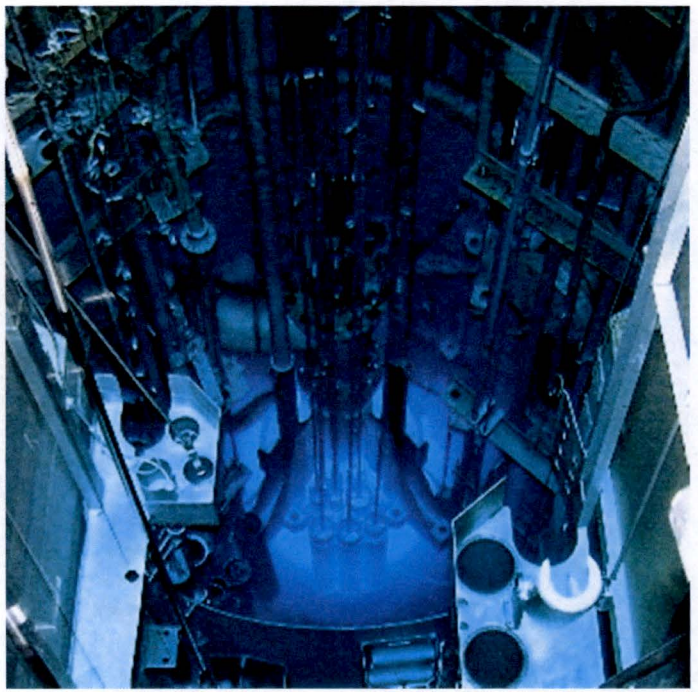
Premier Isotope Producer and Distributor

- Experts in Mo-99 purification into medical grade product since 1975
- Strong record of regulatory compliance (US FDA, EMEA, Health Canada)
- cGMP/GLP - licensed facility
- Global leading supplier of Mo-99 with extensive marketing, sales and distribution expertise
- Global licensed transport container fleet

Nordion/General Atomics/MURR Mo-99 Program

- Nordion has exclusively licensed GA's Selective Gas Extraction (SGE)Technology for Mo-99 production.
- Nordion has agreed to provide private investor funding for the implementation and commercialization of SGE Technology at MURR.
- Nordion has executed a 20-year reactor services agreement with MURR.
- MURR will supply a first-stage extract that will be processed and purified at existing cGMP Nordion facilities.
- Mo-99 supplied by SGE will work seamlessly in all existing Tc-99m generators.

University of Missouri-Columbia Research Reactor



MURR®

Providing quality nuclear research, education and service to a global community

MURR Facility Overview

Location: University of Missouri main campus in Columbia, Missouri, USA [200 km West of St Louis].

History:

- First critical on October 13, 1966 (Licensed at 5 MW).
- Uprated and licensed at 10 MW in 1974.
- Started ≥150 hours/week operation in September 1977.
- Submitted relicensing application in 2006 to the NRC.
- In 2006, became actively involved in the RERTR program to convert from HEU to LEU fuel.

Purpose: Multi-disciplinary research and education facility also providing a broad range of analytical and irradiation services to the research community and the commercial sector.

MURR Facility Overview

- MURR operates 24 hours a day, seven days a week, 52 weeks a year.
- 175 full time-time employees.
- Each and every week MURR supplies the active ingredients for FDA-approved Quadramet® and TheraSpheres®.

