

**2017 Mo-99 TOPICAL MEETING ON
MOLYBDENUM-99 PRODUCTION TECHNOLOGY DEVELOPMENT**

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The Drug Regulatory Pathway to LEU Conversion

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ABSTRACT

Conversion from the use of High Enriched Uranium (HEU) to Low Enriched Uranium (LEU) has been an important goal to Curium for the last several years. This conversion is important to the long term security of Mo-99 supply and accomplishes many non-proliferation goals. In addition to the changes necessary for the radiochemistry process, control of that process and approval by the drug regulatory agencies is critical part of the development pathway. LEU Mo-99 produced with a new process usually needs prior approval by each drug regulatory agency with the country in which the generator manufacture markets their generators. Curium utilized careful global regulatory planning to ensure clear and complete coordination and communications with the key regulatory agencies around the globe. Careful coordination with these agencies in the submission of drug dossiers will improve the likelihood and timing of approvals.