

May 21, 2015 DOCUMENT CONTROL DESK (DCD)

U. S. Nuclear Regulatory Commission

Washington, DC 20555-0001

Subject:Potential Part 21 Issue on Irradiations performed by Steris Isomedix Services (Steris) in
Whippany, New Jersey

- 1. U. S. NRC Inspection Report 99901445/2014-201
- 2. Steris Isomedix Services Letter dated June 18, to Wyle Laboratories, Huntsville, Alabama.
- 3. Steris Isomedix Services Letter dated June 18, to National Technical Systems, Acton, Massachusetts.
- 4. Steris Isomedix Services Clarification Memo dated June 23, 2014
- 5. National Technical Systems letter dated November 12, 2014 to the U. S. NRC.
- 6. Steris Isomedix Services Letter dated December 19, 2014
- STERIS Isomedix Services Position Paper on Isomedix Dosimetry Measurement dated April 27, 2015

Per Reference 5, NTS notified the U. S. NRC of a potential Part 21 condition. This letter notifies the NRC that the variability ranges provided in Reference 5 have changed. Reference 5 also stated that NTS has joined an industry task force to further address this issue. Reference 6 states additional analysis indicated that the variability levels presented in References 2 and 4 would change. Based on the work of the industry task force, Steris completed and issued a position paper, Reference 7, which states that the total variability is 9.4% for all areas except the ceiling.

There were three tasks for NTS to complete in Reference 5. NTS will now complete these tasks based on the new variability provided by Steris in Reference 7. NTS anticipates completing these tasks by July 14, 2015.

If you have any questions, please contact NTS' Senior Director of Nuclear Engineering and Test Services, Tom Brewington at (256) 716-4512 or email at <u>tom.brewington@nts.com</u>. Sincerely,

Megan Toomey Director of Contracts NTS Huntsville

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