Improving the Quality of Life

Distinct Subcultures *working together under the same roof*

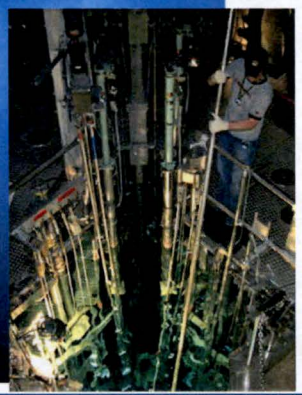
Research & Development

Education

Products & Services

Our core mission is Research

Reactor Operations



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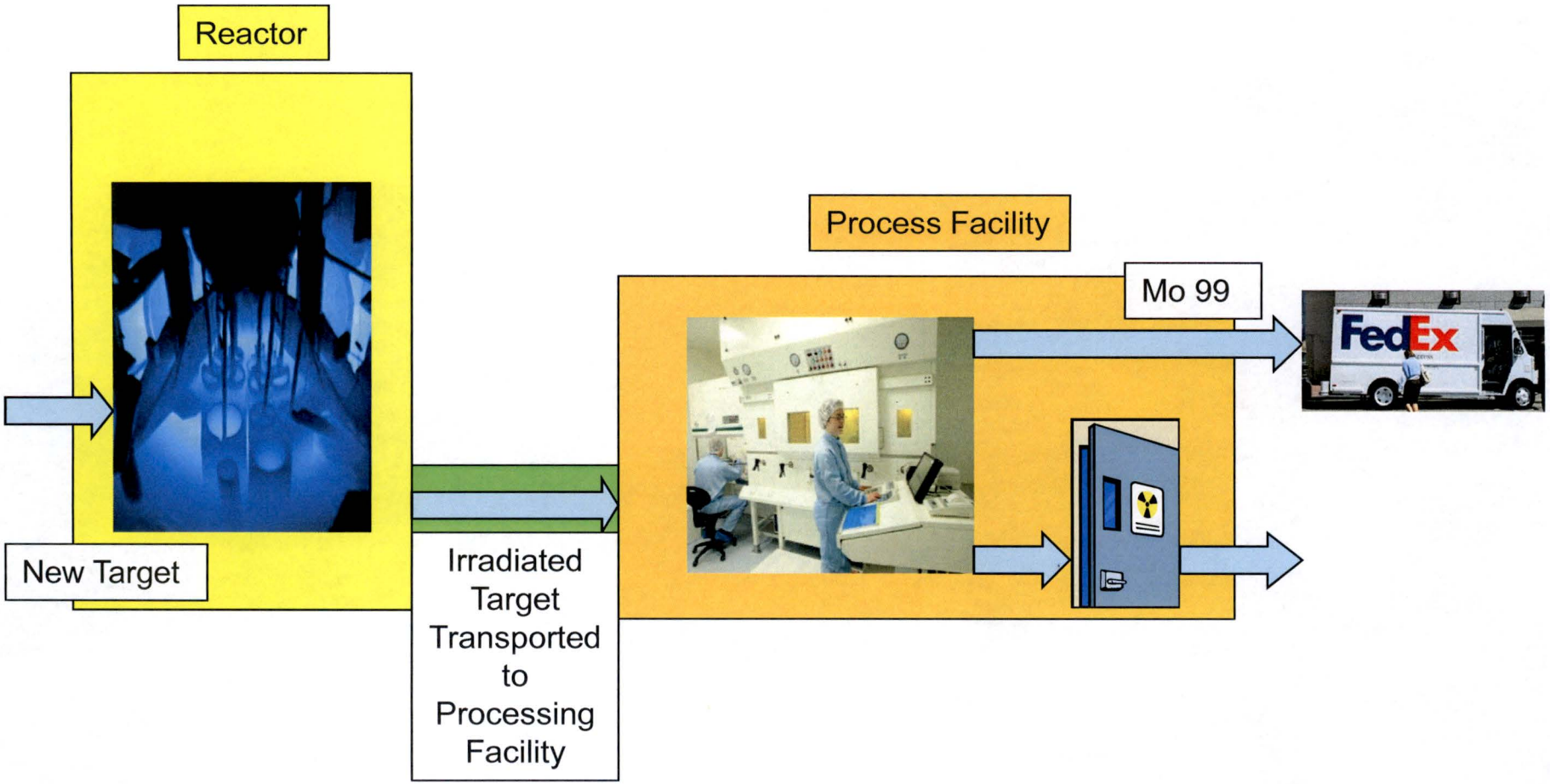
Providing quality nuclear research, education and service to a global community

