

**Mo-99 2016 TOPICAL MEETING ON  
MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT**

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**The Path to Conversion of Low-Enriched  
Uranium (LEU) for the Production of Mo-99**

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**ABSTRACT**

Mallinckrodt began its conversion to LEU targets for the production of Mo-99 at its facility in the Netherlands in 2010. Since that time a new LEU target has been developed, the radiochemistry process has been modified to deal with the complexities of an LEU target, new waste handling techniques have been developed along with appropriate containers for its disposal, the process of obtaining drug regulatory approval has been initiated, and licensing of a transport container for irradiated LEU targets has been completed. Through this process several technical hurdles have been encountered, and resolved in an effective manner using both our internal expertise and through external collaboration with Pacific Northwest National Labs as well as our reactor partners at Nuclear Research Consultancy Group, operator of the High-Flux Reactor, and the operators of the BR2 and Maria reactors. We have engaged the U.S. Food & Drug Administration and the European drug regulatory authorities in an effort to expedite the review of the Drug Master File (DMF) and Active Substance Master Files (ASMF) for LEU-produced Mo-99. Mallinckrodt expects to convert its production of Mo-99 from its current high-enriched uranium-based process to an LEU-based process by the end of 2017.