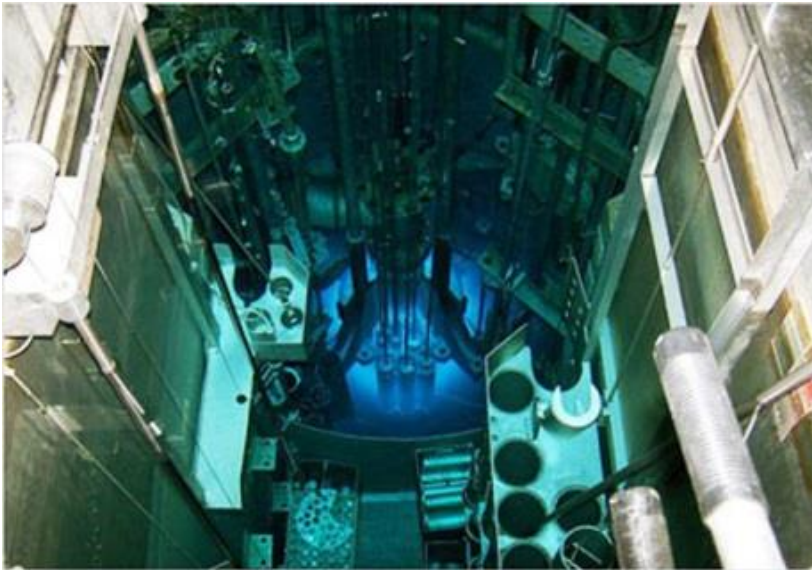


University of Missouri Research Reactor, Nordion and General Atomics Collaborating to Develop a New and Reliable Supply of Mo-99 for the Future



A Canadian-US partnership has been announced to create a "new, reliable supply" of medical isotopes for use worldwide.

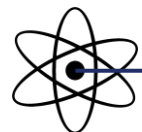


The MURR research reactor (Image: University of Missouri)

April 27, 2015

This meeting segment is to present and discuss the approach to NRC licensing at MURR related to this project

Canada's Nordion and its US parent company Sterigenics International signed partnership agreements on 20 February with the USA's General Atomics (GA) and the University of Missouri Research Reactor Center (MURR).



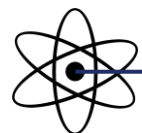
MURR[®]

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



GA SGE Technology Licensing Approach

- Goals for today's and follow-up discussion(s):
 1. Identify the most appropriate licensing approach for this project to support the national Mo-99 supply need;
 2. Obtain a mutual understanding of the clear and concise requirements such that a high quality licensing submittal maybe accomplished;
 3. Maintain frequent communication with the NRC; and
 4. Understand the timeline for obtaining NRC approval of licensing approach.



