



ENCLOSURE 2

Basis for the Submittal of the Principal Design Criteria as a Topical Report

The submittal of the Atomic Alchemy FSAR Chapter 3, Appendix F, “Principal Design Criteria” as a topical report takes exception to the NRC LIC-500, Basic Requirements 4.2, Criteria B for submittal of a topical report based on the following:

Public Interest

Atomic Alchemy intends to design, procure, construct, and operate a Non-Power Production and Utilization Facility (NPUF) with the purpose of producing Molybdenum-99 (Mo-99), among other radioisotopes. Deployment of an NPUF will accomplish three significant objectives that are considered national priorities and of great interest and concern to the public.

First, it will help alleviate the ongoing Mo-99 supply crisis that has resulted from operational interruptions at reactors abroad which produce Mo-99. Second, it will result in a long-term domestic supply of Mo-99 to reduce the U.S. dependency on foreign suppliers. Third, it will result in a Mo-99 supply that does not rely on the use of highly enriched uranium.

Precedent

The NRC has previously reviewed licensee topical reports involving design approaches. These were submitted to the NRC for the purpose of obtaining NRC review and a determination of acceptability for use in establishing the licensee’s design and licensing basis.

Atomic Alchemy’s design approach to utilize 10 CFR 50, Appendix A, “General Design Criteria” as a minimum basis for establishing its principal general design criteria to meet the regulatory requirements of 10 CFR 50.34(a)(3)(i) as referenced in NUREG-1537 Part 1, Appendix A for both its non-power reactors and radioisotope production processes is similar to the design approach utilized by both Shine Medical Technologies (PSAR Table 3.1-3) and Northwest Medical Isotopes LLC (PSAR Table 3.5.2). While 10 CFR 50, Appendix A is not applicable to NPUFs, it does present a minimum basis for developing principal design criteria for meeting applicable Title 10 regulations for a Part 50 construction license.

Increase Efficiency

The prior acceptance of the Atomic Alchemy Principal Design Criteria and its compliance with 10 CFR 50.34(a)(3)(i) will facilitate increased efficiency of the review of the Atomic Alchemy construction application and PSAR submittal under 10 CFR Part 50. The early review and acceptance of the principal design criteria to be described in the PSAR and its relationship to the design basis of the facility is extremely important to providing appropriate quality to the safety-related aspects of the design.

An early NRC review and approval of this design approach and design concepts will result in a greater degree of regulatory certainty and will ensure that the construction application review process can proceed in an efficient and timely manner.