

Steris Part 21 Related Activities



Nuclear Utility Group on Equipment Qualification

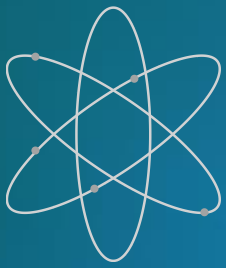
Fall 2014 Joint EQ Technical Conference

November 4-6, 2014

Sand Key, Florida

William Horin, Winston & Strawn, LLP (whorin@winston.com)

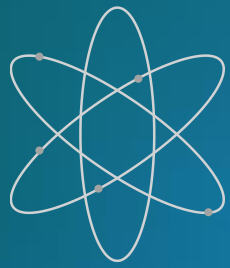
Ronald Wise, NEQ Consulting (ronwise@aol.com)



Steris Part 21 Related Activities

Today's topic is intended to provide an update on recent activities related to the June 2014 Steris-Isomedix Part 21:

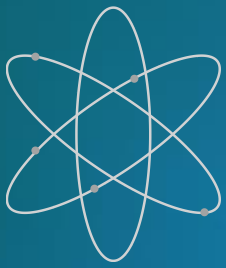
- Issuance of Industry Guidance Position Paper
- Update on Individual / Corporate Responses



Industry Guidance Position Paper

- The Industry Guidance Position Paper was issued in June 2015

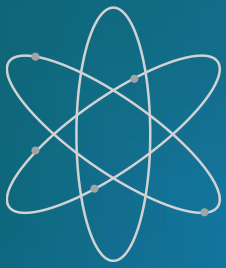




Industry (NUGEQ/IEEE/Sciencetech) Guidance

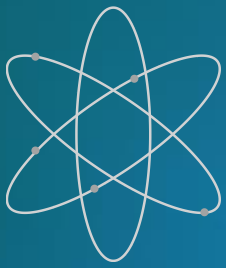
Industry Guidance Position Paper was intended to:

- Supplement and provide guidance and analysis related to Steris Position Paper, “Isomedix Dosimetry Measurement-Nuclear Components, Whippany, NJ Facility” that was previously issued by Steris on 4/27/15
- For use by NUGEQ members as well as for non-member utilities, manufacturers, or other parties responding to the 2014 Steris-Isomedix Part 21



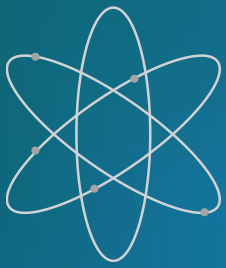
Industry (NUGEQ/IEEE/Sciencetech) Guidance

- Position Paper represents the culmination of the effort of the industry working group
 - More than two dozen members
 - Representing utilities, IEEE, Manufacturers, Test Facilities, Vendors and NUGEQ
 - Developed in collaboration with Steris-Isomedix



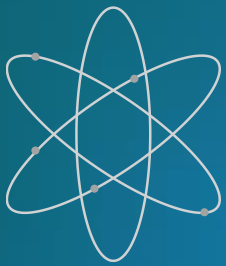
Industry (NUGEQ/IEEE/Sciencetech) Guidance

- Related to evaluating uncertainties resulting from:
 - Dosimeter Variability
 - Density Variability
 - Source Term Decay
 - Intercomparison Variability



Industry (NUGEQ/IEEE/Sciencetech) Guidance

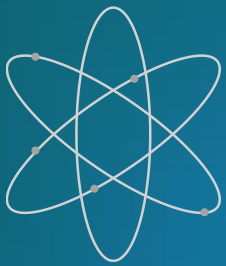
- Provides Guidance on:
 - Evaluation Methods
 - Adjusting the Minimum Reported Dose
 - Application or Use of Required Qualification Margin
 - Specific Considerations for Nuclear Utilities



Update on Individual / Corporate Responses

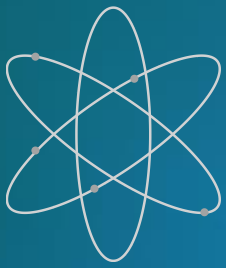
Several updated responses related to the Steris Part 21 have been issued in 2015, including:

- ITT Engineered Valves
- NTS
- Okonite
- ASCO
- Nutherm
- SOR



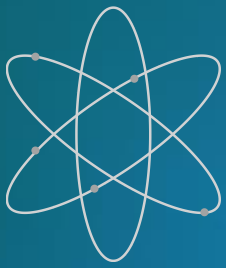
Update on Individual / Corporate Responses

ITT Engineered Valves issued their 2nd interim report on 4/7/15 (NRC Event # 50285) involving the impact of the Steris Part 21 on the M1 EPDM Diaphragms may have as much as 10% unaccounted for uncertainty in the specified radiation requirement.