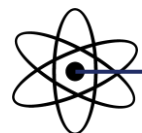


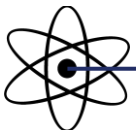
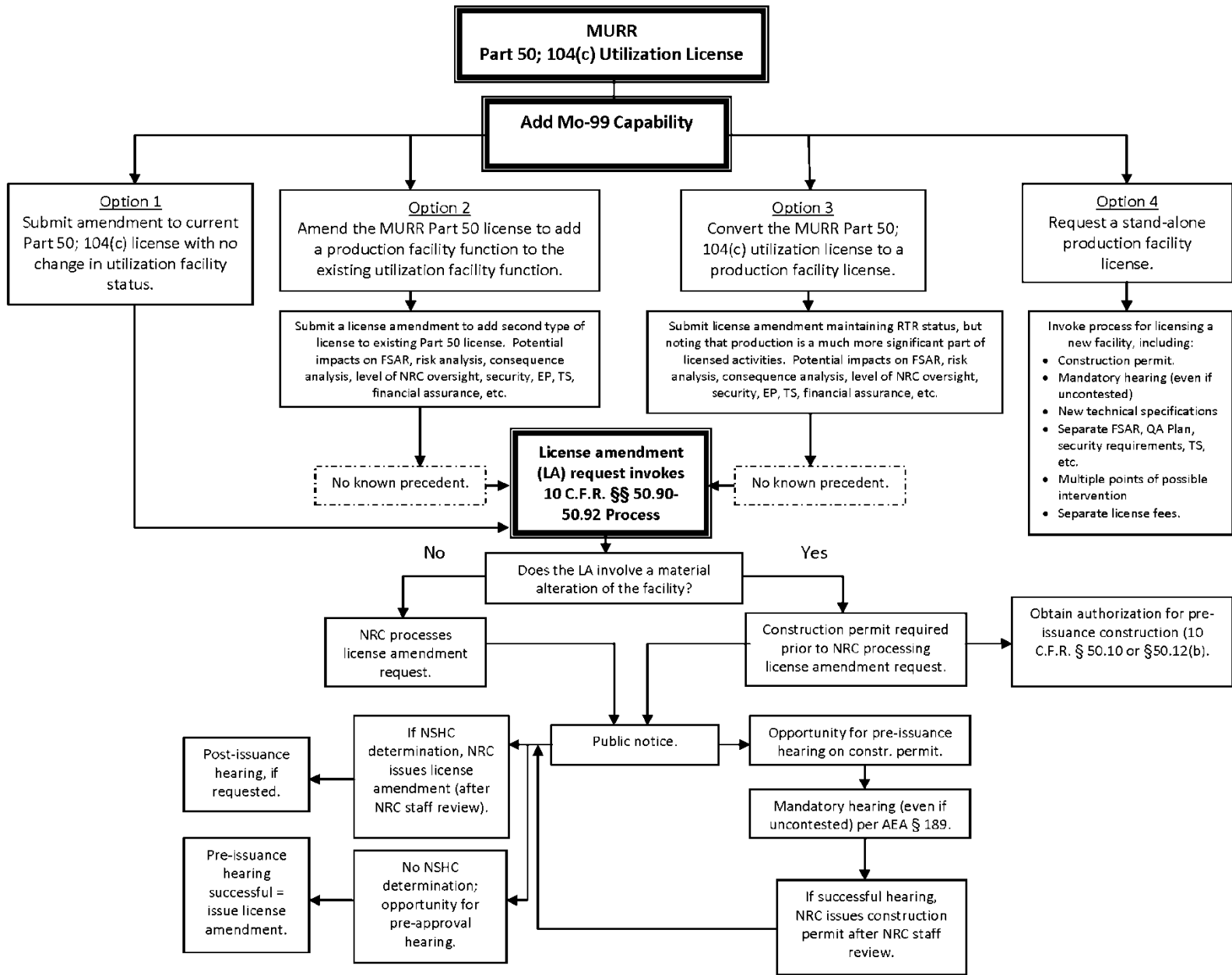
Licensing Approach:

Testing facility as per Definition 10 CFR 50.2 – *Testing facility* means a nuclear reactor which is of a type described in § 50.21(c) and for which an application has been filed for a license authorizing operation at:

- (1) A thermal power level in excess of 10 megawatts; or
- (2) A thermal power level in excess of 1 megawatt, if the reactor is to contain:
 - (i) A circulating loop through the core in which the applicant proposes to conduct fuel experiments; or
 - (ii) A liquid fuel loading; or
 - (iii) An experimental facility in the core in excess of 16 square inches in cross-section.

This project does not meet the definition of a *testing facility*. The project will not require a fueled experiment with a circulating loop through the primary coolant pressurized boundary of the reactor core, nor does it require a liquid fuel loading or a experimental facility in the core in excess of 16 square inches in cross-section. MURR will continue to operate at a maximum thermal power level of 10 MW.



