ITT ENGINEERED VALVES

33 CENTERVILLE ROAD
LANCASTER, PA 17603

Written Notification to the NRC of
10 CFR 21 Event 50285, reported by ITT 07/18/14
Concerning M1 diaphragms, Customer Testing

REPORT BY: Stephen T. Donohue 8/14/14

S. T. DONOHUE, SR. PRINCIPAL ENGINEER & RESPONSIBLE OFFICER DATE

IE20
NRO

1.0 INTRODUCTION

ITT Engineered Valves, LLC (ITT) has identified a potential defect with items considered Basic Components for Nuclear industry service. The items in question are M1 EPDM Diaphragms, which were sold as parts incorporated into valve assemblies or as individual spare parts since the initial release of these products in 2008, and also certain items (ball valve seats, diaphragms) that were qualified via special projects for specific customer applications. The "potential defect" applies to affected items that are intended for Nuclear radiation applications. The problem came to light as a result of an NRC investigation of Steris Isomedix Services (Steris). The NRC found that Steris did not properly account for variances in radiation that could occur depending on where samples were placed in Steris' irradiation chamber. Based on this finding and also ITT's subsequent evaluation of the matter, ITT has concluded that there may be as much as 3.3 to 10% unaccounted uncertainty in the specified radiation dosage called for by ITT during Steris' treatment of samples that were used to qualify ITT's products. Any such affected component that was sold or is being sold will need to be evaluated as to the effect of the uncertainty in the test results on the actual component in service. As this evaluation can only be made by the customer after reviewing the usage and application of the affected item, this defect is best characterized as 'potential' by ITT.

Initial notification of the potential defect was made to the NRC via fax on 7/18/14. The potential defect report was designated Event 50285 shortly thereafter. Per 10 CFR part 21 requirements, this report is the 30-day Written Notification to support the initial fax notification.

2.0 NOTIFICATION OF NONCONFORMANCE and other Steris Correspondence

In June of 2014, ITT received a letter from Steris (Appendix A) which was a notification of a Non Conformance (reference NRC report 99901445, see Appendix B) concerning radiation services which were provided to ITT. The letter advised ITT that there should have been an allowance made for uncertainty in the amount of radiation applied to our Nuclear product line samples depending on where the samples were placed in Steris' irradiation chamber. Consequently, the radiation dosage that was applied could not have properly accounted for the variation when considering the minimum radiation value specified by ITT's

purchase orders. As a result, ITT's qualification testing may have been conducted on samples that received 3.3 to 5.1 percent less (or more) than the minimum target dosage specified.

ITT contacted Steris to inquire whether the variability due to location in the chamber could be better defined. Steris was able to provide a statement which indicated that the maximum dosage variability for ITT was 3.3 - 3.5%, based on the fact that ITT products were always irradiated on Steris's Turntable A (see Appendix C).

A second clarification letter from Steris was received at ITT on August 8, 2014 (see Appendix D). Among other things, the second letter stated that the methods and techniques analyzed by the Nonconformance report pertained to Steris services provided from 2003 onward. Prior to 2003, Steris "cannot recreate the process conditions that were effective prior to 2003", implying that while similar variability may have occurred prior to 2003, Steris cannot advise to what extent.

3.0 INITIAL EVALUATION

On July 15, 2014 ITT's responsible officer convened a meeting of an Evaluation Group in order to review the Steris notification that had been received in June. The Evaluation Group consisted of the Nuclear Product Engineer, Manager of Nuclear Quality Assurance and Product Engineering Manager. From subsequent conversations over the next two days it was decided by the Evaluation Group that there was a possibility that a 10 CFR part 21 event could occur in customer applications due to the increased variation in the test methodology. The initial notification of a potential failure to comply was faxed to the NRC later that week, July 18, 2014.

As regards pre-2003 testing: ITT has been using Steris or its former version, Isomedix, for irradiation services dating back to the 1980's. As far as current products are concerned, pre-2003 qualification would come into play only for ITT's PEEK ball valve seats. Steris/Isomedix was indeed used prior to 2003 to qualify an earlier version of the M1 diaphragm, but that EPDM formulation was phased out, and the last diaphragm from this formulation was sold in 2008. Any such M1 diaphragms still in the field are well beyond their effective service life as defined by ITT.

ITT's PEEK ball valve seats were qualified using irradiated samples in 1988. ITT no longer possesses the details of the radiation dosages that were applied at that time. It is not possible to determine from our records whether the specified radiation dosage was accurate, or whether uncertainty occurred, or even who performed the service (although from all accounts it is believed that ITT has used Steris/Isomedix exclusively over the years); ITT only has summary reports that show what nominal value was applied. At the time of that product's qualification, ITT believed it was using the best test methodology and Nuclear-approved supplier that was available at that time. There have been no issues in performance with these seats since 1988. Lacking any specific evidence of any problem with the irradiation of qualification samples, ITT does not intend to include the PEEK ball valve seats as part of the scope of this 10 CFR Part 21 potential defect.

4.0 POTENTIAL IMPACT OF NONCONFORMANCE

M1 Diaphragms

When the current EPDM M1 diaphragm compound was initially qualified during 2007 – 2008, samples of each size were manufactured and delivered to ITT's R&D lab. After conducting the standard qualification testing of unradiated diaphragms, samples were prepared for life cycle testing of irradiated samples. This consisted of sending samples to Steris for irradiation, retrieving and then testing the sample diaphragms at specific temperatures and pressures based on past customer requirements, ASME N31 Code Cases, MSS SP-100 testing, etc.

