NRC Licensing of Isotope Production Facilities

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ABSTRACT

The United States Nuclear Regulatory Commission (NRC) has primary responsibility for the licensing and regulatory oversight of the construction and operation of production and utilization facilities. There are currently no isotope production facilities in operation. After evaluating existing and emerging technologies and dialog with potential license applicants, the NRC has developed draft guidelines for preparing and reviewing applications for the licensing of production facilities. The licensing processes for facilities utilizing a variety of technologies are discussed, including fission of low enriched uranium and the activation or transmutation of naturally occurring material. Fission processes include the separation of selected fission fragments from conventional targets in heterogeneous reactors, the core of aqueous homogeneous reactors, or the uranium solution of an accelerator-driven subcritical multiplier solution vessel.

TECHNICAL EVALUATION CRITERIA NEEDS ANALYSIS

As the United States anticipated a domestic supplier for the popular diagnostic radioisotope molybdenum-99 (Mo-99) and its daughter technicium-99m (Tc-99m), the staff of the Nuclear Regulatory Commission (NRC) reviewed its regulatory requirements and licensing processes in preparation to license production and utilization facilities. It was determined that the regulatory requirements existed but that guidance on content and format of license applications and NRC staff acceptance criteria was needed for the new technologies being implemented. This paper provides an overview of NRC licensing of isotope production facilities with a focus on guidance prepared for the licensing of new Mo-99 isotope production facilities.

Mo-99 production from raw material to the patient consists of multiple stages frequently done in multiple buildings or sites:

1. Production in a reactor, accelerator, or other source
2. If produced by uranium fission, separation of the Mo-99 from other fission products
3. Processing of the Mo-99 for radiopharmaceutical use
4. Delivery and use in patients

The NRC has sole license jurisdiction for stages 1 and 2 which will be the focus of this paper. The Food and Drug Administration (FDA) is involved in the licensing of stages 3 and 4.

There are three primary technologies to produce an isotope such as Mo-99; activation, fission, and accelerator production, each technology involving unique aspects of licensing with the NRC:

Mo-99 was initially produced by the activation or neutron capture by Mo-98 in natural Mo targets in a reactor. General Electric produced neutron capture Mo-99 commercially at its Vallecitos, California, site until being shut down in the 1970s. Today, most research reactors can produce Mo-99 under existing license provisions for experiments. Also, processes exist for amending a power reactor license to produce Mo-99 by activation of Mo-98.

Mo-99 produced from uranium fission has become the method of choice throughout the world because of its higher specific activity and improved imaging resolution. The NRC-licensed Union Carbide reactor at Tuxedo, New York, later being purchased and licensed by Cintichem, produced "fission moly" as it was called on a commercial basis until its 1989 shutdown and subsequent decommission. Separation of the Mo-99 from other fission products was done in small batches under a special nuclear material license.

Today, there are three forms of fission moly production under consideration. First, as in the Cintichem case, commonly referred to as the conventional target technology, uranium targets removed from the reactor are transferred to a processing facility for the separation of Mo-99 from other fission products and unfissioned uranium from the target; only the fission products in the targets are available for harvesting Mo-99. A second form of the fission Mo-99 technology is the use of an aqueous homogeneous reactor (AHR) where the entire core can be processed to harvest Mo-99; while AHRs were licensed decades ago they have not been used for bulk Mo-99 production. The third variation of the fission Mo-99 technology is the uranium solution tank wherein neutrons from accelerator reactions are continuously injected into a solution tank which serves as a subcritical multiplier. As with the AHR, the entire solution tank liquid inventory is processed to harvest Mo-99.

The third method to produce radioactive Mo-99 is by accelerator production; for example by stripping a neutron from stable Mo-100. In the US, accelerators and accelerator-generated radioactive material may be licensed by the NRC or a State under the Agreement State program.

ADDRESSING LICENSING NEEDS

Preparing for the licensing of domestic Mo-99 production facilities involved many disciplines represented within the NRC. A Mo-99 Working Group was assembled consisting of representatives of the following Offices:

Nuclear Reactor Regulation
Nuclear Material Safety and Safeguards
Federal and State Materials and Environmental Management Programs
General Counsel
Nuclear Regulatory Research
Nuclear Security and Incident Response
International Programs
Congressional Affairs
Public Affairs
Chief Financial Officer

The lead for all Mo-99 activities resides in the Office of Nuclear Reactor Regulation. The working group provides a collaborative environment to address Mo-99 regulatory issues related to production, transportation, and security; a single point of contact for internal and external stakeholders; and good communication throughout the agency. Good communication channels also exist among federal agencies to support the development and production of Mo-99.

