

**2018 Mo-99 TOPICAL MEETING ON  
MOLYBDENUM-99 PRODUCTION TECHNOLOGY DEVELOPMENT**

**SEPTEMBER 23-26, 2018  
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**FDA Regulatory Update on Mo 99 produced by LEU and  
Novel Technologies**

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**ABSTRACT**

The FDA will discuss regulations relevant to the approval of Tc 99m produced from Mo 99 derived from LEU and novel technologies. Recently, the approval of the Radiogenix system, a novel Tc 99m generator, is an example of effective interagency collaboration with the regulated industry and other stakeholders to bring the novel technology to patients. Technical considerations led to a novel approach to regulatory review with contributions from several FDA components. Safe use of the product by the end users was also ensured by review of the user manual. The historic approval, re-established Mo 99 domestic supply without the use of U 235, after 30 years.