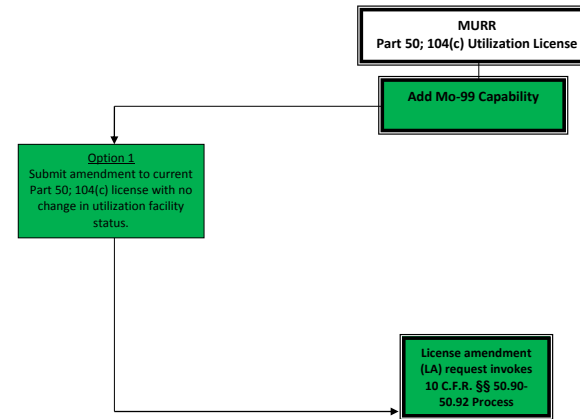


Licensing Approach:

Option 1

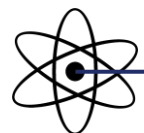
Submit amendment to current Part 50, Class 104(c) license (R-103) with no change in *utilization facility* classification

Example of typical hot cells currently at MURR



Decision Factors Include:

- 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 processing (dissolution) of SNM
- After SGE, chemistry steps are standard and well within MURR's staff experience



Licensing Approach:

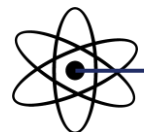
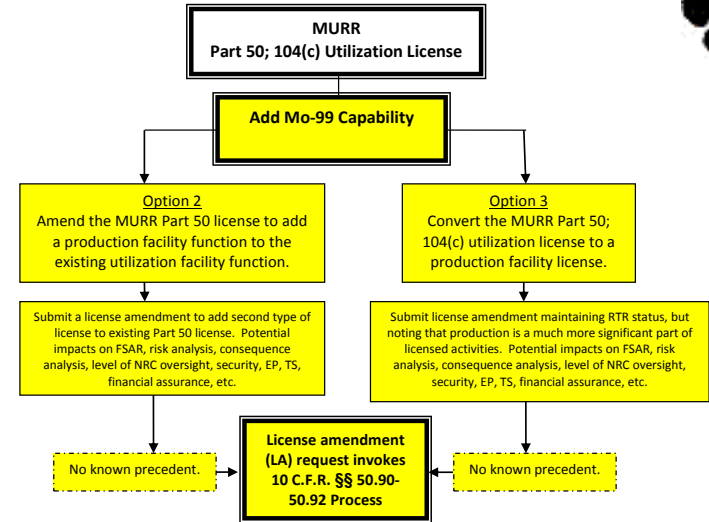


Options 2 and 3

Are variations of applying
production facility classification

Production Facility Definition per 10 CFR 50.2 means:

- (1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233; 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; 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, (ii) facilities in which the 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 processed 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.





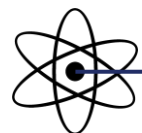
Licensing Approach:

Would implementation of the proposed GA SGE technology at MURR meet the definition of a *production facility*?

<u>Definition Excerpts from 10CFR50</u>	<u>Apply?</u>
(1) Any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233	No
(2) Any facility designed or used for the separation of the isotopes of plutonium ...	No
(3) Any facility designed or used for the processing of irradiated materials containing special nuclear material ...	No*

*10 CFR 50 does not contain a definition for *processing*. In producing Mo-99 from uranium, it seems that the industry implied definition is the disassembly and/or chemical dissolution of uranium targets that have been irradiated and then removed from the reactor into separate facilities for *processing* – chemical separation of Mo-99 from the dissolved uranium target.

In the case of the GA SGE technology, the uranium targets are not removed from the reactor and are never disassembled nor chemically dissolved. Furthermore, the GA SGE technology does not separate uranium or plutonium from the target assembly; thus, does not appear to meet the definition of a *production facility*.



Licensing Approach:

Option 2

Amend the MURR Part 50 license to add a *production facility* function to the existing *utilization facility* classification

Submit a license amendment to add a second type of license to existing Part 50 license

No known precedent

MURR
Part 50; 104(c) Utilization License

Add Mo-99 Capability

Option 2

Amend the MURR Part 50 license to add a production facility function to the existing utilization facility function.

Submit a license amendment to add second type of license to existing Part 50 license. Potential impacts on FSAR, risk analysis, consequence analysis, level of NRC oversight, security, EP, TS, financial assurance, etc.