REGULATORY BASIS

Statutory authority for regulating nuclear activities in the United States is granted by Congressional Acts, the most relevant being:

The Atomic Energy Act of 1954, as Amended
The Energy Reorganization Act of 1974, as Amended
The Energy Policy Act of 2005

Under this statutory authority the NRC has promulgated regulations contained in Title 10 of the *Code of Federal Regulations* (10 CFR). Among the various parts of 10 CFR, the most relevant to isotope production are the following:

Part 2	Rules of practice for domestic licensing proceedings and issuance of orders
Part 20	Standards for protection against radiation
Part 30	Rules of general applicability to domestic licensing of byproduct material
Part 50	Domestic licensing of production and utilization facilities
Part 51	Environmental protection regulations for domestic licensing and related regulatory functions
Part 55	Operators' licenses
Part 70	Domestic licensing of special nuclear material
Part 73	Physical protection of plants and materials
Part 74	Material control and accounting of special nuclear material
Part 150	Exemptions and continued regulatory authority in Agreement States and in offshore waters under section 274
Part 170	Fees for facilities, materials, import and export licenses, and other regulatory services under the Atomic Energy Act of 1954, as amended
Part 171	Annual fees for reactor licenses and fuel cycle licenses and material licenses, including holders of certificates of compliance, registrations, and quality assurance program approvals and government agencies licensed by the NRC

To make its licensing process effective, efficient, and to assist applicants in providing completeness of information for NRC staff review the NRC has published NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors." While these guidelines are not regulatory requirements, they assist in conveying to licensees a format for non-power reactor applications that is acceptable to the NRC staff. NUREG-1537 addresses the format and content of an application, describes the standard review plan used by the NRC staff, and states acceptance criteria to be applied. Based on the expected receipt of new license applications, the NRC staff proceeded to update NUREG-1537 by addressing the new technologies described above through the use of Interim Staff Guidance (ISG).

THE FISSION FACILITY

A nuclear reactor is defined in 10 CFR 50.2 as "an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission in a self-supporting chain reaction." The

conventional target process of producing Mo-99 and the aqueous homogeneous reactor are nuclear reactors under this definition. They are therefore subject to the licensing requirements of 10 CFR Part 50. The subcritical multiplier solution tank does not sustain a chain reaction and is therefore not a reactor under this definition and is treated differently as discussed in the next section of this paper.

Some regulations differ between power reactor and non-power reactor requirements. The nominal US demand for Mo-99 of 6000 six-day Curies per week (a six-day Curie being the activity remaining after six days of decay) results from approximately 700 kilowatts of fission power. Based on this fact, the power level of reactors for fission Mo-99 can be expected to be within the range of currently licensed non-power reactors.

THE PROCESSING FACILITY

In the production of fission Mo-99 the usable product must be separated from all the other unwanted fission products and the unfissioned uranium. As the Atomic Energy Act (AEA) was formulated and implementing regulations were written, this topic was addressed. The AEA defined and placed requirements on production facilities resulting in regulations in 10 CFR Parts 50 and 70. Today, numerous fuel cycle facilities are licensed for the handling of special nuclear material pursuant to 10 CFR Part 70. However, for the processing of irradiated materials containing special nuclear material above a small threshold, a 10 CFR Part 50 production facility license is required; there are no active NRC production facility licenses in existence today.

To be specific, the third definition of a production facility in 10 CFR 50.2 states: "(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 no 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 product 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 U-235 and not more than 15 grams of any other special nuclear material." (Underscore has been added for emphasis.)

Should an application identify a processing batch size of not more than 100 grams of U-235, the applicant may file an application for a license under Part 70 for a special nuclear material facility.

The processing of the Mo-99 from the accelerator-driven subcritical solution tank facility without limit to batch size is defined in Part 50 as a production facility and would require an NRC license. The likely licensing path for this scenario is that it will be considered a production facility with the ancillary use of special nuclear material of which the accelerator is an integral part and therefore the NRC license of the production facility will subsume control of the accelerator rather than it being under the Agreement State jurisdiction.

GUIDANCE DOCUMENTATION

Two primary sources of guidance are the documents:

- NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, 1996.
- NUREG-1520, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Revision 1, May 2010.

Two multi-discipline groups were formed to prepare additional guidance identified in the interim staff guidance (ISG) to NUREG-1537 reflective of licensing production facilities as an addendum to NUREG-1537. NUREG-1537 was developed when there were no more operating aqueous homogeneous reactors (AHRs) and they were therefore not addressed in the document; one team looked at the safety aspects of AHRs and the safety analysis. Much of the same technology is applicable to the solution tank facility. A second team started with NUREG-1537 and expanded it to address a production facility, in large part by referencing appropriate parts of NUREG-1520. Many sections (e.g., site description and financial qualifications) required very little or no augmentation whereas other sections (e.g., facility description) required essentially an entirely new section.

The ISG was prepared with an expanded scope, that being to update the document while providing updated guidance for a heterogeneous reactor, an AHR, a utilization facility, and a production facility. The NRC is currently addressing comments for Chapters 1-6 of the draft ISG that went out for public comment and will be publishing Chapters 7-18 of the ISG for public comments in the near future.

CONCLUSION

The NRC has monitored emerging technologies likely to be deployed for the production of isotopes and in particular, Mo-99. While existing regulations were found adequate, additional guidance was found necessary to address how those regulations apply to emerging technologies for Mo-99 production. NRC has developed Interim Staff Guidance to NUREG-1537 to provide the format and content of an application, describe the standard review plan used by the NRC staff, and acceptance criteria applied to applications.