ITT used Steris to apply radiation to these diaphragm samples. Due to issues with variability in applied radiation levels as discovered by the NRC during the inspection at Steris conducted in May, 2014 (NRC inspection report #99901445), and as a result of ITT's review of that inspection report, ITT has determined that the minimum level of radiation specified by ITT for the M1 qualification project may not have been applied to the samples per ITT's stated minimum requirements. Due to this uncertainty in applied radiation level, it is possible that the actual dosage applied was as much as 10% lower than the minimum specified by ITT.

This 10% uncertainty was an accumulation of two issues:

1. Location in irradiation chamber – As a result of the NRC Notice of Nonconformance, Steris notified ITT in its June 18, 2014 letter that there was more uncertainty associated with the actual radiation dosage applied

than was previously considered. The variation that now had to be accounted for was due to irregularities in measurement and sample placement in the radiation chamber. Followup correspondence from Steris indicated that ITT should have accounted for an additional +/- 3.5% uncertainty when specifying minimum radiation levels for M1 samples.

2. Dosimeter uncertainty - In ITT's purchase orders during the M1 qualification project in 2008, it was specified to Steris that certain levels of radiation should be applied to our samples, with a specified minimum value required. A statement that Steris' dosimeters carried a +/- 6.5% uncertainty was listed in the quotation paperwork, and also included on the certificate of conformance document. Since ITT specified that a minimum level be applied, it was not at all clear that by referencing the 6.5% uncertainty Steris was indicating that ITT had to then account for the dosimeter uncertainty by adjusting our targeted "minimum" desired radiation value accordingly. It was not until reviewing the NRC Nonconformance report 99901445 that it was recognized that ITT's 2008 qualification should have accounted for a 6.5% dosimeter uncertainty.

Customer Projects

Since 2008 there have been several projects that were initiated by ITT's customers that required irradiation application services from Steris. This would occur when ITT products needed to meet a specific customer condition that was not previously validated, so a special test project would be necessary to qualify ITT products for that condition. These projects had results that could have been affected by both the off-carrier location uncertainty and the dosimeter variation uncertainty. ITT is able to locate these customers and inform them of the event, see below.

5.0 AFFECTED CUSTOMERS

There are two subsets of customers affected by the Steris omission: All M1 diaphragm users since 2008, and certain ITT customers who paid for special testing to be conducted on diaphragms and ball valve seats. ITT maintains the ability to identify and contact all customers who have purchased M1 diaphragms.

Customers who purchased services from ITT in order to conduct testing and qualification of irradiated diaphragms since 2008 are as follows:

1. Duke Energy Corporation (Oconee), PO 00151156

2. Exelon Generation Company (Braidwood and Byron), PO 636683-01
3. Luminant Generation Company (Comanche Peak), PO 0731098 6D2

One of these projects concerned ball valve seats and two were for M1 diaphragms. There was a fourth customer who required tests on irradiated samples from Steris, but this 10 CFR Part 21 event has no relevance because the actual dosage applied, which was the absolute minimum that Steris was capable of applying, was so far above the customer's required minimum dosage that it far exceeded any necessary uncertainty allowance.

All three customers listed above have already been contacted by ITT and are being advised as appropriate.

6.0 PLAN OF ACTION

As regards the three customers who purchased services from ITT, each has already been contacted regarding the 10 CFR Part 21 situation with those particular products. The decision to re-qualify or perform the tests at a higher dosage will be made by each customer with ITT's assistance.

All M1 diaphragm users were contacted with a followup letter from ITT in late July, see Appendix E. The letter informs each customer of the basic details of the 10 CFR Part 21 event, specifies that the M1 diaphragm radiation uncertainty is 10%, and lists the affected M1 diaphragm part numbers. Numerous customer correspondences calling for clarification and requests for further information have been received as of this writing. Customers are proceeding with evaluations of M1 diaphragms in service, and determining whether a 10 CFR Part 21 situation applies.

ITT has already commenced with a new M1 qualification effort using irradiated samples that have been properly treated, with the minimum applied radiation dosage accounting for the recently discovered uncertainty. This testing will take several months to complete all sizes and all conditions (in order to satisfy all ITT customers equally). Full qualification of the first of these sizes is expected to be achieved by December 2014, with other sizes attaining qualification through 1st quarter 2015.

As for ongoing M1 sales, ITT intends to continue to provide M1 diaphragms to our customers with a letter alerting them to the situation, and explaining that the

current M1 diaphragms are subject to consideration of potential 10 CFR Part 21 event #50285. See Appendix F.

Any ongoing projects that require radiation services from Steris, and all M1 diaphragm qualification testing is being performed on samples that were irradiated at an appropriate minimum radiation dosage, taking into account all known variances accordingly.

7.0 DEFINITION OF DEFECT (or 'Failure to Comply')

The nature of the potential defect in this case is best described by 10 CFR section 21.3 *Defect* definition as "an error, omission or other circumstance in a design certification or standard design approval that.... could create a substantial safety hazard." The qualification of ITT products is a form of design certification/approval. The variability discovered via the Steris Nonconformance was not accounted for in recent ITT product qualifications, so instead of a full guaranteed minimum dosage, the test samples could have potentially received as much as 3.3 to 10% less. Therefore, it can be said that the radiation test samples used to justify the suitability of ITT products for design conditions that include radiation resistance requirements were not completely radiated to the required level (that is, per 10 CFR Part 21 this is not really a defect but a 'failure to comply').