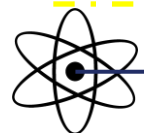
No known precedent.

License amendment (LA) request invokes 10 C.F.R. §§ 50.90-50.92 Process



Decision Factors Include:

- With implementation of this project, MURR still does not appear to satisfy any of the *production facility* definition in 10 CFR 50
- We are unaware of any precedence for establishing a *production facility* within a *utilization facility*
- Requires maintaining two separate Class 104(c) licenses; thus requiring separate NRC oversight and inspections?



Licensing Approach:

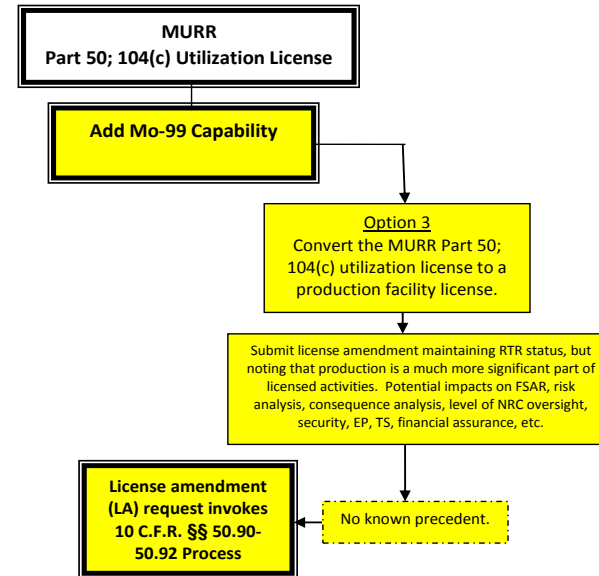


Option 3

Change the MURR Part 50;
Class 104(c) *utilization facility*
license to a *production facility*
license

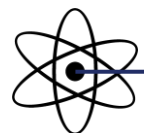
Submit license amendment
maintaining RTR status, but
reclassifying to a *production*
facility

No known precedent



Decision Factors Include:

- With implementation of this project, MURR still does not appear to satisfy the *production facility* definition in 10 CFR 50
- We are unaware of any precedence for converting an existing *utilization facility* into a *production facility*





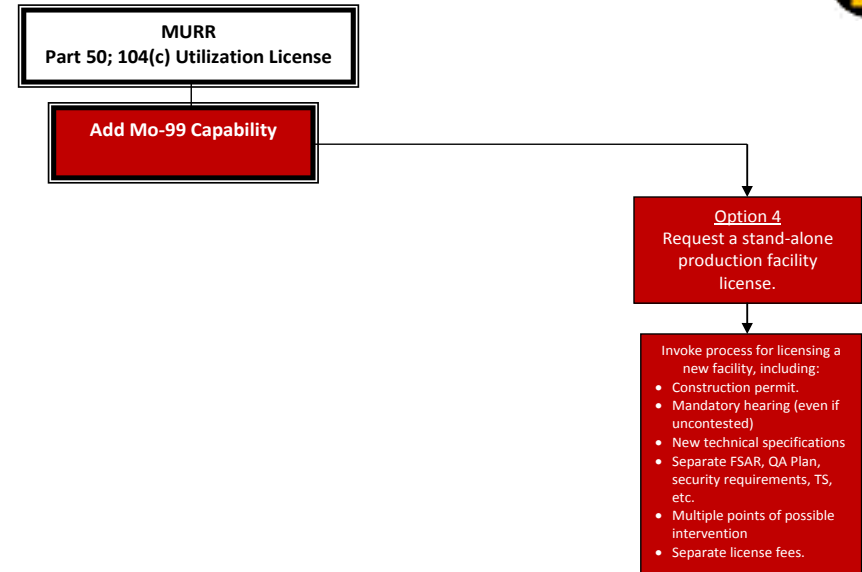
Licensing Approach:

Option 4

Request a stand-alone
production facility license

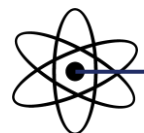


Invoke process for licensing a
new facility but reclassifying
to a *production facility*



Decision Factors Include:

- There are no new buildings nor expansions to existing buildings being constructed
- There is no processing of SNM
- Requires maintaining two separate Class 104(c) licenses; thus requiring separate NRC oversight and inspections



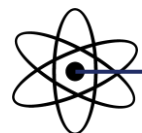


§ 50.92(a) Issuance of Amendment

“(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,....”

