THE OKONITE COMPANY

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July 30, 2015

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Steris Isomedix
NRC 10 CFR Part 50 Inspection and Notice of Nonconformance
Relating to Steris Isomedix Irradiation Processes
Steris Isomedix Part 21 Notice to Okonite dated June 18, 2014

To the Nuclear Regulatory Commission:

Under date of August 27, 2014, The Okonite Company, Inc. ("Okonite") wrote to the Nuclear Regulatory Commission ("NRC") advising it of Okonite's actions taken regarding the potential impact of the above referenced notices on Okonite's Qualification Test Reports 526 Rev. 2 and 527 Rev. 1. For your convenient reference, a copy of our August 27, 2014 letter is attached.

Steris services rendered to Okonite potentially impacted only Okonite's qualification of low and medium voltage cables under the High Energy Line Break Test ("HELB"), and low voltage cables under the Normal Operation test ("NO"). For the reasons expressed in its August 27, 2014 letter, Okonite concluded there and advised the NRC that the continued use by NRC licensees of the potentially impacted cables did not present either a substantial safety hazard, or in fact, any safety hazard.

Okonite further advised in its August 27, 2014 letter that it would nevertheless requalify its low and medium voltage IE cables under the HELB and NO tests. In the course of initiating the requalification process, Okonite learned of an industry initiative to further analyze the Steris irradiation processes as they related to the specific products and samples submitted by Steris customers, such as Okonite. As a concomitant of this initiative, Okonite contracted with Engineered Solutions Group ("ESG") of West Chester, Ohio, to analyze and assess Steris' actual irradiation processes and dosimetry data involving Okonite product samples.

The ESG conclusions resulting from their analysis and assessment are contained in their Report dated July 1, 2015, entitled "Evaluation of the Qualification Impact of Steris Part 21 Report on Dosimetry -- ESG Technical Evaluation ESG-TE-01132015-001 Rev 2." A copy of the ESG Report is attached to this letter.

Briefly and broadly summarized, the ESG Report concludes that the regulatory "requirement for Normal plus Accident plus 10% margin radiation delivery of 50 MRads gamma for Okonite Reports 526 and 527 * * * is validated * * *." See page 9 of the attached Report, under "Summary of Qualification Impact Steris Part 21 Notice."

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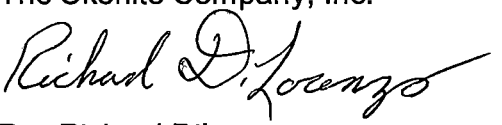
Therefore, based on the ESG conclusions, Okonite advises that requalification of its low and medium voltage IE cables under the HELB and NO tests is unnecessary. Further, based on the ESG conclusion, Okonite unequivocally reiterates the assertion and advice to the NRC in its August 27, 2014 letter that the continued use by NRC licensees of the potentially impacted cables does not present either a substantial safety hazard, or in fact, any safety hazard.

Very truly yours,
The Okonite Company, Inc.



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August 27, 2014

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Washington, DC 20555-0001

**Subject:** Notice Concerning Irradiations Performed by Steris Isomedix, Whippany, New Jersey

This is notice to the NRC of issues arising from a 10 CFR part 50 inspection by the NRC of the irradiation processes conducted by Steris Isomedix.

On or about June 20, 2014 The Okonite Company Inc. ("Okonite") received a Part 21 notice dated June 18, 2014 from Steris Isomedix Services ("Steris") advising that the NRC had issued a Notice of Nonconformance. The Steris Notice stated that Certificates of Processing previously issued to Okonite may have incorrectly reported the amount of radiation certain Okonite samples received in the course of Steris irradiation services.

Okonite requested revised Certificates of Processing from Steris. On August 6 and on August 22, 2014 Okonite received revised Component Irradiation Certificates. The information contained in the revised Certifications impacted Okonite's Qualification Test Reports 526 Rev 2 and 527 Rev 1. Steris provided Okonite irradiation services in preparation for Okonite conducting testing to qualify its 1E cables under the High Energy Line Break ("HELB") and Normal Operation tests.

Under IEEE 383-1974 Steris was to have irradiated all Okonite samples to a minimum 50 MRADs. The Steris letter of June 18, 2014, and the Revised Certificates of August 6, 2014 reveal that:

(1) The samples may indeed have been irradiated to 50 MRADs, but

(2) That if they were irradiated to less than 50 MRADs then at worst certain of the samples for the HELB and the normal operation tests were irradiated to a minimum 47.35 MRADs and others were irradiated to a range of from 48.35 to 48.38 MRADs.