Key Reactor Parameters

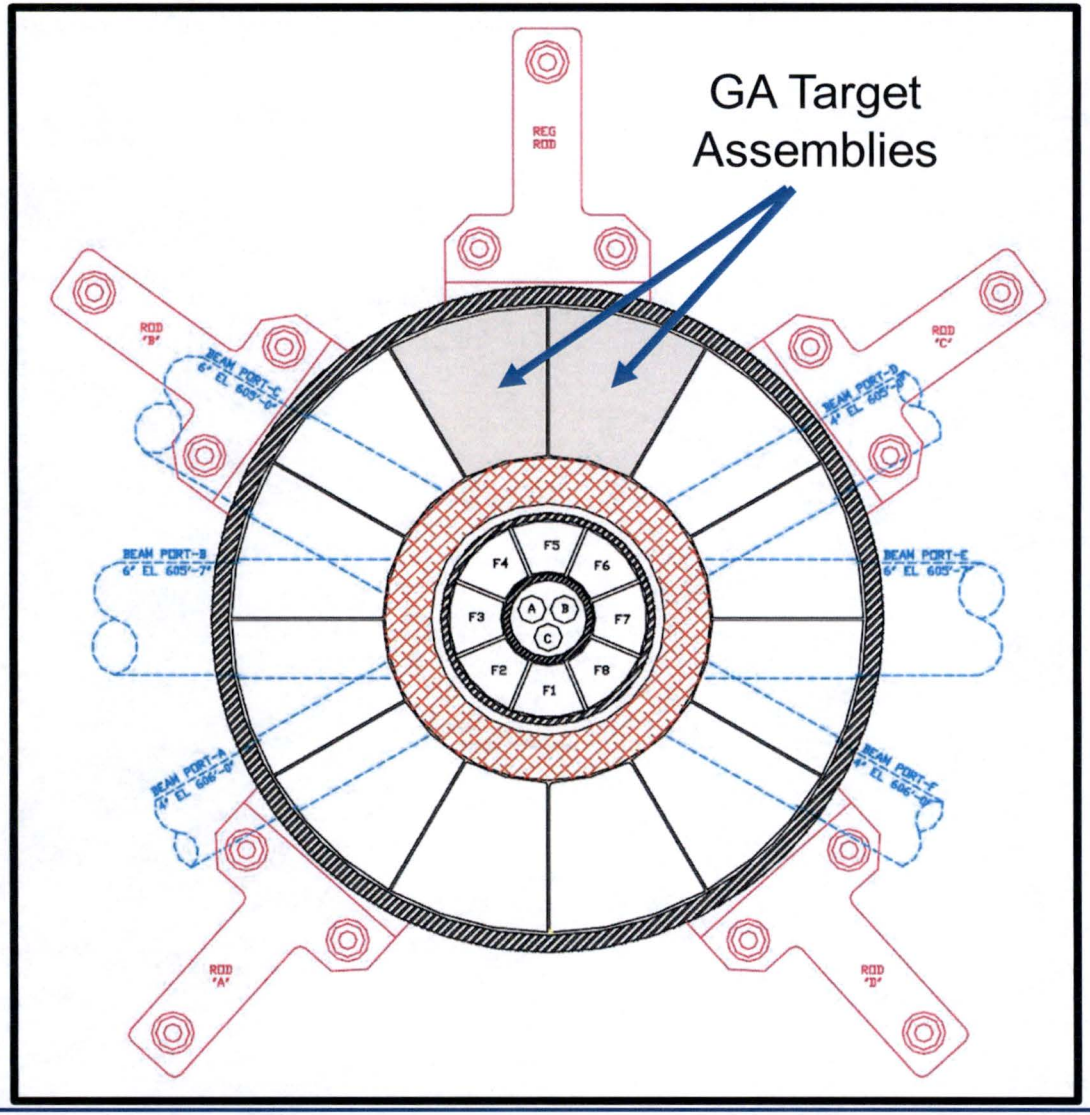
MURR® is a pressurized, reflected, heterogeneous, open pool-type, which is light-water moderated and cooled:

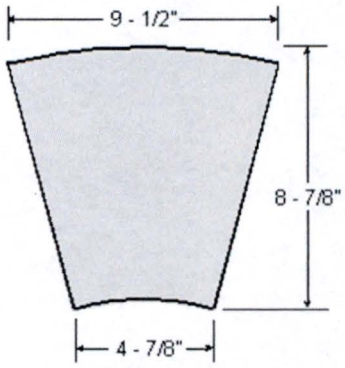
- Maximum power – 10 MW_{th}
- Peak flux in center test hole – 6.0E14 n/cm^2-s
- Core – 8 fuel assemblies (775 grams of U-235/assembly)
- Control blades – 5 total: 4 BORAL® shim-safety, 1 SS regulating
- Reflectors – beryllium and graphite
- Forced primary coolant flow rate – 3,750 gpm (237 lps)
- Primary coolant temps – 120 °F (49 °C) in, 136 °F (58 °C) out
- Primary coolant system pressure – 85 psia (586 kPa)
- Forced pool coolant flow rate – 1,200 gpm (76 lps)
- Pool coolant temps – 100 °F (38 °C) in, 106 °F (41 °C) out
- Beamports – three 4-inch (10 cm), three 6-inch (15 cm)