§ 50.23 Construction Permits

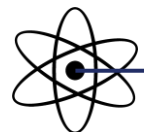
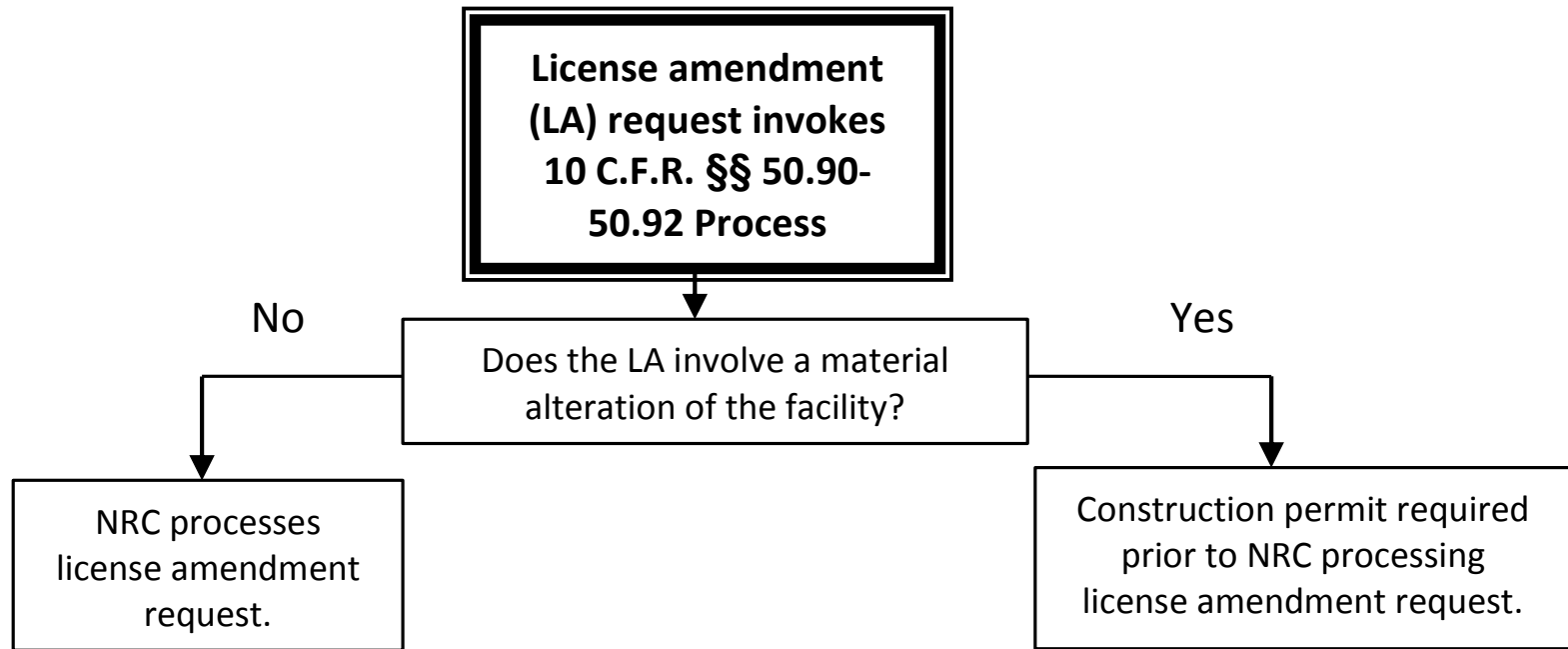
A construction permit for the construction of a production or utilization facility will be issued before the issuance of a license if the application is otherwise acceptable, and will be converted upon completion of the facility and Commission action, into a license as provided in § 50.56. However, if a combined license for a nuclear power reactor is issued under part 52 of this chapter, the construction permit and operating license are deemed to be combined in a single license. **A construction permit for the alteration of a production or utilization facility will be issued before the issuance of an amendment of a license**, if the application for amendment is otherwise acceptable, as provided in § 50.91.