Okonite evaluated the above facts to determine whether in its opinion the slightly less than specified irradiation, if it occurred, left the electric cables Okonite sold to licensees in such a condition that their continued use would create a substantial safety hazard. Okonite concluded that continued use of such cables does not create a substantial safety hazard.

These are the reasons supporting Okonite's conclusion:

The only samples impacted by the Steris irradiation were those used to qualify low and medium voltage cables under the high energy line break test, and low voltage cables under the normal operation test. Cables constructed of materials identical to those irradiated by Steris were submitted for LOCA testing. Steris had no involvement in the LOCA testing. The first step in LOCA testing is irradiating cables to 50 MRADs. Thus whether or not Steris irradiated Okonite's samples to 50 MRADs, cables constructed of the identical material irradiated by Steris were in fact irradiated to 50 MRADs by the entity that performed the LOCA testing.

As required by LOCA protocol, the cables were then heat aged and then subsequently irradiated to 150 MRADs. All the cables in question passed LOCA. Therefore, Okonite concluded that since its cables, which are known to have been definitely irradiated to 50 MRADs in the LOCA testing and then heat aged and further irradiated to 150 MRADs passed LOCA, they would similarly pass the high energy line break test had Steris irradiated the samples comprising those cables to the minimum 50 MRADs.

With respect to the normal Operation qualification test on the low voltage specimens, again the severity of the LOCA test performed by another entity where the identical materials were subjected to a full 200 MRADs of radiation, were thermally aged to simulate design life and subjected to the postulated LOCA conditions, all far exceed the conditioning required for the Normal Operation qualification. Based on passing this more severe test protocol it would seem that the now reported possibility of a 2.5 MRAD reduction in the prescribed 50 MRAD radiation dose would have no significant effect on the test results obtained in the Normal Operation qualification test.

Although Okonite has concluded that the continued use of its cables comprised of the same material Steris irradiated does not present a substantial (or for that matter any) safety hazard, nevertheless, out of an abundance of caution, Okonite is notifying the licensees of the information contained in this letter. Okonite will welcome and consider any comment it receives from any licensee and if necessary will communicate further with the NRC with respect to any such comment.

Okonite has also concluded that it should requalify its low and medium voltage 1E cables under the High Energy Line Break and Normal Operation tests. Okonite is currently pursuing this

avenue and is seeking completion by 60 days from and after August 6, 2014. If the requalification is not complete by then, Okonite will nevertheless report to the NRC the status at that time, and advise it of the anticipated completion date.

Very Truly Yours
The Okonite Company

Richard DiLorenzo

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# ENGINEERED SOLUTIONS GROUP

**8748 Rupp Farm Drive**
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**July 1, 2015**

Engineered Solutions Group

# Evaluation of the Qualification Impact of Steris Part 21 Report on Dosimetry

## ESG Technical Evaluation ESG-TE-01132015-001 Rev 2

Note: Revision 2 was performed to incorporate updated variance value of 6.02%, increased from the original 5.1%. This has a minor effect on the calculations, but not on the conclusion.

## 1. INTRODUCTION

During the environmental qualification test programs performed to provide qualification for Okonite FMR and Okoguard Cables in Okonite Reports 526, Rev. 2 (Reference 1) and 527, Rev. 1 (Reference 2), respectively, the cable specimens were irradiated as part of the pre-conditioning requirements for the cable specimens.

The preconditioning requirements are mandated by IEEE 323-1974/1983/2003 (Reference 3) for Environmental Qualification and also in IEEE 383-1974/2003 (Reference 4) and are intended to put the cable test specimens in their most vulnerable state (most degraded by postulated effects seen during service life) prior to exposure to the Design Basis Accident Testing. In the case of these cables, the Design Basis Accident was a High Energy Line Break (HELB) simulation outside of containment. For this testing, the postulated radiation level, expressed as a total of the Normal plus Accident plus 10% accident radiation margin was taken as 50 Megarads (or MRads) (5E7 rads) of gamma radiation.

