University of Missouri Research Reactor Center

Mo-99 at MURR

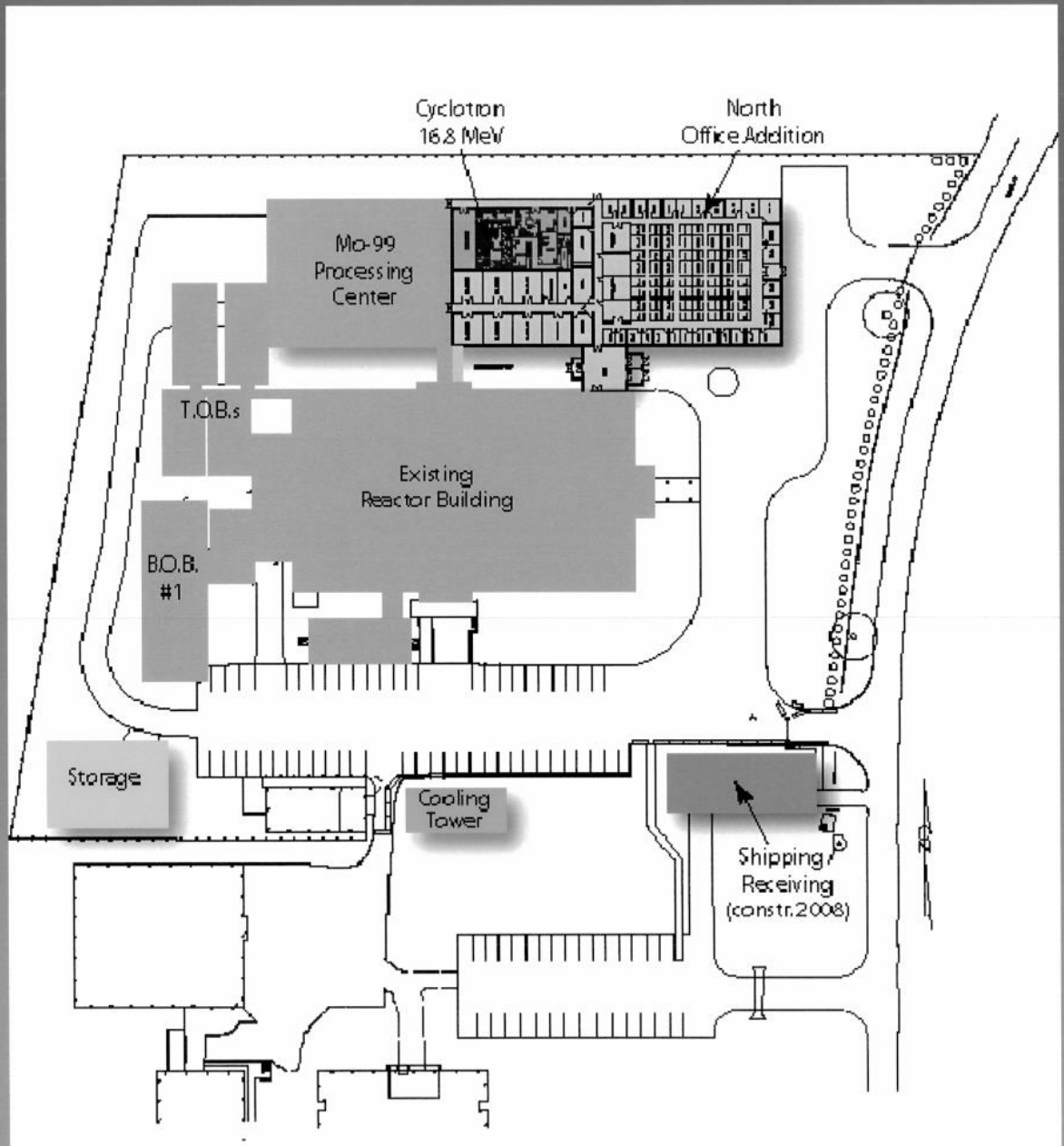
- Tc-99m is used in over 80% of all medical isotope procedures worldwide.
- National need ~35,000 procedures/day in U.S.
- Use is expected to increase 3% to 7% annually for the next ten years.
- More than 30 different radiopharmaceuticals use Tc-99m for disease detection & organ structure & function.

