16.0 OTHER LICENSE CONSIDERATIONS

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 16, “Other License Considerations,” states that “[t]he SHINE facility utilizes new and appropriately-qualified components and systems to conduct production operations,” and that “[d]iscussions regarding used components and systems are not applicable to the SHINE facility.” Additionally, SHINE stated that its facility “does not contain equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies,” and that discussions regarding the medical use of the facility are not applicable.

The U.S. Nuclear Regulatory Commission staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that the final design of the SHINE facility does not contain prior use components, contain equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies, or raise other license considerations. Therefore, the staff concludes that an evaluation of the guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996, and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.

17.0 DECOMMISSIONING AND POSSESSION-ONLY LICENSE AMENDMENTS

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 17, “Decommissioning and Possession-Only License Amendments,” states that a decommissioning report is provided in FSAR section 15.3, “Financial Ability to Decommission the SHINE Facility.” SHINE also stated that because SHINE is not requesting a possession-only license amendment, discussions related to a possession-only license amendment are not applicable to the SHINE facility.

The U.S. Nuclear Regulatory Commission staff evaluation of SHINE’s financial ability to decommission the SHINE facility is described in chapter 15.0, “Financial Qualifications,” of this safety evaluation report. The staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that SHINE is not requesting a possession-only license amendment. Therefore, the staff concludes that an evaluation of the possession-only license amendment guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996, and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.

18.0 HIGHLY ENRICHED TO LOW-ENRICHED URANIUM CONVERSION

The SHINE Medical Technologies, LLC (SHINE, the applicant) final safety analysis report (FSAR) chapter 18, “Highly Enriched to Low Enriched Uranium Conversion,” states that because the SHINE facility is a new facility that uses low-enriched uranium, discussions related to uranium conversion are not applicable to the SHINE facility.

The U.S. Nuclear Regulatory Commission staff evaluated the descriptions and discussions of the SHINE facility in the FSAR and finds that the final design of the SHINE facility does not utilize highly enriched uranium. Therefore, the staff concludes that an evaluation of the uranium conversion guidelines of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996, and the “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012, is not required.