The cable qualification testing, including sub-contractor services such as irradiation service, was conducted under the Quality Assurance controls of 10CFR50 Appendix B (Reference 5), NQA-1-1994 (Reference 6), and 10CFR21 (Reference 7). The irradiation was performed per Okonite Cable PO 905252 during April-May 2005. Pursuant to the requirements of 10CFR21, a 10CFR21 Notice was issued regarding the irradiation of the cable specimens (Reference 8). The Part 21 Notice indicates that the radiation facility, Steris in Whippany, NJ, failed to account for the potential dosimetry variance associated with the fact that the specimens were irradiated inside of the irradiation hot cell in a location described as "off carrier", meaning that the specimens were located against the outer walls of the hot cell and that various production inventory was circulated between the gamma source (Co-60) and the cable specimens. The

method for quantifying dosimeter uncertainty, ASTM 51707, Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing, was initially released in 1997. This standard was subsequently adopted and used by Steris from September 8, 2000 to present and provides a more realistic means of evaluating the accuracy of dosimetry. The use of this methodology reduced the error at the 2σ level from ±8% to ±6.5% for each dosimeter (Reference 9).

Off-carrier irradiation projects at Steris Whippany are conducted at the perimeter of the gamma hot cell and typically (as is the case for the Okonite cable irradiated per Okonite PO 905252) with a source-to-target orientation involving the presence of product carriers moving between the source and the items that are being irradiated. The significance of this is that the variances in the density of the carrier inventory at various times during the irradiation of the cable specimens may have resulted in uneven gamma radiation distribution to the cable specimens due to the "shading effect" of the production inventory. The production inventory refers to the typical production irradiation of various consumer goods for the purpose of sterilization. It should be noted also that the sterilization process requires that the highly penetrating gamma radiation penetrate the production inventory's full thickness to ensure that the sterilization of the products is uniform and thorough. Therefore, even though there is a small shielding effect due to the "shading" of the production inventory, the vast majority of the gamma radiation fully penetrates the inventory and would be available for irradiation of the cable specimens located behind the production inventory carriers.

The Part 21 Notice merely states that the shading effect of the production inventory carriers must be accounted for when calculating the dose received by the cable specimens. Therefore, this evaluation is written to describe the actual conditions of the irradiation process applied to the cables and the dosimetry applicability with respect to the actual effective dose of gamma radiation that was applied to the cables.

## 2. SPECIMEN DESCRIPTIONS

In order to facilitate the handling and to protect the cable specimens (ranging from 14-24 feet for each coiled cable specimen), Okonite packaged ten sets of specimens labelled per Table 1 (below):

**Table 1: Specimens**

| Box No. | Box Description | Specimen Description |
|---|---|---|
| 1 | Screen 12"x12"x2" | Normal Service FMR-N LV Power Cables (Ref. 1) |
| 2 | Screen 12"x12"x2" | Normal Service FMR-N LV Power Cables (Ref. 1) |
| 3 | Screen 12"x12"x2" | Specimens Not Used in This Set of Qualification Tests |
| 4 | Screen 12"x12"x2" | Specimens Not Used in This Set of Qualification Tests |
| 5 | Screen 12"x12"x2" | HELB Service FMR-N LV Power Cables (Ref. 1) |
| 6 | Screen 12"x12"x2" | HELB Service FMR-N LV Power Cables (Ref. 1) |
| 12 | Screen Package 24"x24" | HELB Service Okoguard Power Cables (Ref. 2) |
| 13 | Screen Package 24"x24" | HELB Service Okoguard Power Cables (Ref. 2) |
| 26 | Screen Package 24"x24" | Specimens Not Used in This Set of Qualification Tests |
| 27 | Screen Package 24"x24" | Specimens Not Used in This Set of Qualification Tests |

Reference 8 documents the entire package supplied under Okonite PO 905252 and desc irradiation. Only Specimen packages 1, 2, evaluation.