Update on Individual / Corporate Responses

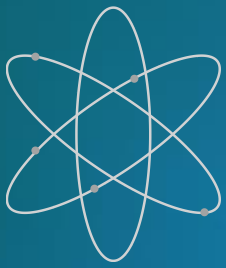
- This interim report reiterates ITT's approach will be to provide appropriately qualified diaphragms by qualifying a new M1 EPDM compound due to obsolescence of the original EPDM compound that had been in place since 2008
- The new M1 diaphragms have been qualified to radiation levels that have been increased by 10% to account for the



Update on Individual / Corporate Responses

NTS issued an interim update on May 21, 2015 regarding the Potential Part 21 issue related to irradiations performed by Steris.

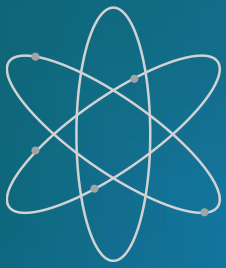
- This update was in response to the Steris Position Paper that was issued on April 27, 2015
- Update indicated that NTS was proceeding with evaluating whether the actual dose envelops customer-specified requirements.



Update on Individual / Corporate Responses

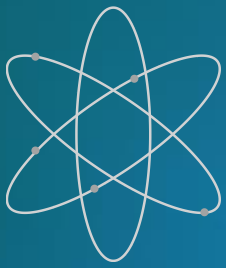
Okonite issued an update on July 30, 2015 that indicated:

- The Steris Part 21 had potential implications for only two (2) qualification test programs (Reports 526 and 527)
- Okonite reiterated their previous conclusion that continued use of potentially impacted cables did not represent a substantial safety hazard



Update on Individual / Corporate Responses

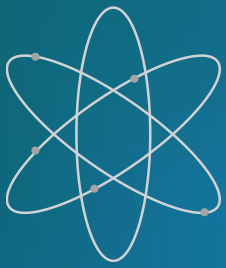
- Based on additional analysis that was performed since their earlier initial notification the minimum reported dose for Okonite Reports 526 and 527 continue to satisfy the required minimum dose of 50MRads



Update on Individual / Corporate Responses

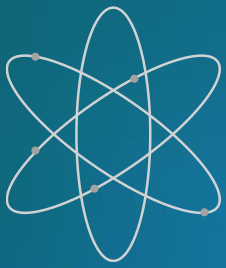
ASCO issued an interim update on 12/16/2014 (NRC Event # 50681) and a subsequent update on 8/19/2005 which indicated:

- They have completed their review and calculated the minimum radiation exposure applied during the qualification of ASCO nuclear products at Steris



Update on Individual / Corporate Responses

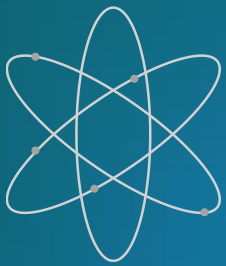
- The minimum dose is less than what was originally reported in the qualification test reports for the following products:
 - NP Series SOVs
 - NS Series SOVs
 - NT Series SOVs
 - Scram Solenoid Pilot Valves
 - Temperature/Pressure Switches



Update on Individual / Corporate Responses

NuTherm Issued an Updated Response on 8/31/2015 (NRC Event # 50359)

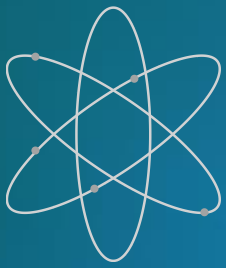
- Identified one customer (SOR) as potentially being impacted
- Minimum irradiation dose meets customer's TID requirement, but did not meet TID requirement including 10% IEEE 323 qualification margin



Update on Individual / Corporate Responses

In response to Notification by NUTHERM, SOR issued an interim report on 9/2/15 (NRC Event # 51363) and a subsequent updated response on 9/21/15 which indicated:

- Issue Affects SOR 141 Series switches
- Qualification Report SOR-12043R has been updated (Revision 1) to reduce the qualification level from 35MRad to 33.8MRad



Steris Part 21 Related Activities

Questions or Comments?

- Any other Steris P21 related issues or notifications?