Licensing Approach:

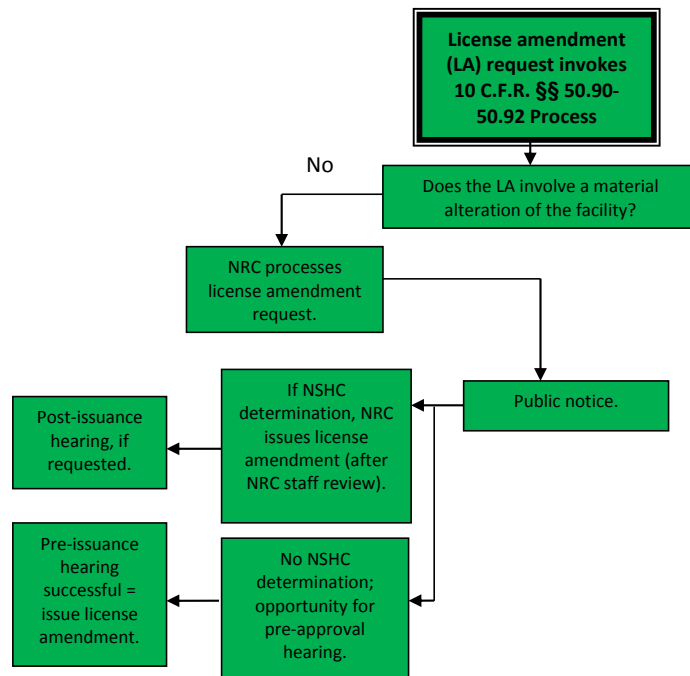
- Does the licensing action involve an “alteration” or “material alteration” to the facility?
- The word “alteration” as used in § 50.23 and “material alteration” as used in § 50.92(a) are not defined in Part 50





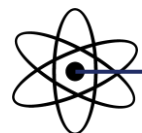
Licensing Approach:

No Material Alteration



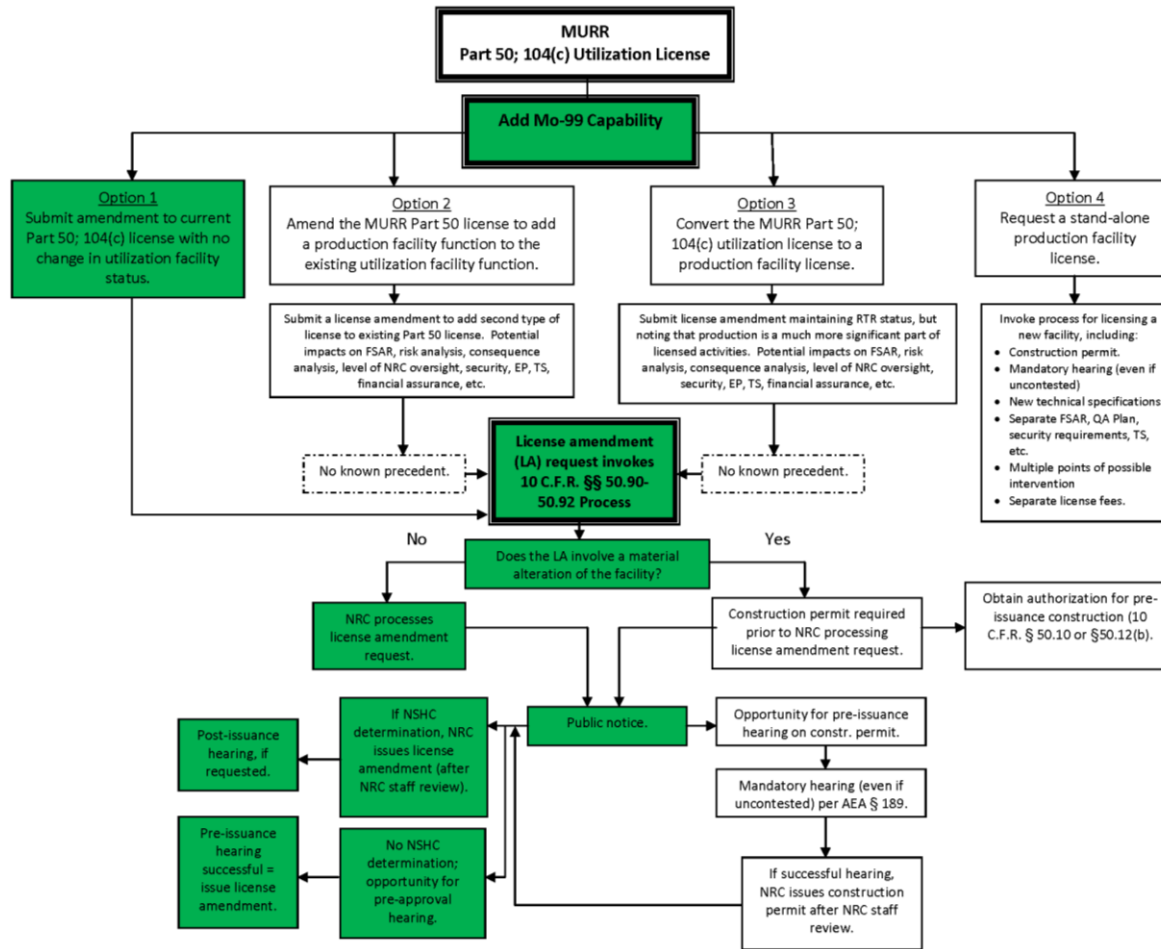
Decision Factors Include:

- 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 processing (dissolution) of SNM
- After extraction and collection using the GA 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



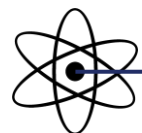


MURR's Proposed Licensing Approach



Option 1

- 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 does not require a construction permit

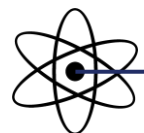




MURR's Proposed Licensing Approach

- Part 50 License Amendment Justification -

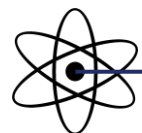
1. Appears to be the most straight forward and applicable;
2. Historical basis for clear and concise regulatory requirements; and
3. Provides the most expeditious pathway to begin meeting U.S. patient needs.





MURR Licensed Power Level – 10 MW_{th}

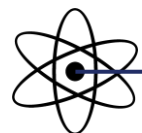
- Reactor power level is determined using a power calorimetric and a secondary heat balance as a double check.
- Calculation includes power (heat) generated by the reactor core and also conservatively includes heat generated in the reflector regions by experiments, structural materials, stored irradiated fuel etc. – (Primary coolant delta-T x flow) + (Pool coolant delta-T x flow).
- GA SGE coolant loop will be instrumented (flow and temperature) such that power (heat) generated by target assembly will be known.
- MURR feels that power generated by SGE target should not be included in licensed power level determination.



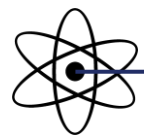


Summary

- Implementation of GA SGE technology does not reclassify MURR from a *research reactor* to a *testing facility*.
- Option 1 appears to be the most straightforward and applicable licensing approach.
- No guidance on what a “alteration” or “material alternation” means.
- Unaware of what the implications are of being reclassified from a *utilization facility* to a *production facility*.
- Unaware if a facility can be classified as both a utilization and production facility.
- Heat generated by SGE target assembly should not be included in the MURR licensed power level.



Thanks for your attention, questions?



MURR[®]

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