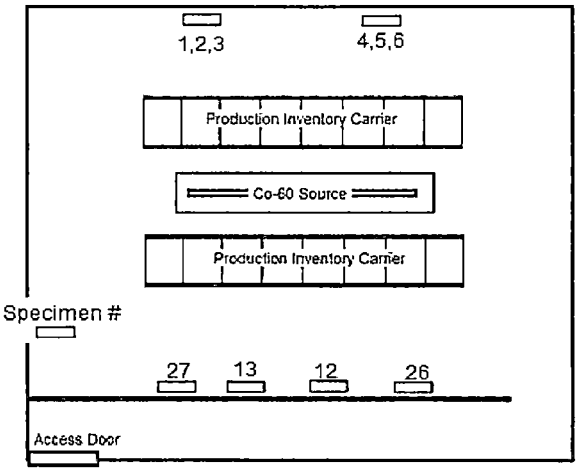


Figure 1: Steris Radiation Hot Cell

## 3. STERIS IRRADIATOR FACILITY

Figure 1 shows an overhead view of the radiation Hot Cell at Steris' Whippany, NJ facility. Also shown are the positions of the specimen boxes (all 10 boxes are shown) with respect to their relative position to the Co-60 gamma radiation source. The hot cell facility is constructed with very heavy shield walls to ensure that the gamma radiation does not escape and consists of a deep water-filled pool which houses the rack of Co-60 source "pencils". The source rack is raised from the pool and enters protected area to prevent inadvertent contact with the rack by items to be irradiated.

The Production Inventory Carriers provide a means of moving items to be irradiated (Steris' normal production process is to provide radiation sterilization for various medical

and food products) in /out/around the hot cell. The carriers are constructed of a light aluminum frame that confines the inventory to be irradiated. As discussed previously, the carrier frame design and the loading of the inventory within them are designed to ensure full radiation penetration of the inventory. A large fraction of the gamma radiation completely penetrates the carries/inventory and enters the "off-carrier" area around the perimeter (see Figure 1). This area is the typical location for the irradiation of special projects, such as nuclear qualification equipment samples.

## 4. DOSIMETRY

Each of the cable specimen boxes was instrumented with a Harwell Red Perspex 4034 dosimeter (supplied in controlled lots) as shown on Figure 2. The boxes were 12" x 12" x 2" for Boxes 1-6 and approximately 24" x 24" for Steel screen 12, 13, 26, and 27. The dosimetry strategy for this project was to establish box locations in the hot cell (see Figure 1) and whenever boxes were rotated (flipped 180° for uniform dose distribution) or replaced with other boxes the dosimetry applied during the initial run was applied to that location/box. This was specifically applicable to Boxes 1-6, which were irradiated two at a time (1 & 4 first, then 2 & 5, and finally 3 & 6). Steel screen 12, 13, 26, and 27 were rotated but were not changed out with other boxes.

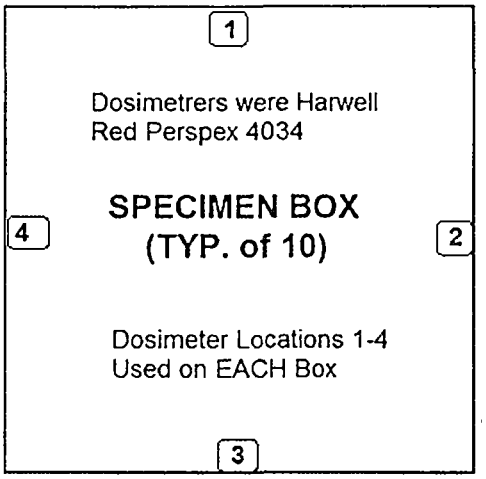


Figure 2: Dosimeter Placement

The Steris dosimetry process utilizes these dosimeters by placing them in representative locations (Figure 2) in order to capture the worst case location as far a minimum exposure and then exposing the dosimeter-laden specimens to a short irradiation cycle of 2-3 hours. Then, the source was dropped and the dosimeters removed and read. In this project, the "dosimetry run" was 2.31 hours. Since these dosimeters have a range limit of approximately 6 MRads (6E6 rads) it is not possible to gain meaningful data by leaving them in place for the entire 50 Mrad irradiation cycle. During the dosimetry run, the product carriers were in place (see Figure 1) so a GENERIC representation of the carrier effect (shading) was obtained. The variability of the shading of the carriers is the basis of the Part 21 notice. The removed dosimeters were read out upon removal in an adjacent area of the facility (very little time elapsed

between dosimeter removal and readout) in order to establish the dose rate for these specimen locations.

The dosimeters are removed and read using a Beckman DU-640C spectrophotometer. This device reads the optical absorbance of the irradiated sample dosimeter at a specific light frequency. The mechanism of the Perspex 4034 dosimeter is that the doped plastic changes its optical transmissibility with accumulated radiation damage (dose). Once each dosimeter has been read, its optical absorption change is adjusted for the measured dosimeter chip thickness (thickness affects optical properties such as absorption). The adjusted specific optical absorption is then correlated to an effective amount of radiation dose per Harwell's dosimetry tables. The specific indicated dose for each dosimeter is then divided by the irradiation time (in this case, 2.31 hours) and the dose/time provides dose rate for each dosimeter. Table 2 has been compiled based on the data provided by Steris (Reference 8).