STERIS
Isomedix Services

June 18, 2014

Re: Isomedix Service Whippany NJ NRC Inspection Findings

Dear Valued Customer:

As a valued Customer of STERIS Isomedix Services' gamma processing services, we want to make you aware of the results of an inspection recently conducted by the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR) Part 50, Appendix B with respect to equipment qualification testing of nuclear safety-related components processed in off-carrier positions at the Whippany, New Jersey facility. The NRC issued a Notice of Nonconformance stating that the measuring and testing equipment used to determine the applied radiation dose reported to you on the Isomedix Certificate of Processing provided with each run did not account for all the uncertainties involved (i.e., density of unrelated products in carriers, off-carrier location within the irradiator and Cobalt-60 source decay) and therefore the actual radiation dose applied to components could be less than requested and as reported on the Certificate of Processing.

STERIS Isomedix Services has completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. This evaluation determined that there may have been variability in readings as great as ± 5.1% of the dose delivered for components processed in off-carrier positions, depending on the location within the irradiator where the component was processed. As a result, the actual dose delivered to your component may have differed up to ± 5.1% from the value reported on the Certificate of Processing. This variability is in addition to the standard measurement uncertainty of the Red Perspex 4034 dosimetry system (± 6.5%) noted in all purchase quotations. Because Isomedix is unable to evaluate the affect this variation may have on the components processed, we are notifying you under the requirements of 10 CFR Part 21.

Isomedix strives to provide processing services in strict compliance with Customer specifications and Isomedix quality processes and procedures. We apologize for any inconvenience that this unique situation may have caused. If you have questions or require additional information, please contact me at (973) 887-2754 or Scott_Comstock@STERIS.com.

Very Truly Yours,

Scott Comstock
Plant Manager
STERIS Isomedix Services
9 Apollo Drive
Whippany, NJ 07981

May 15, 2014

Ms. Yais Geissler, QC/RC Manager
Steros Isomedix
9 Apollo Drive
Whippany, NJ 07981

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 99901445/2014-201 AND NOTICE OF NONCONFORMANCE

Dear Ms. Geissler:

From April 1 to April 3, 2014, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Steris Isomedix (Steris) facility in Whippany, NJ. The purpose of the limited-scope inspection was to assess Steris's compliance with the provisions of selected portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance."

This inspection specifically evaluated Steris's control over radiation testing services associated with the equipment qualification testing of nuclear safety-related components. The enclosed report presents the results of the inspection. This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

The NRC inspectors found that the implementation of your QA program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspection team determined that Steris was not fully implementing its quality assurance program in the areas of Test Control and Control of Measuring and Test Equipment consistent with regulatory and contractual requirements, and applicable procedures. The specific findings and references to the pertinent requirements are identified in the enclosures to this letter.

Please provide a written statement or explanation within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, (if applicable), should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that

you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

/RA/

Richard A. Rasmussen, Chief
Electrical Vendor Inspection Branch
Division of Construction Inspection
and Operational Programs
Office of New Reactors

Docket No.: 99901445

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 99901445/2014-201 and Attachment

NOTICE OF NONCONFORMANCE

Steris Isomedix
9 Apollo Drive
Whippany, NJ 07981

Docket No. 99901445
Report No. 2014-201

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted of Steris Isomedix (hereafter referred to as Steris), at their facility in Whippany, NJ, from April 1-3, 2014, it appears that certain activities were not conducted in accordance with NRC requirements that were contractually imposed upon Steris by its customers or by NRC licensees.

A. Criterion XI, "Test Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied."

   Criterion XII, "Control of Measuring and Test Equipment," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

   Contrary to the above, as of April 3, 2014, Steris failed to ensure that the measuring and testing system (e.g. the dosimeters, associated procedures, and dosimetry reading equipment) used to determine the applied radiation dose to nuclear components was properly controlled and calibrated. Specifically, the "Technical Report on Analysis of Dosimetric Uncertainties for Routine Use of the Red 4034 Dosimetry System", dated June 28, 2013, created by Steris for assessing the accuracy of radiation dose measurements, failed to account for all uncertainties in the process as related to the irradiation of nuclear components. Steris failed to account for the density of other product placed into the irradiation chamber, source decay, and location within the irradiation chamber. As a consequence, the actual radiation dose applied to nuclear components could be less than what was requested by Steris's customers.

This issue has been identified as Nonconformance 99901145/2014-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Chief, Electrical Vendor Inspection Branch, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include for each noncompliance: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that

will be taken to avoid noncompliances; and (4) the date when your corrective action will be completed. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Dated this 15th day of May 2014.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND OPERATIONAL PROGRAMS
VENDOR INSPECTION REPORT

Docket No.:	99901445
Report No.:	99901445/2014-201
Vendor:	Steris Isomedix 9 Apollo Drive Whippany, NJ 07981
Vendor Contact:	Ms. Yais Geissler, QS/QC Manager, Yais.Geisller@Steris.com
Background:	Steris performs radiation aging services to the nuclear industry associated with the equipment qualification of nuclear safety-related components.
Inspection Dates:	April 1-3, 2014
Inspection Team Leader:	Jeffrey Jacobson, NRO/DCIP/EVIB
Inspectors:	Ronald LaVera, NRO/DSEA/RPAC Jack Tway, State of New Jersey, Observer
Approved by:	Richard A. Rasmussen, Chief Electrical Vendor Inspection Branch Division of Construction Inspection and Operational Programs Office of New Reactors

EXECUTIVE SUMMARY

Steris Isomedix
99901445/2014-201

The NRC inspection team performed an inspection at the Steris-Isomedix (Steris) facility in Whippany, New Jersey to review the processes being utilized by Steris to control radiation testing for nuclear safety-related components. The radiation testing is generally performed on component test specimens and simulates actual radiation doses that would be received by installed components in end of life conditions. Steris uses a batch processing irradiation system that consists of a Cobalt 60 source which is contained in a storage pool of water. Component irradiation is initiated by raising the source out of the shielding/storage pool of water. When the source is in the pool, the radiation levels inside the room are minimal, allowing personnel access to load and unload product. Once the product is loaded into the room, personnel are evacuated and the cobalt 60 source is raised for a predetermined period of time depending on the radiation dose level requirements of the particular product.