Typical Molybdenum 99 Project



Mo-99 Irradiation Positions





Typical MURR Reflector Element

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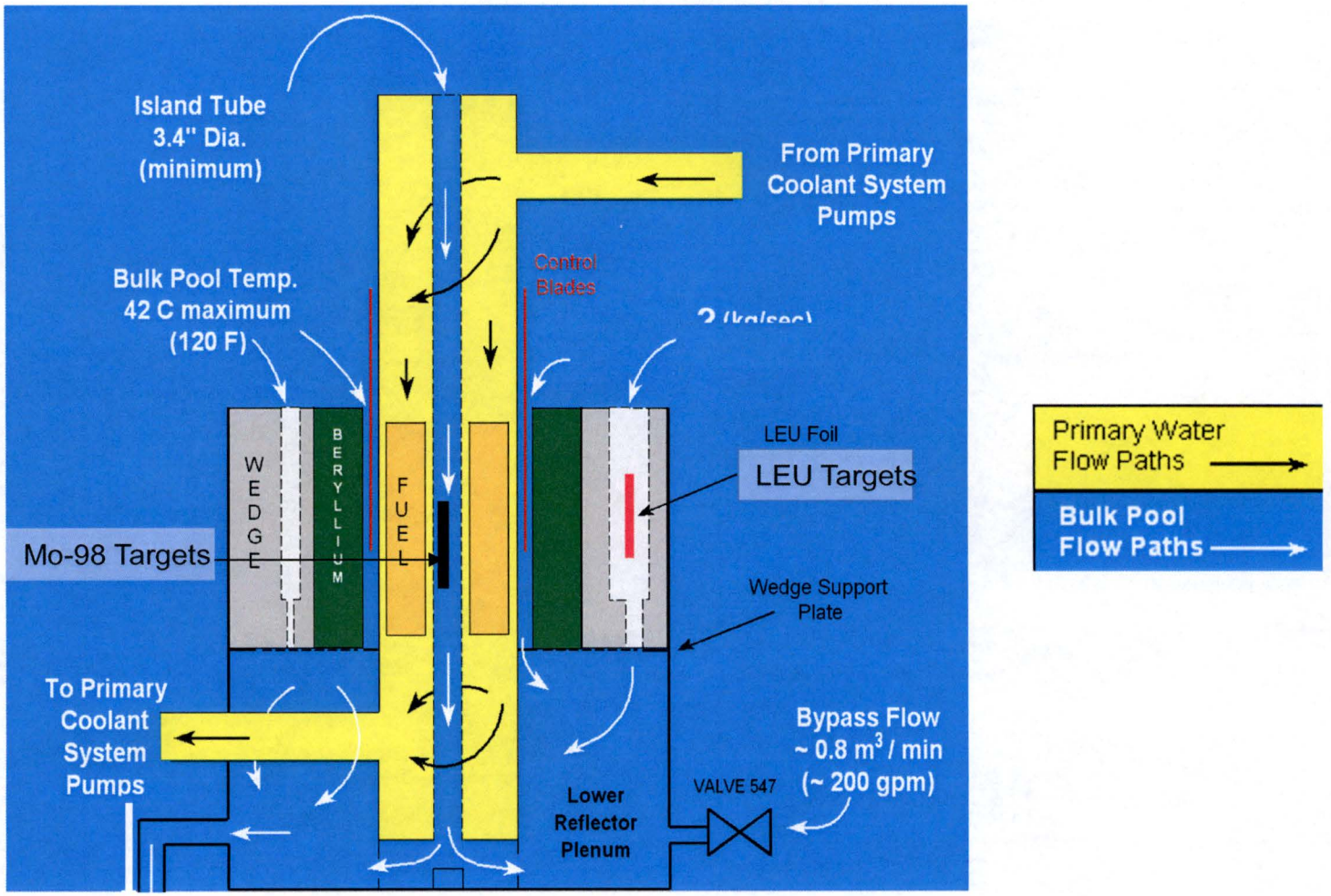
University of Missouri Research Reactor