Mo-99 at MURR

- Overall objective is to develop the capability to produce Mo-99 from LEU targets.
- Eventual production objective is ~50% of current US weekly demand.
  - Current U.S. weekly demand is estimated to be 6000 six-day Curies (Ci) per week
  - 6000 six-day Ci equates to about 40,000 Ci (End-of-Irradiation), Synonymous with "Out-of-Reactor" Ci

Mo-99 at MURR

- Currently no US production of Mo99
- Need for reliable domestic supply of Mo99 to produce Tc99m
- Medical supply of Tc99m has been interrupted in the past
  - Limited number of capable reactors world wide
  - Aging reactor operation causing a decrease in supply
  - Foreign supply has been interrupted in the past
- Viewed as a National Security issue



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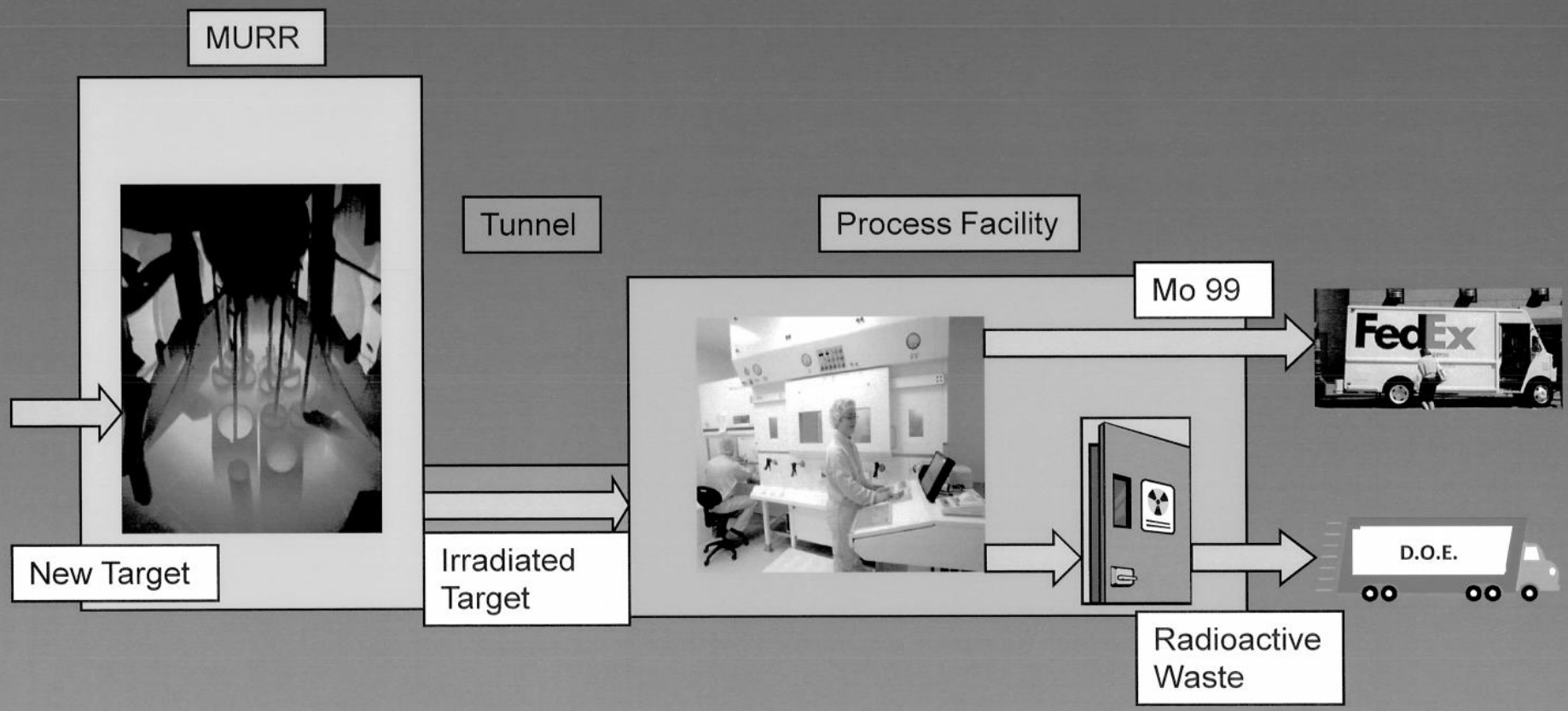
Process


MURR
New Target
Tunnel
Irradiated Target
Process Facility
Mo 99
FedEx
D.O.E.
Radioactive Waste

Project Goals

- ASAP, provide a reliable supply of high quality, domestically produced, cost competitive Mo99 to the U.S.
- Maintain MURR Core Values
  - Safety focus
  - Environmental stewardship
  - Community involvement
  - Compliance with all applicable regulations
- Assemble a strong team to accomplish project