The focus of the inspection was on ensuring that the processes used at Steris were sufficient to ensure that nuclear components were being properly irradiated to customer requirements, specifically with regard to the radiation dose rate and total applied dose. The team toured the Steris facility, including the pre-irradiation storage area, the carrier preparation area, the post irradiation storage area, the control room, the dosimetry room and the irradiation cell. The team observed several in process nuclear components inside the radiation cell. Purchase orders for the nuclear components being processed during the inspection were reviewed by the team.

The team identified that unlike the process used to verify the radiation dose applied to the majority of commercial product, the process used at Steris to verify the radiation dose applied to nuclear components did not include continuous direct dosimetry measurements of radiation. Instead, a dose rate study was performed which was used to determine the dose rate in the area where the nuclear components were located, and then an assumed total dose was calculated based upon the dose rate and time within the irradiator. The team identified this method of calculating radiation dose failed to properly account for several factors that could impact the accuracy of the calculation. The process used at Steris failed to consider factors associated with in-carrier product density, source decay, and product placement within the irradiator into the overall dosimetry uncertainty analysis. As a consequence, the actual radiation dose applied to nuclear components could be less than what was requested by Steris's customers. This was identified by the team to be a Nonconformance of Criterion XI, "Test Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities," and Criterion XII, "Control of Measuring and Test Equipment." Nonconformance 99901445/2014-201-01.

The team also reviewed procedures and records, interviewed personnel, and inspected equipment utilized at Steris to read the dosimeters used to measure radiation dose and for establishing dosimeter calibration curves. No findings of significance were associated with this review.

Lastly, the team reviewed documentation associated with several recent nuclear orders for component irradiation services. While no findings of significance were identified, the team did identify as an observation that the Certificates of Conformance issued by Steris could be enhanced by clearly indicating the overall error range of the dosimetry process.

REPORT DETAILS

Steris-Isomedix performs radiation services for various industries. The large majority of product (medical devices, cosmetics, dried food product, etc.) irradiated at Steris is for sterilization/sanitization purposes. Steris also performs radiation aging services to the nuclear industry associated with the equipment qualification of nuclear safety-related components. Steris uses a batch processing irradiation system. The irradiator used at Steris consists of a Nordion model JS 8900 licensed for 4.6 Mega Curies of Cobalt 60. The cobalt source consists of two stainless steel racks of 12 modules containing 42 pencils each of Cobalt 60. In order to maintain uniform irradiation patterns and strength, source pencils are redistributed or replaced on an approximately annual basis. Component irradiation is initiated by raising the source rack assemblies out of the shielding/storage pool of water, which is contained inside a concrete lined room (the irradiator cell). When the source is in the pool, the radiation levels inside the irradiator cell are minimal, allowing personnel access to load and unload product. Once the product is loaded into the cell, personnel are evacuated and the cobalt 60 source is raised for a predetermined period of time depending on the radiation dose level requirements of the particular product.

The irradiator cell can be used to irradiate up to nine commercial product carriers, four off carrier commercial product dollies, three turn tables for commercial or component irradiation, one horizontal ceiling hung commercial product rack located above the water side of the source, and three vertical component ceiling irradiation racks located on the opposite side of the source.

1. Measurement of Applied Radiation Dose

   a. Inspection Scope

      The team reviewed the process used by Steris to measure the radiation dose applied to nuclear components. The focus of the inspection was on ensuring that the processes used at Steris were sufficient to ensure that nuclear components were being properly irradiated to customer requirements, specifically with regard to the radiation dose rate and total applied dose. The team toured the Steris facility, including the pre-irradiation storage area, the carrier preparation area, the post irradiation storage area, the control room, the dosimetry room, and the irradiation cell. The team observed several in process nuclear components inside the radiation cell. Purchase orders (POs) for the nuclear components being processed during the inspection were reviewed by the team. PO DL00043808, from Fluid Components International LLC to Steris was for the irraditation of three electrical enclosures. The PO invoked Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, ISO/ASTM 51276-02 and ISO/ASTM 51707-05 for determining dose and dose rate. The total dose requested was 233 Mega Rads at a dose rate not to exceed one Mega Rad per hour. PO 280034059, from Kenetrics, was for the irradiation of 50 coated steel panel samples. The total dose requested was 1100 Mega Rads at a dose rate not to exceed one Mega Rad per hour. The dose rate was later changed by the customer from a maximum to a minimum of 1 Mega Rad per hour.

      The team also reviewed documentation associated with nuclear components that had been recently processed by Steris. PO 4500635691, from Fauske and Associates, was for the irradiation of Eaton starter coils. The requested dose was 10 megarads and the applied dose rate was not to exceed 0.5 megarads per hour. This material had been processed at Steris during the period of March 29-31, 2014.

b. Findings and Observations

The team identified that the majority of the commercial product irradiation at Steris is performed on carrier tracks and the radiation is directly measured via dosimetry. Commercial product is loaded outside the irradiator cell on carriers that are hung from tracks on the warehouse ceiling and then manually pushed into the irradiator cell. Inside the irradiator cell the carriers are hung from tracks that surround the Cobalt 60 source. Some commercial product is also processed "off carrier" in predetermined locations within the cell. Once all product is loaded into the cell, personnel leave the room, the cobalt 60 source is remotely raised, and the product is irradiated. A typical cycle time (the time from when the source is raised to when it is lowered) is a few hours. Usually commercial product is only left in the irradiator cell for one cycle. Once irradiated, the products are removed from the cell, and the process is repeated with new products.

