2018 Mo-99 Topical Meeting on Molybdenum-99 Production Technology Development

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Licensing and Oversight Enhancements and Preparations for Medical Radioisotope Facility Application Reviews and Construction Inspection

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ABSTRACT

In support of the establishment of a domestic supply of molybdenum-99 (Mo-99), the U.S. Nuclear Regulatory Commission (NRC) issued construction permits to SHINE Medical Technologies, Inc. (SHINE) and Northwest Medical Isotopes (NWMI) for facilities dedicated to the production of medical radioisotopes in February 2016 and May 2018, respectively. Within the last year, the NRC has issued licensing guidance for medical use applicants and licensees possessing the NorthStar Medical Radioisotopes RadioGenix technetium-99m generator system. The NRC staff has also issued materials license amendments to Niowave, Inc. in support of its radioisotope production program. In anticipation of receiving operating license applications and beginning construction inspection activities in 2019, the NRC staff is engaging with licensees through public meetings, updating guidance documents, identifying staff roles and responsibilities, developing facility-specific construction inspection plans, and considering the impact of rulemakings on proposed medical radioisotope facilities.