**Table 2: Dosimetry Readings**

| Box No. – Dosimeter Number | Dose Run (MRads) | DR Exposure Time (Hours) | Dose Rate (MR/hr) | Total Irradiation Exposure (Hours) | Total Dose (MR) | AVG Box Radiation (MR) |
|---|---|---|---|---|---|---|
| 1,2,3-D1 | 1.66 | 2.31 | 0.72 | 70.46 | 50.63 | 53.84 |
| 1,2,3-D2 | 1.81 | 2.31 | 0.78 | 70.46 | 55.21 | |
| 1,2,3-D3 | 1.87 | 2.31 | 0.81 | 70.46 | 57.04 | |
| 1,2,3-D4 | 1.72 | 2.31 | 0.74 | 70.46 | 52.46 | |
| 4,5,6-D1 | 1.63 | 2.31 | 0.71 | 70.46 | 49.72 | 53.07 |
| 4,5,6-D2 | 1.74 | 2.31 | 0.75 | 70.46 | 53.07 | |
| 4,5,6-D3 | 1.82 | 2.31 | 0.79 | 70.46 | 55.51 | |
| 4,5,6-D4 | 1.77 | 2.31 | 0.77 | 70.46 | 53.99 | |
| 12-D1 | 1.84 | 2.31 | 0.80 | 62.5 | 49.78 | 56.55 |
| 12-D2 | 2.2 | 2.31 | 0.95 | 62.5 | 59.52 | |
| 12-D3 | 2.26 | 2.31 | 0.98 | 62.5 | 61.15 | |
| 12-D4 | 2.06 | 2.31 | 0.89 | 62.5 | 55.74 | |
| 13-D1 | 1.85 | 2.31 | 0.80 | 62.5 | 50.05 | 56.21 |
| 13-D2 | 2.02 | 2.31 | 0.87 | 62.5 | 54.65 | |
| 13-D3 | 2.29 | 2.31 | 0.99 | 62.5 | 61.96 | |
| 13-D4 | 2.15 | 2.31 | 0.93 | 62.5 | 58.17 | |

The variance factor (the amount of shading produced by the carrier assemblies on the specimens) was calculated at 6.02% by Steris based on their knowledge of the density/absorption characteristics of the production inventory within the carriers. There is an inherent inaccuracy associated with each individual Red Perspex 4034 dosimeter of +/-6.5% per the manufacturer, Harwell, using the ASTM 51707 methodology for

calculating dosimeter accuracy. However, this accuracy value represents a compilation and integration of numerous potential error sources, some of which do not apply to the procedure used by Steris for this particular effort (Reference 9). A list of potential error sources is given below:

- Single dosimeter error: Error is statistically associated with using only ONE dosimeter, whereas Steris used an array of dosimeters
- Lot/Batch Accuracy: Variation in lot/batch can be observed. However, dosimeter chips manufactured from a single lot of methacrylate material will all be chemically identical, including the optical doping component that responds to the radiation exposure. In this project there will be no batch-batch error, as the dosimeters used were all from Harwell dosimeter lot control batch HK.
- Shelf Life Effects: Although very minor, there is a potential for shelf life effects for dosimeters that remain in storage at elevated temperatures for long periods of time, coupled with their reaction to naturally occurring background radiation. Steris consumes large quantities of these dosimeters and their time in storage is very limited. This ensures that the dosimeters are fresh and accurate. Additionally, the dosimeter storage area is an air-conditioned area ensuring optimal storage temperatures.
- Relative Humidity (RH) effects: If the chips are exposed to very high levels of RH over time, they will lose accuracy. They are provided in nitrogen-blanketed sealed packets by Harwell and are attached to the specimens using tape applied to the outside of the foil packet. The dosimeters remain within their packets until they are removed individually, measured for exact thickness, and then read out in laboratory conditions. Therefore, no RH effects are possible, preserving optimal accuracy.
- Dosimeter thickness variation: Each dosimeter chip is measured with a calibrated high-accuracy micrometer to disclose its exact thickness to provide for thickness variation compensation. This ensures optimal accuracy.
- Dose Rate Effects: Dosimeters are designed to integrate exposure, but the RATE of exposure has some effect as well. Dose rates of 0.5 to 1.0 MRads/hour are in mid-range providing optimal dosimetry accuracy.
- Cumulative dose Effect: The dosimeters are most accurate at their mid-range of total dose. The usable dose limit for these dosimeters is up to 6 MRads. For this project, the dosimeters exposures during the dosimetry run were roughly 2 MRads, close to mid-scale for optimal accuracy.
- Radiation energy level effect: The dosimeters exhibit a small error associated with the range of the radiation energy level they are measuring. Very high and