Unlike how most commercial product is irradiated, for the nuclear components, the processing is usually done "off carrier." For the nuclear components, the components are placed in various locations within the irradiator cell, outside of the path of the commercial products. Since the large majority of product processed at Steris is commercial, the process is optimized for the efficient processing of that product and any nuclear components are processed in locations within the irradiator that do not interfere with the commercial product processing. In addition, the nuclear components often require larger radiation doses which are applied at lower dose rates that require multiple cycles.

The team reviewed the Steris procedures governing the exposure of components, PROC-00829 and PROC-00830. With regard to measuring the total accumulated radiation dose, PROC-00830 notes that commercial dosimetry systems do not exist for reliably measuring the accumulated dose above five Mega Rads, and that since most nuclear components require irradiation above five Mega Rads, that special techniques are required. PROC-00830 describes two general methods for determining total delivered dose, 1) cumulative dose measurements from a series of individual dosimeter measurements, or 2) through the use of dose rate and exposure duration. The Whippany facility uses the second method to determine component doses.

In this method, a dose study is performed by placing dosimeters near the components to be irradiated or a dummy component to determine the initial exposure rate at the irradiation location. The exposure used for the dose study is determined during the course of one or more irradiation cycles of commercial products. Using the dosimeter readings obtained from this one cycle, a dose rate is calculated for the given location, and then that dose rate is used to calculate the total time the component is required to stay in the irradiator to achieve the required dose based upon an extrapolation of the measured dose rate. Consequently, for the nuclear components, direct radiation measurements are not taken continuously for the entire time the components are being irradiated.

The team reviewed in detail the methodology used by Steris to perform the extrapolation and identified a number of concerns associated with this extrapolation process. First, the team determined that conditions inside the irradiator cell can change from cycle to cycle, and such changes can impact the dose rate at a given location. For example, the team determined that the dose rate at the locations inside the cell that are typically used for nuclear components can be affected by other product that is put inside the cell.

During the inspection, the team observed nuclear components that were suspended from the cell ceiling at a location that could be partially shielded by the in-carrier product. The degree of shielding provided by the in-carrier product could vary over time, and from cycle to cycle depending on the density of the product contained in the carriers. Thus, the amount of shielding provided by the in-carrier product during the dose rate study could vary from that provided during subsequent irradiation cycles. A rough approximation of the effect of difference in shielding between minimally dense in-carrier product and dense in-carrier product was determined during the inspection to be approximately 10% for the location in question. This value was obtained during the inspection by placing dosimeters near several nuclear components that were being irradiated, placing low density product in the carriers, measuring the dose received, calculating a dose, and then repeating the process with high density product in the carriers. This factor was not previously considered in the Steris uncertainty analysis for the dosimetry system contained in "Technical Report on Analysis of Dosimetric Uncertainties for Routine Use of the Red 4034 Dosimetry System," dated June 28, 2013.

Secondly, the team identified that PROC-00830 does not require decay correction of the source during exposure of components and does not require a dose rate study at the end of the exposure. Steris personnel indicated that the source exposure rate decreases by approximately 1% per month. The team noted that at least one of the components undergoing irradiation required a radiation exposure duration of several months duration. As such, dose rates towards the end of the irradiation process for nuclear components could be significantly less than calculated.

Lastly, the team identified that Steris preforms calibration studies and generates specific calibration curves for the Harwell dosimeters used to measure dose. The calibration curves are generated for predetermined zones within the irradiation cell. A large part of the calibration study involves the placement of alternate dosimeters alongside the Harwell dosimeters in various locations within the predetermined zones. The intercomparison studies are performed at three month intervals. During the inspection, the team questioned the basis for including the ceiling rack location where the nuclear components were located within Zone A, which mainly encompasses areas on the floor surrounding the carriers. The team determined that no intercomparison studies were performed at this ceiling location, thus calling into question the appropriateness of using a Zone A calibration curve for this location.

The team reviewed Steris Procedure PROC-00045, which defines how zones are determined at Steris. The procedure states that statistically equivalent dose zones are defined as dose values that fall within one-half of the dosimetry system uncertainty reported at the 95% confidence level. Steris also produced an internal memo during the inspection, dated December 12, 2006, that discussed the appropriateness of combining the ceiling and Zone A areas. The memo concluded that it was acceptable to combine the zones until the next source loading. Also, the memo stated that the measured dose rates in the two areas differed by approximately 4.3%, which is greater than the one-half uncertainty values stated for the dosimetry system 6.5%. Consequently, the combination of zones did not appear to be appropriate. Also, the memo only allowed the combination of zones until the next source loading. Since the date of the memo, several source loadings have occurred but a reanalysis was not performed. During the inspection, Steris was not able to verify the appropriateness of using the Zone A curve for components being irradiated that were hung from the ceiling. This could potentially add an additional error term to the uncertainty analysis.

In summary, the team identified that Steris had failed to properly account for issues associated with in-carrier product density, source decay, and product placement within the irradiator into its overall error analysis. As a consequence, the actual radiation dose applied to nuclear components could be less than what was requested by Steris's customers. This was identified by the team as a nonconformance of Criterion XI, "Test Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and Criterion XII, "Control of Measuring and Test Equipment." (Nonconformance 99901445/2014-201-01).

c. Conclusions

The team identified that Steris had failed to properly account for issues associated with in-carrier product density, source decay, and product placement within the irradiator into its overall error analysis. As a consequence, the actual radiation dose applied to nuclear components could be less than what was requested by Steris's customers. This was identified by team to be a Nonconformance of Criterion XI, "Test Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and Criterion XII, "Control of Measuring and Test Equipment."(Nonconformance 99901445/2014-201-01).

