

Regulatory Activities Related to Licensing Medical Radioisotope Production Facilities

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ABSTRACT

The paper provides an update on U.S. Nuclear Regulatory Commission (NRC) activities related to the licensing of Medical Radioisotope Production Facilities. The NRC has received nine letters of intent from potential applicants seeking to domestically produce molybdenum-99. The NRC staff is reviewing a construction permit application for a radioisotope production facility and is coordinating its environmental review with the Department of Energy consistent with the American Medical Isotopes Production Act. To promote efficient review of applications, the NRC staff has clarified regulatory requirements and issued exemptions to facilitate processing of applications. The NRC staff also continues to hold public meetings with potential applicants to receive information on proposed designs and schedule, discuss relevant guidance, and encourage submission of high-quality applications. These efforts and the NRC's regulatory framework will enable the NRC staff to perform an efficient, a thorough, and a timely review of any submitted application for a medical radioisotope production facility.