Steris Dosimetry Measurement Notice of Nonconformance

Control of Measuring and Test Equipment

Notification to Wyle

- Letter of June 18, 2014
- The actual dose delivered may have differed up to +/- 5.1% as reported on the Certificate of Processing
- The variability is in addition to the uncertainty of the dosimetry system of +/- 6.5%
- Memo of June 23, 2014
- The variability range stated as +/- 3.5% to +/- 5.1%
- This variability should not be combined with the dosimeter system uncertainty
- The variability range is for testing since 2003

Industry Task Force

- NTS became a participant in the Industry Task Force evaluating this nonconformance and its effect on qualification programs
- NTS participates in Task Force teleconferences
- NTS participated in the recent site visit to Steris

NTS Approach

- NTS will approach this issue in a manner similar to the Wyle approach used for a similar type problem that occurred with the Georgia Tech Radiation Facility
- Determine the actual dose as closely as possible for every issued Steris purchase order or use a conservative value
- Evaluate the effect on each qualification program
- Suggest options:
  - Reduce qualified life
  - Accept less margin
  - Determine a radiation specific requirement based on equipment location and re-evaluate
  - Recommend shielding
  - Re-test

NTS

Extent of Condition (NTS / Wyle)

- To date, NTS has identified approximately 38 Steris purchase orders potentially affected by the nonconformance
- We expect this number to increase
- This has been a challenge due to the asset sale of Wyle Test Labs to NTS

Remaining Tasks

- The extent of the radiation dose problem needs to be bounded and finalized by Steris in conjunction with the Industry Task Force
- Steris to provide NTS with revised Certificates of Processing or some official document with the actual dose for every issued purchase order