2. Calibration of Dosimetry System

a. Scope

The team also reviewed procedures and records, interviewed personnel, and inspected equipment utilized at Steris to read the dosimeters used to measure radiation dose and for establishing dosimeter calibration curves.

The team determined that Steris uses a Harwell Red Perspex polymethylmethacrylate dosimeter, whose material changes opacity when exposed to gamma radiation. The change in opacity is measured at Steris with a Beckman model DU-640 Spectrophotometer. Since dosimeter thickness also effects opacity, the dosimeter thickness is measured with a Metralight MX Series laser micrometer. The team verified that both devices were currently calibrated and that periodic performance checks had been satisfactorily completed within the prescribed time frames. Steris staff stated that only one batch of dosimeters is used at a time. The Whippany facility is currently using Red 4034 batch MW dosimeters. The team confirmed that the Steris batch acceptance testing was documented on PROC-00077, Form 1, dated January 15, 2014.

Steris personnel stated that the calibration of the Whippany dosimetry system was accomplished by intercomparison exposures performed with a different, Alanine based type of dosimeter, provided by the Steris Chicago facility in accordance with provisions of PROC-00038. Temperature strips are used to monitor temperature near the dosimeter during irradiations. Any dosimeter coefficient of variation that exceeds 3% is evaluated using the outlier evaluation process. The Chicago office then performs intercomparisons with dosimeters that were irradiated to known values by the National Institute of Standards and Technology (NIST).

The team identified that the opacity of the perspex material is dependent on pre-irradiation, irradiation, and post irradiation temperature effects. During the facility tour, the team observed that the post irradiation dosimeter reading station was monitored with a currently calibrated temperature strip chart recorder. Steris personnel stated that dosimeter pre-irradiation storage temperature is maintained at 15-25 °C, and is monitored with a calibrated strip chart recorder. Steris personnel also stated that temperature strips were used to assess product irradiation temperature during irradiations, as described in PROC-00038, such as during the quarterly intercomparison studies, following source redistribution, or for recalibration of an existing batch.

b. Findings and Observations

No findings of significance were identified associated with this review.

c. Conclusions

The team reviewed procedures and records, interviewed personnel, and inspected equipment utilized at Steris to read the dosimeters used to measure radiation dose. The team also reviewed records and procedures used at Steris to establish dosimeter calibration curves. No findings of significance were identified.

3. Review of Previously Supplied Certificates of Conformance

a. Scope

The team reviewed P.O. 4500635691, from Fauske and Associates, for the irradiation of several Eaton starter coils. The PO required the application of a total dose of 10 Mega Rads at a dose rate not to exceed 0.5 Mega Rads per hour. This work had been recently completed at the time of the inspection.

b. Findings and Observations

The team reviewed Steris documentation that indicated that the starter coils were processed at Steris from March 29-31, 2014. The team identified that the Steris Certificate of Conformance (C of C) provided to Fauske indicated that the specimens were irradiated to a minimum of 10.003 Mega Rads, but the C of C did not address the 6.5% uncertainty number which Steris stated applies to all components. As such, the team was concerned that Steris customers may not be accounting for this uncertainty when specifying the requested radiation dose. In this particular case, it was not clear from review of the paperwork whether the 6.5% was factored into the total requested dose. The team identified as an observation that the C of Cs provided by Steris could be enhanced by clearly indicating the 6.5% error range in the stated dose applied.

No findings of significance were identified associated with this review.

c. Conclusions

The team reviewed purchase orders to Steris and related documentation for recent nuclear components sent to Steris for irradiation services. No findings of significance were identified but the team did identify that Steris could enhance their C of Cs by clearly indicating the applicable error range in the stated dose applied.

4. Entrance and Exit Meetings

On April 1, 2014, the inspectors presented the inspection scope during an entrance meeting with Mr. Scott Comstock, Steris Whippany Plant Manager and other Steris personnel. On April 3, 2014, the inspectors presented the inspection results during an exit meeting with Mr. Bruce Dewart, Steris Vice President of Operations, and other Steris personnel.

ATTACHMENT

1. PERSONS CONTACTED AND NRC STAFF INVOLVED

Name	Title	Affiliation	Entrance	Exit	Interviewed
Yais Geissler	QC/RC Manager	Steris-Whippany	x	x	x
Chris Van Koppen	Warehouse Manager	Steris (Chester)	x	x	x
Mark Thomas (phone only)	Director of Plant Operations East	Steris (Corporate)		x	
Scott Comstock	Plant Manager	Steris-Whippany	x	x	x
Michael Ezzo (phone only)	Zone Director, Quality Systems	Steris (Corporate)		x	
Bruce Dewart (phone only)	Vice President Operations	Steris (Corporate)		x	
David Snyder	QS/RC Regional Manager	Steris (Chester)	X	X	x
Ronald LaVera	Inspector	NRC	X	X	x
Jeffrey Jacobson	Inspection Team Leader	NRC	X	X	x
Jack Tway	Observer	State of New Jersey	X		

2. INSPECTION PROCEDURES USED:

IP 43002, "Routine Inspections of Nuclear Vendors"
IP 43004, "Inspection of Commercial-Grade Dedication Programs"
IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance"

3. ITEMS OPENED, CLOSED, AND DISCUSSED:

Item Number	Status	Type	Description
99901445/2014-201-01	OPEN	NON	Criterion XII and XII