very low energy radiation types impact the sensitivity of the dosimeter. However, the chart used by Steris per Harwell technical literature is specifically devised for Co-60 radiation, which has energy levels of 1.17 MeV and 1.33 MeV, which are the specific isotopic energy levels for which the Red Perspex was designed.

- Time elapsed between exposure and dosimeter readout: Best accuracy is achieved by reading dosimeters quickly after irradiation. The Steris methods read the dosimeters immediately after removal for optimal accuracy.
- Temperature of irradiation exposure: The dosimeters are useful and accurate over a considerable temperature range. The stated accuracy is applicable over this entire range. The room temperature conditions (approximately 70°F) represent the temperature under which the dosimeters are "calibrated", so measurements made at these approximate temperature conditions (as is done at Steris) provides optimal accuracy.
- Differential temperature between radiation exposure and readout: There is little or no temperature difference between the exposure and readout temperatures of these dosimeters at Steris. Both are indoor personnel areas. Minimal temperature differential ensures optimal accuracy.
- Radiation timer error is considered to be minimal in the present day Steris set up.
- Source decay for the source terms over the approximately 4 day irradiation period is also considered insignificant, based on the 4.5 year half-life of Co-60.
- Variance of the carrier assemblies of 6.02% is a significant error contributor and will be addressed.

The above factors provide significant mitigation with respect to the actual dosimeter error uncertainty for this project.

## 5. DISCUSSION

Based on the discussions above, particularly within the DOSIMETRY section, the two error sources that must be addressed are the +/- 6.5% error term (Dosimeter Error or DE) associated with each individual Red Perspex dosimeter and the +/- 5.1% "variance effect" (or VE) calculated by Steris to represent the limiting variance in the shading effect of the product inventory carriers. Reference 9 indicates that the use of four dosimeters on each specimen and the application of the Square Root of the Sum of the Squares (SRSS) statistical methodology present an error term for the combination of four dosimeters at a value of 50% of the average individual dosimeter error value. This is calculated as follows for 4 dosimeters (as were used for the subject cable project):

Statistical Average Error for 4 dosimeters rated for 6.5% accuracy:

$$[(4 \times (6.5)^2)^{1/2} / 4] = 3.25\%$$

Therefore, the individual dosimeter error input value of 6.5% may be reduced based on the arguments that the dosimeters are being used in their most optimal manner per the discussion in the previous section regarding the contributing factors to error. For the purpose of this discussion, the potential error reduction discussed above shall be considered "margin". However, the SRSS error reduction for the use of four dosimeters reduces the error term for the dosimeters to 3.25%.

Both terms represent random error, which may be combined using the Square Root of the Sum of the Squares methodology. Using SRSS, total error (TE) would be calculated:

$$TE = (DE^2 + VE^2)^{1/2} = (3.25^2 + 6.02^2)^{1/2} = 6.85\%$$

With this assumed error, the measured dose would have to be 1.0685 x 50 MRads = 53.425 MRads to satisfy the requirement. Ten of the sixteen dosimeter readings from Table 1 satisfy this criterion. Each box has at least two dosimeters that meet this requirement. That indicates that even with the most conservative approach to the error terms, every box had some portion that was exposed to the required 50 MRads. Since these cables were subsequently installed into an accident simulation chamber, including the portions that exceeded the 50 MRads requirement, the qualification level of 50 MRads for Normal plus Accident plus Margin is justified. Note that some of the dosimeters recorded dose measurements of up to 61.96 Mrads, which could be even higher if the dosimetry and variance factors are applied in a positive direction.