Schedule Goals

Start Design	6 / 2009
Final Design	3 / 2010
License Application	6 / 2010
Construction Complete	9 / 2011
NRC License Issued	9 / 2011
FDA Certificate of Process	12 / 2011
Facility Operational	12 / 2011

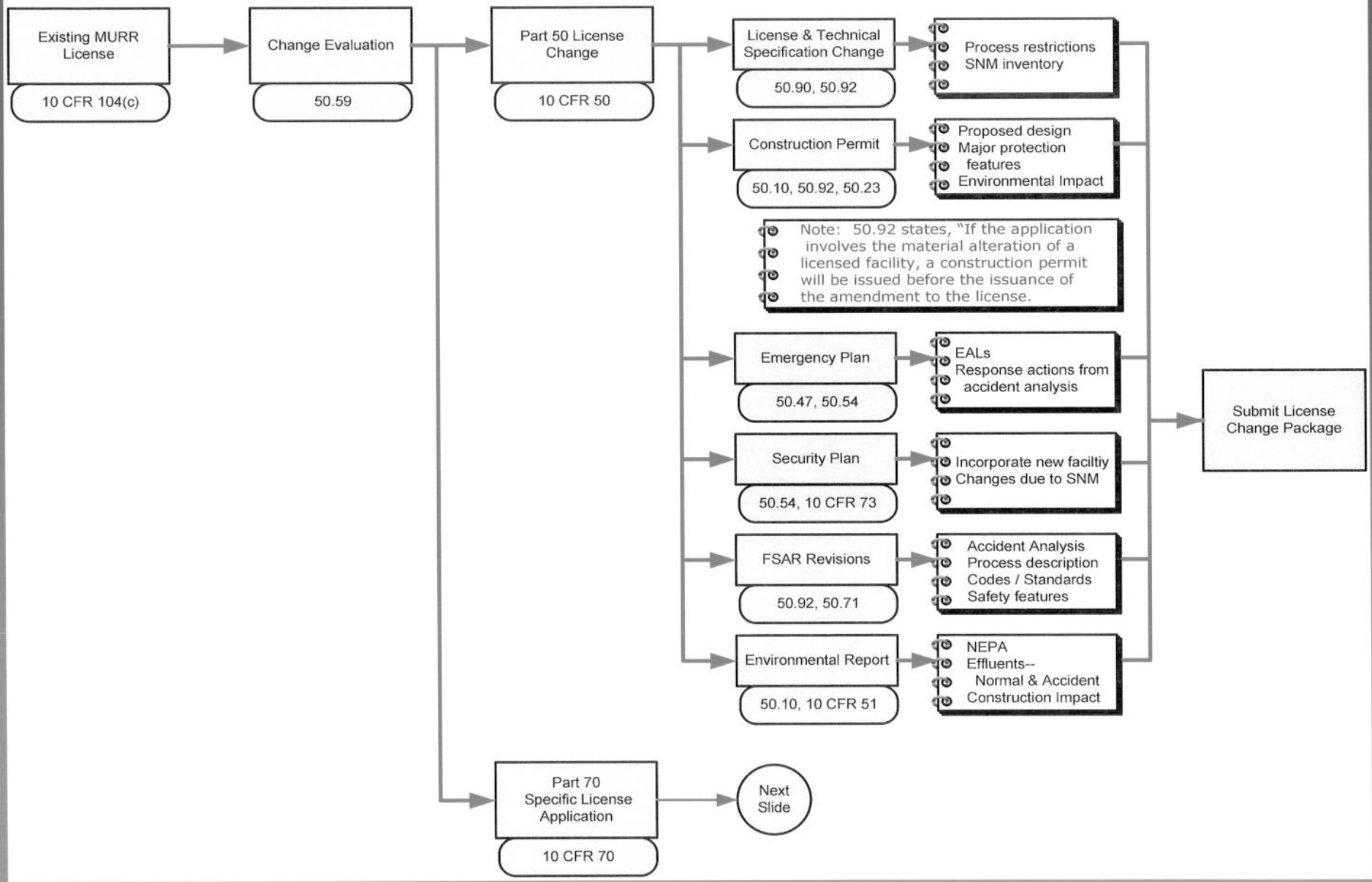
Licensing Approach

- Goals:
  - Identify the path to gain an operating license as quickly as possible to support the aggressive schedule.
  - Identify the path to allow the facility to be constructed as quickly as possible to support the aggressive schedule.
  - Mutual understanding of clear concise requirements so that a high quality submittal can be accomplished.
  - Maintain frequent communication with NRC
    - Pre-submittal interaction to support aggressive schedule.