4. DOCUMENTS REVIEWED:

Documents Reviewed:

- Beckman-Coulter DU Series 600 Spectrophotometer Operational Qualification 3 # 718208AD November 2009, for Model DU 640 serial number 4324039
- Beckman DU Series 600 Spectrophotometer Operating Instructions
- Steris Isomedix Services Daily/Weekly Verification Beckman DU-640 S/N 4324039
- "Technical Report on Analysis of Dosimetric Uncertainties for Routine Use of the Red 4034 Dosimetry System," dated June 28, 2013
- PROC-01067 Form 1 "Transit Dose Setup & Summary Report," dated 19 October 2012
- PROC-00010 Revision 7 "Equipment Operation", Effective Date 31 January 2013

- PROC-00035 Revision 6 "Off Carrier Processing" Effective Date 19 October 2012
- PROC-00036 Revision 12 "Routine Use - Red 4034 Perspex Dosimetry System," Effective date 2 March 2014
- PROC-00038 Revision 8 "Red 4034 On-Site Intercomparison - Facility Responsibilities," Effective Date 18 December 2013.
- PROC-00040 Revision 8 "Spectrophotometer Calibration and Performance Verification," Effective Date 16 October 2012
- PROC-00829 Revision 3 "Whippany Reactor Component QA Program," Effective Date 28 January 2013
- PROC-00830 Revision 7 "Whippany Reactor Component Processing," Effective Date 14 January 2014
- PROC-01067 Revision 1 "Irradiator Transit Dose Assessment," Effective Date 30 May 2012
- Harwell Dosimeters LTD CB/D CC4 Certificate of Conformance for Harwell Red 4034 Dosimeters, dated December 2008, Reference AR4715, for dosimeter batch 4034 MW, dispatched the week beginning 18 November 2013.
- IAEA-TECDOC-1070 1999 "Techniques for High Dose Dosimetry in Industry, Agriculture and Medicine - Proceedings of a Symposium Held in Vienna, 2-5 November 1998," article IAEA-SM-356/51 "The Influence of Ambient Temperature and Time on the Radiation Response of Harwell Red PMMA Dosimeters," B. Whittaker, M.F. Watts
- Journal of the ICRU Volume 8 No. 2 (2008) Report 80, Oxford University Press
- P.O. DL00043808, dated March 28, 2014, from Fluid Components International LLC to Steris
- P.O. 280034059 dated, 2/18/2014, from Kenetrics to Steris
- P.O. 4500635691, dated 3/26/2014, from Fauske and Associates to Steris

Attachment C - Data Summary for Off-Carrier Areas

The following is a summary of the results from 14-001WH, "Off-Carrier Dose Rate Variability Study" and how these results in addition to the effects of source decay and intercomparison adjustments can affect the determination of final dose for off-carrier processing at the Whippany, NJ facility. The adjustments for intercomparisons are only applicable to the ceiling zone and assume that the dosimeters used to establish a dose rate for the ceiling are read on Dolly A/Turntable A curves. The following represent the variability to 1σ or within one standard deviation of the mean dose rate. The summary will apply to each of the four identified off-carrier processing areas:

Turntable A

Variability from density variation: ±3.34%
Source Decay: -0.25% (per week)
Intercomparison Variability: N/A

Total Variation$_{week}$ = $\sqrt{0.0334^2 + 0.00250^2}$ = 3.3%
Total Variation$_{month}$ = $\sqrt{0.0334^2 + 0.01^2}$ = 3.5%

Dolly

Variability from density variation: ±3.42%
Source Decay: -0.25% (per week)
Intercomparison Variability: N/A

Total Variation$_{week}$ = $\sqrt{0.0342^2 + 0.00250^2}$ = 3.4%
Total Variation$_{month}$ = $\sqrt{0.0342^2 + 0.01^2}$ = 3.6%

Area B

Variability from density variation: ±3.66%
Source Decay: -0.25% (per week)
Intercomparison Variability: N/A

Total Variation$_{week}$ = $\sqrt{0.0366^2 + 0.00250^2}$ = 3.7%
Total Variation$_{month}$ = $\sqrt{0.0366^2 + 0.01^2}$ = 3.8%

Ceiling

Variability from density variation: ±2.78%
Source Decay: -0.25% (per week)
Intercomparison Variability: ±4.1%

Total Variation$_{week}$ = $\sqrt{0.0278^2 + 0.00250^2 + 0.041^2}$ = 5.0%
Total Variation$_{month}$ = $\sqrt{0.0278^2 + 0.01^2 + 0.041^2}$ = 5.1%

STERIS
Isomedix Services

DATE: June 23, 2014

TO: File

FROM: Scott Comstock, Plant Manager

SUBJECT: Clarification Memo - Nuclear Regulatory Commission (NRC)

We apologize for any confusion regarding the previously sent notification letter.

The Whippany facility was recently inspected by the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR) Part 50, Appendix B with respect to equipment qualification testing of nuclear safety-related components processed in off-carrier positions at the Whippany, New Jersey facility.

The NRC issued a Notice of Nonconformance stating that the measuring and testing equipment used to determine the applied radiation dose reported to you on the Isomedix Certificate of Processing provided with each run did not account for all the uncertainties involved (i.e., density of unrelated products in carriers, off-carrier location within the irradiator and Cobalt-60 source decay). STERIS Isomedix Services has completed an evaluation of the dose rate variability of items processed in off-carrier locations in the irradiator. Below is a short summary regarding the evaluation and variability:

1. This evaluation determined that there may have been variability in readings as great as ± 5.1% of the dose delivered for components processed in off-carrier positions, depending on the location within the irradiator where the component was processed.