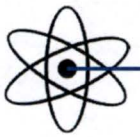
Preferred Licensing Approach

Part 50 License Amendment

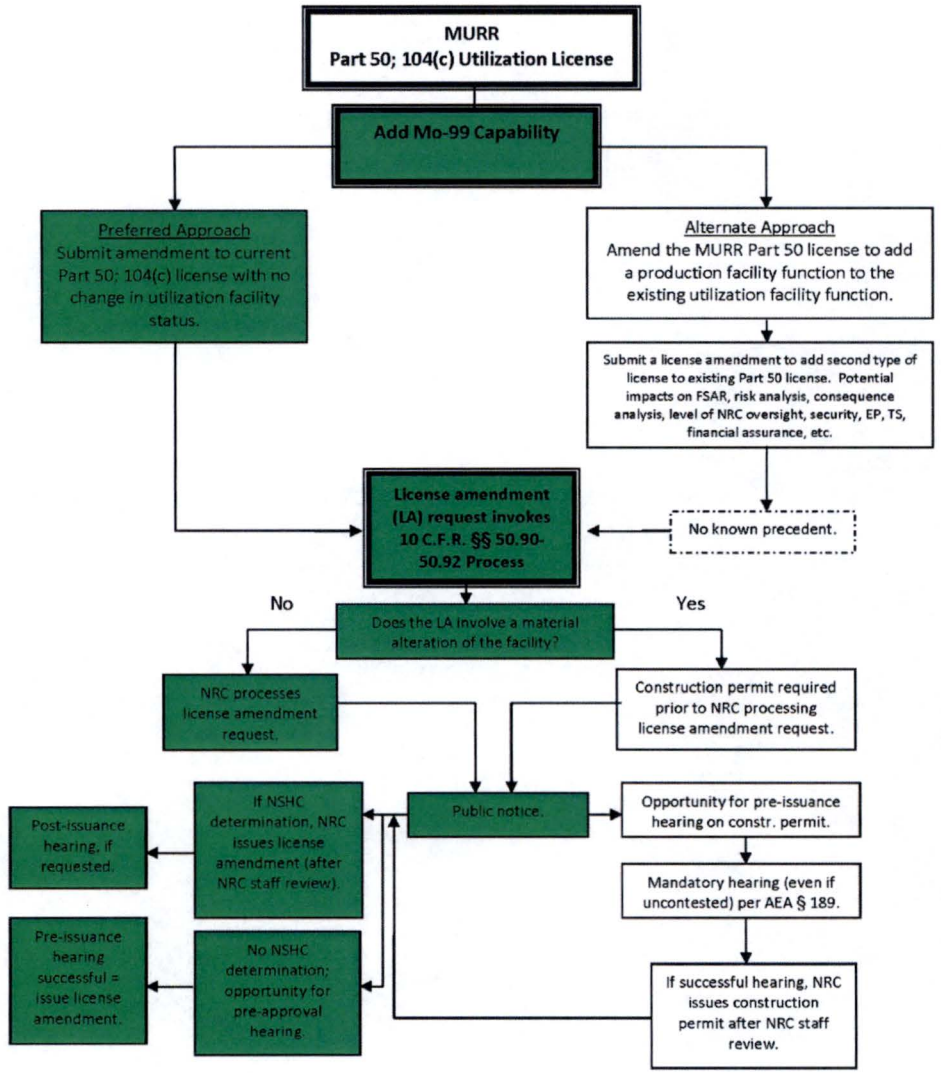
- Appears to be the most straight forward and applicable.
- MURR will meet applicable requirements of Part 70.
- Historical basis for clear / concise regulatory requirements.
- Provides the most expeditious pathway to begin meeting U.S. patient needs.

10 CFR 50.92(a)

"(a) In determining whether an amendment to a license, construction permit, or early site permit will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses, construction permits, or early site permits to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license,…. "



Preferred Licensing Approach



Preferred Licensing Approach

Decision Factors

- MURR to submit an amendment to the current Part 50, Class 104(c) license with no change in *utilization facility* status.
- Implementation of GA SGE technology at MURR is not considered an "alternation" or "material alteration" to the facility and thus should not require a construction permit.
- SGE will be an experimental facility classified as a "secured experiment."
- MURR has a technical specification that describes the use of irradiated non-fuel targets as an experiment, consequently the proposed activities involving these targets would be considered an experiment pursuant to the MURR technical specifications.

Preferred Licensing Approach

Decision Factors, con't.

