

## 16.0 OTHER LICENSE CONSIDERATIONS

Northwest Medical Isotopes, LLC (NWMI or the applicant) Preliminary Safety Analysis Report (PSAR) Chapter 16.0, "Other License Considerations," states that the NWMI Radioisotope Production Facility (RPF) "will only use new and appropriately qualified components and systems..." Additionally, NWMI states that the NWMI RPF will "not include equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies."

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) evaluated the descriptions and discussions of the NWMI production facility in the PSAR and finds that the preliminary design of the NWMI production facility does not include prior use components, and that the NWMI production facility will not be used for direct medical therapy. The staff concludes that an evaluation using the guidelines of "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" (Reference 11), for other license considerations is not required because:

- (1) All equipment to be installed in the NWMI production facility will be new and purpose-built. No prior use components will be used in the construction of the NWMI production facility or support systems; and
- (2) The NWMI production facility will not contain equipment or facilities associated with the direct medical administration of radioisotopes or other radiation-based therapies.