Due to the protocol used by Steris to measure delivered dose, the approach to nuclear qualification specimen irradiation is taken as requiring that ALL dosimeters on every box meet the radiation criteria stated as 50 MRads. This project involved the irradiation of a coiled length of cable and that length was to be subjected to subsequent testing. The intent of the IEEE 383 standard (Reference 4) on cable qualification is to subject the test specimen cables to testing while the cable is in its aged condition (with respect to radiation, the stated value of radiation exposure was 50 Mrads). Therefore, we may look at the average dose for each cable specimen box. The lowest average delivered dose is for Boxes 4, 5, and 6 with a measured 53.425 MRads. Using our SRSS error correction as calculated above, the minimum delivered dose becomes 49.645 MRads, which is within 0.72% of the required dose of 50 MRads. All the boxes, including 4, 5, and 6,

had between 2 and 4 dosimeters above the 53.425 MRad requirement, guaranteeing that at least a significant portion of the cable within each box received the required radiation dose or more.

Further, based on the above discussions concerning the bases for the error "rating" attributed to the individual dosimeters by Harwell, the +/- 6.5% (the value used as input to the SRSS calculation shown above) is very likely overly conservative. Each source of error term for the dosimeters is discussed in the DOSIMETRY section. By engineering judgment and application of statistical methods, the stated +/- 6.5% could be reduced to approximately half that value (+/-3.25%) based on the extremely tight controls, optimal environmental conditions, single dosimeter batch, special handling and storage, and the other factors discussed. Engineering judgement based on interpretation of the technical bases is appropriate in this analysis considering the statistical nature of the dosimetry error calculations for deriving uncertainty and even in determining the radiation requirement for the end application. Application of margin, acceptable confidence levels (number of standard deviations) and other inputs to the analyses of radiation dosimetry contain numerous engineering judgements backed by technical justifications.

However, for the purpose of this evaluation, and to retain a source of margin for the conclusion that the 50MRads radiation requirement of Okonite PO 905252 has been met, this additional margin is applied to support the conclusion without numerical inclusion into the final determination.

## 6. SUMMARY OF QUALIFICATION IMPACT STERIS PART 21 NOTICE

The requirement for Normal plus Accident plus 10% margin radiation delivery of 50 MRads gamma for Okonite Reports 526 and 527 (References 1 and 2, respectively) is validated based on the following considerations:

- Specimens were each fitted with four dosimeters increasing reliability of measured radiation dose. Dosimeter "array" enhances accuracy and reduces error to 3.25%.
- Dosimetry application was extremely well controlled with respect to placement, environmental conditions, time/temperature/RH of exposure and dosimeter readout.
    - A single batch of fresh certified dosimeters were utilized for the measurements

  - The dosimeters were utilized with all use parameters (dose rate, energy, total dose) in mid-range for optimal accuracy
  - Each dosimeter was left in its sealed packet until readout and each dosimeter was individually measured for thickness to improve accuracy.
- The data in Table 1 verifies that some or all of each cable specimen was exposed to the required 50 MRads over its length. The 50 MRads requirement as installed in the nuclear plant will have some element of dose variance due to the cable being located within cable tray or conduit and will be subject to shading effects from various other adjacent equipment in the nuclear plant. This variance will significantly exceed the 0.72% variance for the lowest dose box.
- Thermal aging performed during specimen preconditioning prior to accident testing addressed the entire length of the cable specimens subjected to HELB testing and also to specimens qualified for Normal Environment. The specimens that were subjected to HELB testing contained sections along their length that experienced the full 50 MRads and above. Therefore, the intent of the 50 MR radiation dose qualification requirements as imposed by References 3 and 4 are satisfied.

## 7. REFERENCES

1. Okonite Report 526, Rev. 2, "*Nuclear Environmental Qualification Test Report of EPR Insulated Low Voltage Power Cable*"
2. Okonite Report 527, Rev. 1, "*Nuclear Environmental Qualification Test Report of EPR Insulated Low and Medium Voltage Power Cables*"
3. IEEE 323-1974/1983/2003 "*Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations*"
4. IEEE 383-1974/2003, "*IEEE Standard for Qualifying Class 1E Cables and Field Splices for Nuclear Power Generating Stations*"
5. 10CFR50 Appendix B, "*Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*"
6. NQA-1 (1994), "*Quality Assurance Requirements for Nuclear Facility Applications*"
7. 10CFR21, "*Reporting of Defects and Non-Compliance*"
8. Steris Project File 271827, "*Okonite Cables*"
9. Steris Memorandum to File entitled "*Dose Rate Variability for the Whippany, NJ Facility (Off-Carrier Processing)*"
10. "*Industry Guidance Position Paper – Responding to the 2014 STERIS 10CFR21– Nuclear Components, Whippany, NJ Facility*", J. White, B. Horin, and R. Wise, Revision 0, 2015

Engineered Solutions Group

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