- MURR Technical Specifications definition 1.5 "Experiment":
  - **"Any device or material which is exposed to significant radiation from the reactor and is not a normal part of the reactor".**
- MURR Technical Specifications definition 1.24 "Secured Experiment":
  - **"A secured experiment is any experiment which is rigidly held in place by mechanical means with sufficient restraint to withstand any anticipated forces to which the experiment might be subjected".**
- MURR Technical Specifications 3.6 "Experiments":
  - **Clearly allows for fueled experiments.**

Preferred Licensing Approach

Classification of the SGE Target Assemblies as an Experiment

The term "experiment" is defined in Appendix A of Regulatory Guide 2.2, "Development of Technical Specifications for Experiments in Research Reactors," and in ANSI/ANS-15.1-2007, "The Development of Technical Specifications for Research Reactors." The definitions in these documents are as follows:

In Regulatory Guide 2.2:

- *An experiment, as used herein, is any of the following:*
- *An activity utilizing the reactor system or its components or the neutrons or radiation generated therein;*
- *An evaluation or test of a reactor system operational, surveillance, or maintenance technique;*
- *An experimental or testing activity which is conducted within the confinement or containment system of the reactor; or*
- *The material content of any of the foregoing, including structural components, encapsulation or confining boundaries, and contained fluids or solids.*

In ANSI/ANI-15.1-2007:

- *Experiment: Any operation, hardware, or target that is designed to investigate non-routine reactor characteristics or that is intended for irradiation within the pool, on or in a beam port or irradiation facility. Hardware rigidly secured to a core or shield structure so as to be a part of its design to carry out experiments is not normally considered an experiment.*

Preferred Licensing Approach

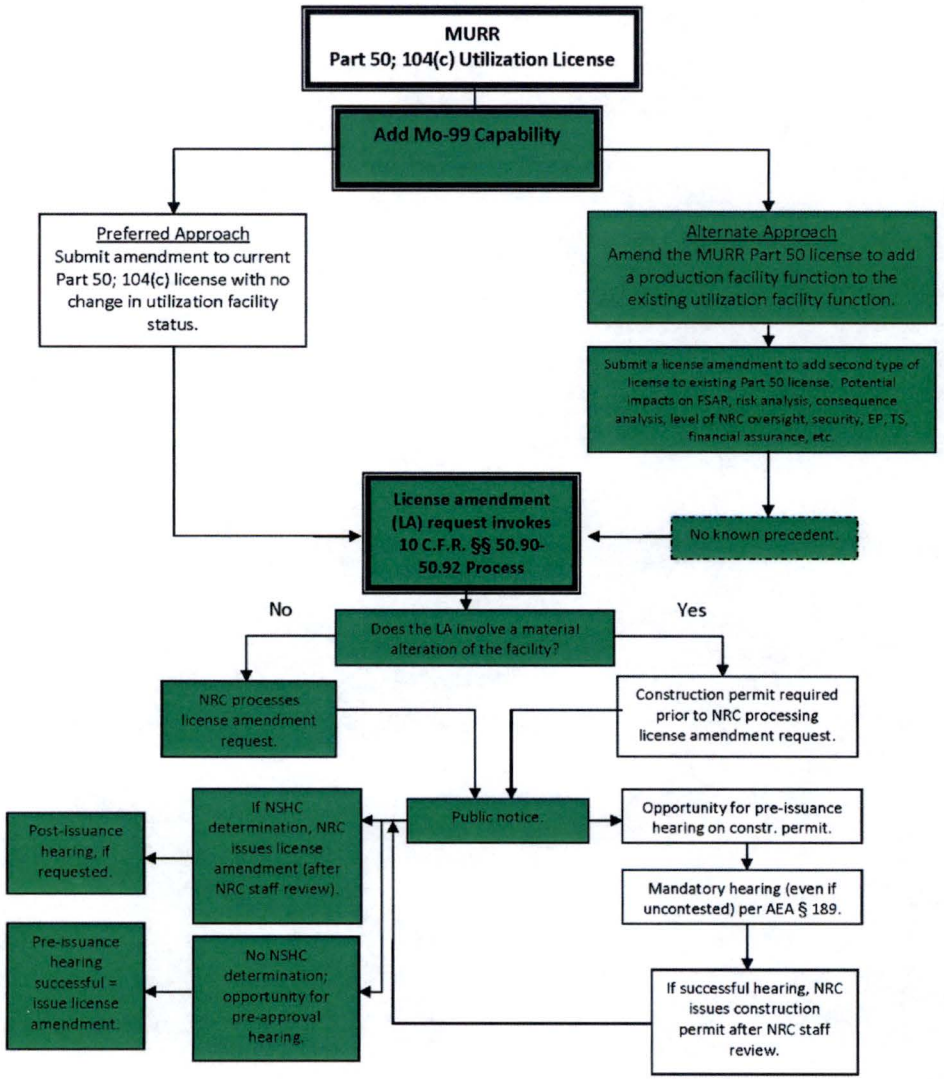
Classification of the SGE Target Assemblies as an Experiment

The SGE experimental facility will utilize the MURR reactor and its generated neutrons to irradiate the SGE target assemblies located in the reflector region.