Licensing Approach

- Reviewed licensing approaches
  - Part 50 Amendment to existing license
    - Expansion of Part 50 License to meet applicable requirements of Part 70.
  - 10 CFR Part 70
    - Part 70 specific license

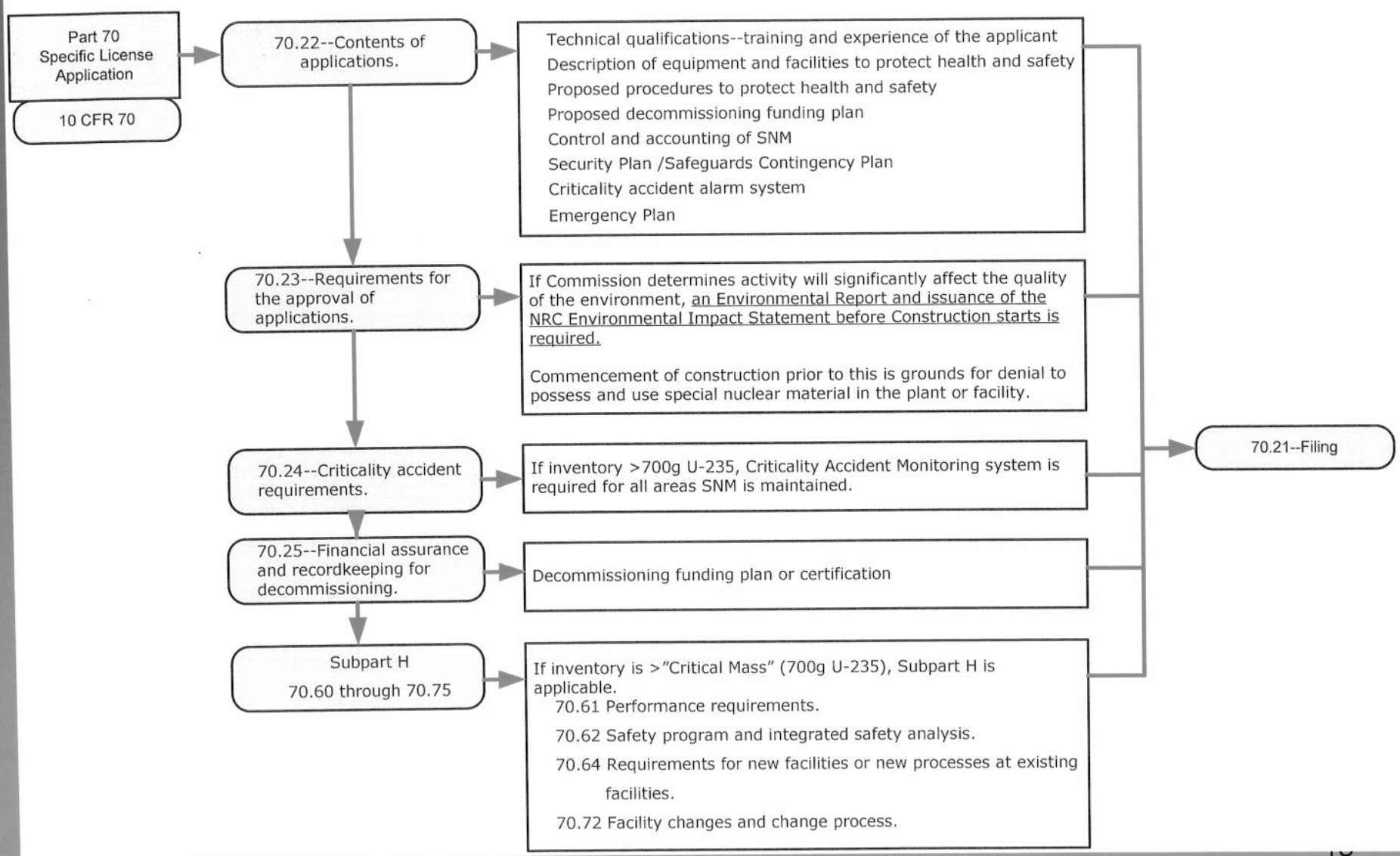
Licensing Road Map



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,…. "

Licensing Road Map



Preferred Licensing Path

Part 50 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.

Summary

- Licensing approach supports the project goal to provide a reliable supply of high quality, domestically produced, cost competitive Mo99 to meet U.S. needs as soon as possible.
- MURR Core Values

  Safety focus — Environmental stewardship

  Community involvement — Compliance with applicable regulations
- Maintain communications with NRC during the project.
  - Project status Meetings
  - NRC experience / Lessons Learned / Domestic / International