NTS
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HUNTSVILLE OPERATIONS

November 12, 2014

Document Control Desk
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 – INTERIM REPORT

References:

1. U.S. NRC Inspection Report 99901445/2014-201.
2. Steris Isomedix Services Letter dated June 18, 2014 to Wyle Laboratories, Huntsville, Alabama.
3. Steris Isomedix Services Letter dated June 18, 2014 to National Technical Systems (NTS), Acton, Massachusetts.
4. Steris Isomedix Services Clarification Memo dated June 23, 2014.
5. Steris Isomedix Services Presentation to the IEEE SC2 Committee on Qualification, October 28, 2014.

Pursuant to the requirements of 10CFR Part 21, this letter notifies the NRC of a potential Part 21 condition. As a result of the 10 CFR Part 50 inspection by the NRC of the irradiation process conducted by Steris Isomedix, Steris notified Wyle Laboratories and NTS (per References 2 and 3) that the actual dose delivered to our test specimens may have differed up to +/- 5.1% from the value reported on Steris' Certificate of Processing. Per Reference 4, Steris provided clarification to their initial letter and stated that the worst case variability ranges from +/- 3.5% to +/- 5.1% based on density variation, source decay, and intercomparison variability. Per Reference 5, Steris provided additional variability percentages based on test specimen location within the radiation test cell.

This radiation test service has been provided to our customers to support multiple equipment qualification projects. Although all projects included margin in the requirements imposed on Steris, NTS has not determined whether a defect as defined in 10CFR Part 21 exists at this time. NTS has joined an industry task force and formed a team to address this issue and is performing the following evaluation:

1. Determine which NTS and Wyle Laboratories projects are potentially affected by this issue by correlating purchase orders issued to Steris by NTS and Wyle Laboratories for equipment qualification projects.
2. NTS will request a revised Certificate of Processing from Steris that documents the actual radiation dose applied to the test specimens under each Wyle and NTS purchase order issued to Steris. NTS will also request that each revised Certificate of Processing identify the total variation and the test specimen location within the radiation test cell.
3. NTS will determine whether the actual dose envelops customer-specified requirements. For every equipment qualification project where the actual radiation dose is less than

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that reported to our customers, NTS will notify those customers formally and work with them to determine if a defect as defined by 10 CFR Part 21 does exist. If it is determined that a defect exists which would create a substantial safety hazard, notification to the Commission will be made in accordance with 10CFR21.21(d)(3)(i).

NTS plans to complete this evaluation by January 30, 2015. Please note that the assets of Wyle Laboratories were purchased by National Technical Systems (NTS) March 1, 2014. It should also be noted that the NTS Acton, Massachusetts facility has been closed, and all operations moved to the NTS Huntsville, Alabama facility. This notification letter is issued for any potential Part 21 condition occurring at either facility.

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 tom.brewington@nts.com.

Sincerely,

Megan Toomey
Sr. Contracts Manager