- As such, the use of the target assemblies is consistent with the definition of an experiment in both of the cited documents.
- Precedence: NRC considered the Massachusetts Institute of Technology's (MIT) Research Reactor (MITR) Fission Converter to be categorized as an "experiment" that required a standalone cooling system.

The SGE experimental facility will not result in "substantial changes" to MURR or "transform" the MURR facility into something it previously was not.

Alternate Licensing Approach



Alternate Licensing Approach

50.2 Definition – Production Facility:

- (1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233 [not MURR]; or
- (2) Any facility designed or used for the separation of the isotopes of plutonium, *except laboratory scale facilities designed or used for experimental or analytical purposes only* [not MURR]; or
- (3) Any facility designed or used for the processing of irradiated materials containing special nuclear material EXCEPT *(i) laboratory scale facilities designed or used for experimental or analytical purposes,*

MURR is a laboratory scale facility designed or used for experimental or analytical purposes, thus should be exempted from 3(ii) and 3(iii)

- (ii) facilities in which only special nuclear materials contained in the irradiated material to be processed are uranium enriched in the isotope U-235 and plutonium produced by the irradiation, if the material contains not more than 10-6 grams of plutonium per gram of U-235 and has fission product activity not in excess of 0.25 millicuries of fission products per gram of U-235, and (iii) facilities in which processing is conducted pursuant to a license issued under parts 30 and 70 of this chapter, or equivalent regulations of an Agreement State, for the receipt, possession, use, and transfer of irradiated special nuclear material, which authorizes the processing of the irradiated material on a batch basis for the separation of selected fission products and limits the process batch to not more than 100 grams of uranium enriched in the isotope 235 and not more than 15 grams of any other special nuclear material.

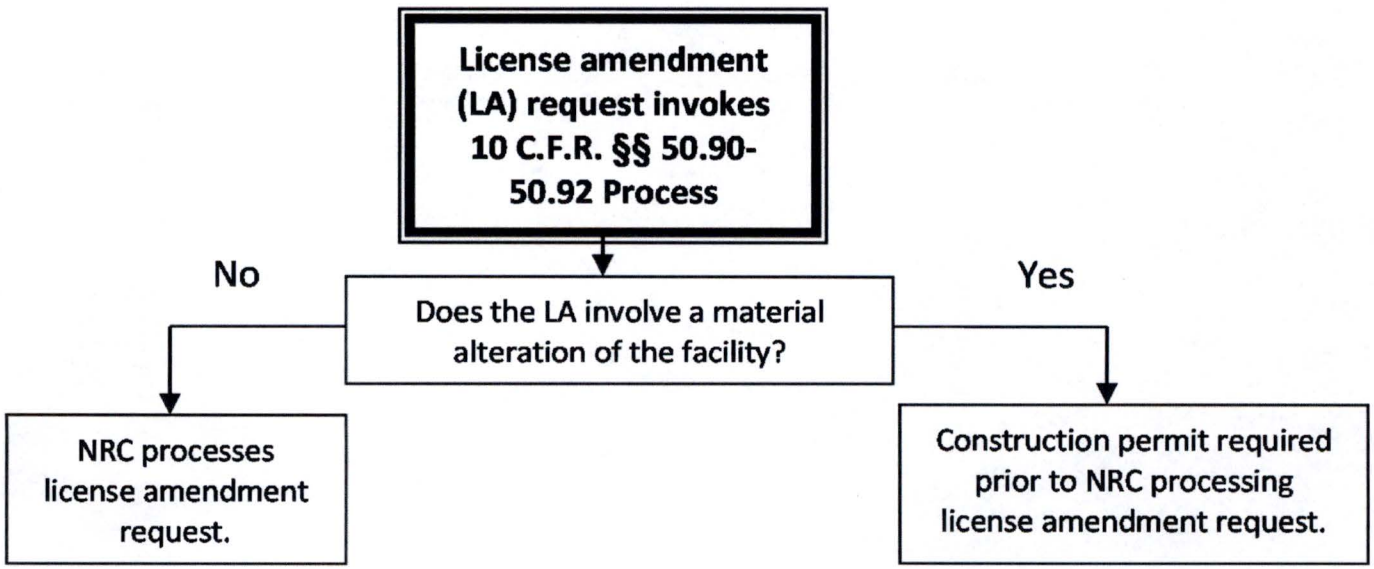
Alternate Licensing Approach

Decision Factors

- With implementation of this project, MURR still does not appear to satisfy any of the *production facility* definition in 10 CFR 50
- MURR believes it would be unprecedented if the NRC required it to obtain a production facility license within its existing utilization facility license.
- A separate production facility license does not appear to be necessary in this instance.