2. As a result, the actual dose delivered to your component may have differed up to ± 5.1% from the value reported on the Certificate of Processing.

3. The worst case variability is based on density variation, source decay and intercomparison variability.
   a. The variability ranges from ± 3.5% to ± 5.1%

4. The study takes into consideration conditions that were effective since 2003.
   a. We cannot recreate the process conditions that were effective prior to 2003.

5. The dosimeter system uncertainty remains ± 6.5%.
   a. This value is mutually exclusive to the variability discussed 3a and they should not be combined.

Isomedix is unable to evaluate the affect this variation may have on the components processed, we notified customers under the requirements of 10 CFR Part 21. At your request, STERIS shall retrieve processing run records and determine the location your equipment was irradiated.

Scott Comstock, Plant Manager

Date 6/23/14

STERIS Isomedix Services
9 Apollo Drive, Whippany, NJ 07981

ITT

ENGINEERED FOR LIFE

ITT Engineered Valves, LLC

33 Centerville Road
Lancaster, PA 17603
tel 717.509.2200

July 24, 2014

Address of Affected Company

Subject: Potential Part 21 Issue concerning radiation of ITT samples

As the direct result of a Notice of Nonconformance filed by the NRC against STERIS Isomedix Service (Steris), ITT Engineered Valves, LLC (ITT) has deemed it necessary to file a potential 10 CFR part 21 incident, effective July 18, 2014 (event #50285). This filing concerns certain elastomeric parts provided by ITT as Basic Components that are incorporated into diaphragm valves for Nuclear service. Steris is a supplier of irradiation services; ITT uses Steris to apply radiation to diaphragm samples that are then used in qualification testing to verify the design of our M1 diaphragms. Due to issues with variability in applied radiation levels as discovered by the NRC during an inspection at Steris conducted in May, 2014 (NRC inspection report #99901445), and as a result of ITT's review of that inspection report, ITT has determined that the minimum level of radiation specified by ITT for past qualification projects may not have been applied to the samples per ITT's stated minimum requirements. Due to this uncertainty in applied radiation level, it is possible that the actual dosage applied was as much as 10% lower than the minimum specified by ITT. As diaphragms are considered Basic Components, ITT determined that a potential 10 CFR part 21 incident filing was warranted.

This 10% uncertainty was an accumulation of two issues:

1. Location in irradiation chamber – As a result of the NRC Notice of Nonconformance, Steris notified ITT on June 18, 2014 that there was more uncertainty associated with the actual radiation dosage applied than was previously considered. This variation that now had to be accounted for was due to irregularities in measurement and sample placement in the radiation chamber. Followup correspondence from Steris indicated that ITT should have accounted for an additional +/- 3.5% uncertainty when specifying minimum radiation levels.
2. Dosimeter uncertainty - In ITT's purchase orders during the M1 qualification project in 2009, it was specified to Steris that certain levels of radiation should be applied to our samples, with a specified minimum value required. A statement that Steris' dosimeters carried a +/- 6.5% uncertainty was indicated during the quote stage. Since ITT specified that a minimum level be applied, it was not at all clear that Steris was indicating that ITT had to then account for the dosimeter uncertainty by adjusting our targeted "minimum" desired radiation value accordingly. It was not until reviewing the NRC Nonconformance report that it was recognized that ITT's 2009 qualification should have accounted for a 6.5% uncertainty.

ITT is now approaching all customers with this information, as the aggregate 10% uncertainty affects all M1 diaphragm qualifications performed in the last 5 years, as well as other projects completed for

specific customers during that time. In particular this includes the M1 diaphragms that have been sold since 2009, part numbers 44681, 44680, 44673, 44674, 45557, 44676, 44677, 44678, 45558. There were also some limited test projects that were conducted for individual customers during that same time frame that could have been affected. These customers will be notified as well.

Any M1 diaphragms intended for use in radiated service are potentially affected by this event. ITT is at this point advising affected users of the potential difference in the reported dose. ITT will also be contacting all affected users to assist in determining if a defect as defined by 10 CFR Part 21 does exist. This notification is the first step in that process.

All ongoing and future product qualification testing that is to be carried out at Steris will account for the entire range of uncertainty. If I can answer any questions at this stage please do not hesitate to contact me per below.

Regards,

S. T. Donohue
stephen.donohue@itt.com
Senior Principal Engineer
ITT Engineered Valves, LLC
(717) 509-2417

ITT

ENGINEERED FOR LIFE

ITT Engineered Valves, LLC

33 Centerville Road
Lancaster, PA 17603
tel 717.509.2200

August 17, 2014

Subject: Potential 10 CFR Part 21 issue

ITT Engineered Valves, LLC is obligated to report that the elastomer M1 diaphragm component supplied per this order is subject to the considerations of Potential 10 CFR Part 21 event #50285.

The event concerns the radiation dosage uncertainty that was considered when the M1 diaphragm was qualified for customer applications that included irradiation. Sample diaphragms for M1 qualification were irradiated and tested, but the actual applied dose could be considered to be only 90% of the target qualification value.

The same approach is being taken with installed M1 diaphragms: ITT is providing this information so that customers may evaluate the usage of the M1 diaphragm in their system and evaluate whether a 10 CFR Part 21 situation applies. For further reference, see event #ML14210A053 concerning event 50285 at www.NRC.gov, or contact ITT Product Engineering per below.

Regards,

S. T. Donohue
stephen.donohue@itt.com
Senior Principal Engineer
ITT Engineered Valves, LLC
(717) 509-2417