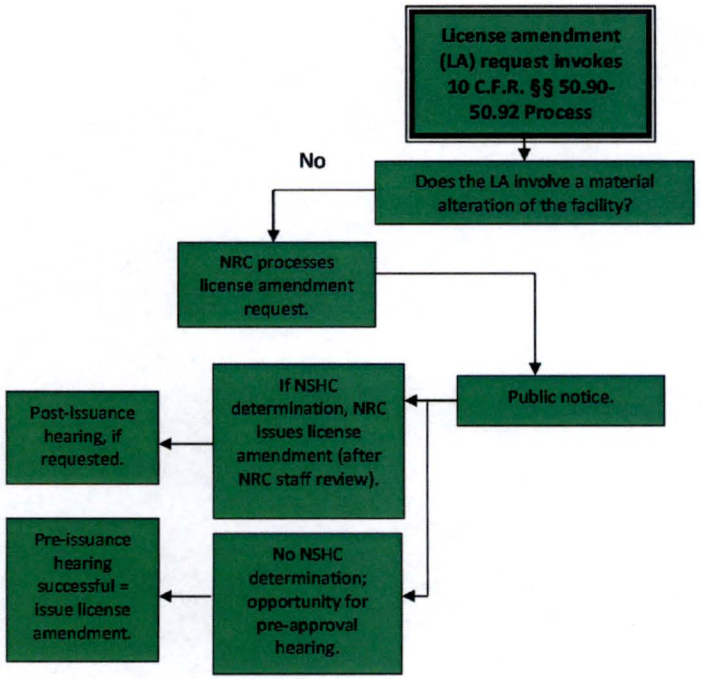
Licensing Approach: Material Alteration

- **Does the licensing action involve an "alteration" or "material alteration"?**
- **The word "alteration" as used in § 50.23 and "material alteration" as used in § 50.92(a) are not defined in 10 CFR 50.**
- **Key additions are hot cells (with supporting system), which have not previously been categorized as an alteration.**



Licensing Approach: Material Alteration

No Material Alteration



Decision Factors:

- No construction of new buildings or expansions to existing buildings
- Project requires installing typical, standard equipment that currently exists at MURR – such as hot cells, heat exchangers, pumps, etc.
- Irradiating targets in MURR's graphite reflector region is common AND is outside the primary pressure boundary
- No dissolution of SNM
- After extraction and collection using the SGE technology, chemistry steps are standard and well within MURR's staff experience
- MURR believes there is no "alteration" or "material alteration" to the facility
- **Construction Permit should NOT be required.**

Licensing Approach: Material Alteration

Construction permit should not be required.

Precedence:

- In only one instance has a construction permit been issued before an amendment of an operating license, that is, an amendment to the operating license of a research reactor at the University of Maryland. The material alteration was the complete removal of existing control rods, rod drive mechanisms, core instrumentation, and control room equipment and replacement with those of a different design. The change rendered major portions of the safety analysis inapplicable.
- A construction permit was NOT required for the Massachusetts Institute of Technology's (MIT) Research Reactor (MITR) Fission Converter that required a standalone cooling system.

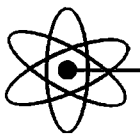
The SGE experimental facility will not result in "substantial changes" to MURR or "transform" the MURR facility into something it previously was not.

Conclusions

- MURR currently plans to submit an amendment to the current Part 50, Class 104(c) license with no change in *utilization facility* status.
- Implementation of GA SGE technology at MURR is not considered an "alternation" or "material alteration" to the facility and thus should not require a construction permit.

BREAK

Proprietary Session



Summary

- Licensing approach supports the project goal to provide a reliable supply of high quality, domestically generated, cost competitive Mo-99 to meet U.S. needs as soon as possible.


Thank you for your attention, questions?